GLOBAL HEALTH: A NORMATIVE ANALYSIS OF INTELLECTUAL PROPERTY RIGHTS AND GLOBAL DISTRIBUTIVE JUSTICE

by

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Date: 25 April 2007
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Dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Philosophy in the Graduate School of Duke University

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ABSTRACT

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Abstract

In the past several years, the impact of intellectual property rights (IPRs) on access to medicines and medical technologies has come under increased scrutiny. Motivating this are highly publicized cases where IPRs appear to threaten access to particular medicines and diagnostics. As IPRs become globalized, so does the controversy: In 1998, nearly forty pharmaceutical companies filed a lawsuit against South Africa, citing (among other issues) deprivation of intellectual property. This followed South Africa’s implementation of various measures to enable and encourage the use of generic medicines – a move that was particularly controversial for the newly available (and still patented) HIV medicines. While many historical, legal, economic, and policy analyses of these cases and issues exist, few explicitly normative projects have been undertaken.

This thesis utilizes interdisciplinary and explicitly normative philosophical methods to fill this normative void, engaging theoretical work on intellectual property and global distributive justice with each other, and with empirical work on IPR reform. In doing so, it explicitly rejects three mistaken assumptions about the debate over IPRs and access to essential medicines: (i) that this debate reduces to a disagreement about empirical facts; (ii) that intellectual property is normatively justified solely by its ability to “maximize innovation”; and (iii) that this controversy reduces to irresolvable
disagreement about global distributive justice. Calling upon the best contemporary approaches to human rights, it argues that these approaches lend normative weight in favor of reforming IPRs – both that they should be reformed, and how – to better enable access to essential medicines. Such reforms might include modifying the present global IPR regime or creating new alternatives to the exclusivity of IPRs, both of which are considered in light of a human right to access to essential medicines. Future work will be needed, however, to better specify the content of a right to “essential medicines” and determine a fair distribution of the costs of fulfilling it.
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CHAPTER 1. Intellectual Property Rights and Access to Medicines in Conflict

1.1 Setting the Stage: Disagreements Over Intellectual Property Rights

Intellectual property rights – once the near exclusive domain of legal and economic scholarship – fall increasingly under the spotlight of the mainstream media. Nowhere is this increased attention more evident than in health in general and global health in particular. The impact of intellectual property rights (IPRs) on the sharing of scientific knowledge and access to medicines, vaccines, and diagnostics, is now being scrutinized. Examples from the real world best illustrate this increased scrutiny.

1.1.1 Medicine Pricing in South Africa

In an effort to provide more equitable health care, post-apartheid South Africa passed the Medicines and Related Substances Control Amendment Act (No 90 of 1997). The “Medicines Act” represented one way for the South African government to implement a Constitutional right to basic health care. The Medicines Act, among other concerns, endeavored to control medicine prices by eliminating “perverse” incentives for physicians and pharmacists to prescribe certain medicines when others would be either cheaper or more effective or both; by specifically calling for parallel importation
(i.e., importing a patented medicine from a foreign country if doing so would be less expensive than purchasing the same medicine locally); compulsory licensing (“when a government allows someone else to produce the patented product or process without the consent of the patent owner,” (World Trade Organization, 2005) with remuneration to the patent owner), and pricing surveillance via a National Drug Pricing Committee (Communication Unit (Department of Health), 2 March 2001). Of particular interest in this case was the pricing of antiretroviral medications to fight the HIV/AIDS epidemic in South Africa. In response to the Medicines Act, 41 pharmaceutical companies filed a lawsuit in 1998 alleging that the Medicines Act itself violated the South African Constitution, restricted free trade, and allowed the South African government to

...deprive owners of intellectual property in respect of pharmaceutical products of such property, alternatively to expropriate such property without any provision for compensation to be paid in respect thereof.1

The US government initially responded in support of the pharmaceutical companies by pressuring South Africa to repeal the law; for a time, it even placed South Africa on its Special 301 “Watch List” relating to international intellectual property protection.2 When protesters from ACT UP and other AIDS advocacy groups took this

2 The Office of the United States Trade Representative routinely “examines in detail the adequacy and effectiveness of intellectual property rights” in many countries around the world. Countries falling below a
disagreement from the South African courtroom into the budding US presidential campaign of then Vice President Al Gore, many took notice. (Protesters who shout, “Gore’s greed kills! AIDS drugs for Africa!” tend to attract such notice.) Eventually, South Africa reaffirmed the Act’s consistency with current international trade laws, and the pharmaceutical companies dropped the lawsuit in April 2001 (with little doubt that the increasing public pressure influenced this outcome).  

Nevertheless, questions remained: Do IPRs limit access to medicines? If so, is this limitation justified by the costs of innovation? How can we make sense of this controversy?

1.1.2 Yale University, BMS, and d4T

A second, related example illustrates in more detail the controversy over intellectual property rights and access to medicines. In 2000-2001, HIV treatment cost US$10-15,000 per patient per year in the U.S. and Europe, a price clearly too high for most developing countries. However, the growing generic medicine industry in India desired level of intellectual property protection may be placed on the Special 301 Watch List or Priority Watch List, which means they warrant bilateral attention to remedy intellectual property problems. The most egregious intellectual property abuses are given “Priority Foreign Country” status, and “Section 306 Monitoring” is used to follow-up on previous reports and bilateral negotiations. Whatever the case, the impact on another country’s economics and trade status with the U.S. as a result of these categorizations can be substantial. See http://www.ustr.gov and http://www.uspto.gov/web/offices/dcom/olia/ir_trade_special301.htm, respectively. Accessed 3 April 2007.  

and elsewhere promised to make medicines more affordable, thereby facilitating less costly HIV treatment. Yet, according to some, patents stood in the way. A good example of this was the controversy over d4T pricing in South Africa.

In December 2000, the international NGO Médecins Sans Frontières (MSF) asked Bristol-Myers Squibb (BMS) to allow importation of generic d4T (stavudine or Zerit) into South Africa. Cipla Limited, a generic company in India, had offered MSF d4T at US$0.05 per tablet (compared to BMS’s $2.23), dropping yearly triple-drug cocktails to US$350 per patient – a remarkable price reduction (McNeil, 2001).

BMS held an exclusive license on d4T from Yale University, where William Prusoff had discovered d4T as an effective HIV medicine in 1984.4 Yale’s “use patent” on the molecule (which had been first synthesized in 1966 under a National Cancer Institute grant to the University of Michigan) was filed in 1986, and FDA approval for HIV came in 1994. In short, MSF was asking Yale and BMS to not enforce their exclusive, proprietary rights in South Africa. At the time, sales of d4T were approximately US$500 million per year, with Yale earning about US$40 million per year in licensing revenue from the patent.

BMS and Yale initially resisted, but Amy Kapczynski and the nascent Yale AIDS Action Coalition joined MSF in pressuring the university and BMS to drop prices and

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agree not to enforce their exclusive rights (Lindsey, 2001a). As a result of this mounting public pressure (and no doubt a result of the growing global public awareness from yet another high profile case), a rapid d4T price reduction occurred, from US$1600 to US$55 per patient per year. In addition, in August 2003 Aspen Pharmacare (a South African generic company) began selling d4T for 40% less than even the BMS reduced price.5

The d4T case is important, in so far as it is one prominent example of an access to medicine controversy where multiple players are involved: a U.S. university whose research is mainly funded by the U.S. federal government; a private corporation; a foreign (developing country) government; and various non-governmental organizations (NGOs) and civil society groups.

What role do (or could) these various actors play in the debate over IPRs and access to medicines? Would it be possible to minimize the impact of patents on access to medicines through differential licensing arrangements (e.g., had Yale offered a non-exclusive license to BMS while licensing d4T more openly in developing countries) or simply not enforcing patents in the developing world?

5 A potentially new controversy is currently brewing, with Yale and the related molecule, Ed4T, licensed to Oncolys BioPharma. Yale, however, suggests that it will not enforce patent rights in some countries, such as India. See (Check, 2006).
1.1.3 Free Trade Agreements and Access to Medicines

The controversy over patent and access to medicines was not limited to individual countries (e.g., South Africa), nor individual companies’ medicines (e.g., d4T). Instead, the controversy also rises to the level of bilateral and multilateral trade negotiations where important IPR policy negotiations frequently occur.

In recent years, bilateral and multilateral free trade agreements (FTAs) have come under fire for their impact on access to medicines. One prominent example is the Central American Free Trade Agreement (CAFTA) between Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, the Dominican Republic, and the U.S (Replogle, 2004). Although CAFTA is not solely concerned with intellectual property and access to medicines, the public health community and human rights activists felt certain provisions unduly limited access to generic medicines. Whereas most of the CAFTA countries had weak intellectual property laws that allowed generic drugs to be sold, CAFTA increases IPR protection in several ways – including ways to go beyond other negotiated international agreements. For instance, CAFTA requires signatories to extend the patent term on products if the patent holder experiences unreasonable delays in obtaining the patent or marketing approval for the medicine by the national drug regulatory agency. This patent extension would delay generic entry, increase the cost of

*As of this writing, only Costa Rica had yet to ratify the treaty.*
medicines, and thereby reduce access to important medicines, such as antiretrovirals for HIV. (Even though many Central American governments negotiated voluntary price reductions with some pharmaceutical companies, generic equivalents are reported to be one-quarter the price – a key difference for low- and middle-income countries.)

Following on CAFTA, some suggested that

“The rights of patent owners are placed above human rights, especially the right to health”, says Guillermo Murillo, assistant director of Agua Buena, a human rights organisation based in San José, Costa Rica. (quoted in (Replogle, 2004 1612)

Others, however, suggested that the high cost of drug development necessitated IPR protection to allow these costs to be recouped:

“What we want is a fair, open market”, says Rodolfo Lambour, executive director of the Central American Federation of Pharmaceutical Laboratories, which represents major international pharmaceutical companies in the region. “We’re not against generics”, says Lambour, “they can come into the market once intellectual property rights expire.” (quoted in (Replogle, 2004 1612)

Meanwhile, because the agreement promised to open U.S. markets to textiles from these six countries, it also required balancing the benefits of this open market against the possible costs of medicine prices. CAFTA is but one example of a broader phenomenon concerning the impact of FTAs on access to medicines (Correa, 2006a).

In Thailand, the trade-off was succinctly put regarding the U.S. – Thailand FTA:

Washington said the agreement would save lives by spurring innovation and by making multinationals more confident to sell drugs in the country. But Thai officials saw the proposal as a morbid bargain: either refuse the U.S. offer and scuttle a trade deal with the United States worth billions of dollars, or accept it and lift the price of AIDS drugs beyond the reach of the poor. (Giridharadas, 2006)
What is most worrisome, however, is this: Recent empirical findings from the Jordan-U.S. FTA suggest that some of the proposed benefits of such agreements (e.g., increased foreign direct investment) have failed to materialize while higher drug prices have indeed occurred (Oxfam, 2007).

As the previous two examples, this raises numerous questions: Ought this sort of exchange between trade and health be made? Is this an issue of human rights, and if so, what would that mean? How do we make sense of the IPR/access controversy in the context of unequal power and influence in global politics?

### 1.1.4 Global Avian Flu Pandemic Stockpiling

A fourth example widens the controversy and growing unrest over IPRs even further by showing that it is not only of interest to developing countries: With a global avian influenza pandemic looming in late 2005, stockpiles of oseltamivir (the primary antiviral of choice) appeared critical. However, at then available rates of production, obtaining enough oseltamivir for twenty percent of the world’s population would have taken ten years, according to Klaus Storh (director of the WHO’s Global Influenza Program). Developed and developing countries took notice.

Responding to calls for generic production (which some claim could take as long as two years to operationalize), Swiss pharmaceutical company Roche initially stated that it would not share its patent to allow generic production of oseltamivir, nor would
it disclose “commercially sensitive” production information that might allow more precise estimates of Roche’s ability to meet global oseltamivir needs (Russell, 13 October 2005). The company later expressed willingness to sublicense oseltamivir production so long as the production could “realistically produce substantial amounts of the medicine for emergency pandemic use, in accordance with appropriate quality specifications, safety and regulatory guidelines.” (Roche Media News, 18 October 2005) Several countries, such as South Korea, announced that they would attempt generic production without Roche’s permission (though Roche had claimed that this would not be possible due to the shortage of a natural product necessary for oseltamivir’s manufacture) (Cheong-won, 31 October 2005). Roche, which nearly two years earlier had expressed a commitment to make the drug available for the pandemic (based on then available supply data; (Roche Investor Update, 29 January 2004)), agreed to donate three million doses to an international stockpile, with the first one million doses available early in 2006 (WHO News Release, 24 August 2005). While this move on Roche’s part is laudable, the US National Vaccine Advisory Committee estimates that forty million courses are the minimum needed to support critical pandemic responses in the U.S. alone (Pavia).

As of late 2006, Roche had voluntarily licensed oseltamivir production to 15 contractors in 10 different countries, and had developed a new production process that
no longer depended on natural materials and increased production capacity (Yeh, 2006). The concern about supplies remained, however, both for developed countries (such as the U.S.) and for the ability of developing countries to meet Roche’s licensing terms.

Was Roche wrong in its actions? If not, why not? If so, what could be done about it?

1.1.5 Patenting the Human Genome

One final example widens the debate even more, suggesting that the debate is not just about access to medicines. The race to sequence the human genome was, in some sense, as much a race for intellectual property rights to the DNA sequences as it was a race to find them. Yet concerns over IPRs in this context were less about access per se (Myriad’s patenting of BRCA1/BRCA2 diagnostic testing being the notable exception; see below). They were more about whether DNA sequences (humankind’s “common heritage”) should be patented, whether this might hinder the eventual development of new technologies and treatments, and whether access to this basic knowledge ought to be in any sense restricted.

The publicly funded, multinational Human Genome Project had agreed upon a set of “Bermuda Rules” early in the project (February, 1996). These rules stated a commitment to releasing DNA sequences into the public domain within twenty-four hours of sequencing. At the same time, the public side of the project expressed concern
that private companies – and J. Craig Venter’s Celera in particular – would eventually own the human genome sequence. The concerns were partly practical, in that the public researchers worried whether the private sector’s intellectual property rights would block their future research use of the genome sequence. But they were also moral, in that many also held a commitment to the human genome as something which is part of a common human heritage, not to be owned by anyone.

Interestingly, however, the push to release sequences into the public domain did not come solely from the public sector: In 1995, Merck & Co., Inc., in collaboration with Washington University in St. Louis, announced the release of 15,000 expressed human gene sequences into the Merck Gene Index (Merck & Co. Inc. (press release), 1995). This project’s stated goal was to stimulate biological research and enhance drug development (Williamson, 1999). Not long thereafter (October 1996), Myriad Genetics, Inc., launched BRCAnalysis diagnostic testing based on its intellectual ownership over the breast cancer predisposition genes BRCA1 and BRCA2; Myriad had previously settled a patent dispute with the University of Utah and the National Institutes of Health (Marshall, 1997, No Author Listed, 20 February 1995). The resulting monopoly price of US $2400 seemed high to some (Dobson, 29 June 1997), and actions by Myriad to prevent others from performing or using the patented genes were also questioned (Roth, 2005). And around the same time these sequences were being released into the public domain and
BRCA testing became available, DNA-based patents on the whole began to grow at an exponential rate. Most interestingly, the institution with the most patents is not a private corporation, but the University of California. As the dust continues to settle from this genome “race,” some estimates indicate that about 20% of human genes are covered by United States intellectual property (Jensen and Murray, 2005).

How will IPR ownership over parts of the human genome affect access to follow-on products? Will the preponderance of ownership in developed countries prove problematic for potential global uses of the information from the HGP?

1.1.6 Starting to Make Sense of the Controversy

Without question, these cases are more complex than the vignettes allow. They each raise an array of important issues, and other cases could be equally demonstrative. Nevertheless, it is important to notice several key similarities, as well as differences.

Consider first the similarities. First, all three cases involve a dispute over IPRs at some level – in these examples, patents. Simply stated, one is inclined to draw a distinction between “pro-patent” and “anti-patent” groups, even if this grossly oversimplifies and obscures the real disagreements that arise in this area. Second, all involve many different institutional players, including private companies, public

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7 LeRoy Walters et al., unpublished paper.
8 For a global perspective on genomics, see (Advisory Committee on Health Research, 2002).
institutions or universities, governments, civil society groups, and others. This adds to the complexity of each case, because these institutions’ missions can conflict under certain circumstances. Third, these conflicts occur at an increasingly global level, either because the institutions themselves come from different parts of the globe, or because the IPRs in question may be codified and protected in different states, or because the case itself has important global consequences. Finally, it is clear that a driving force behind such cases is access – i.e., the idea that someone, somewhere should be able to obtain something that he or she cannot, perhaps as a result of IPRs.

The differences are no less obvious. Perhaps most importantly, exactly to what individuals are granted or denied access differs. While the South Africa and avian influenza cases involve a discrete object (i.e., a medication), the Human Genome Project example invoked ideas of access to fundamental knowledge, or the building blocks of knowledge, upon which to base further scientific advancement. In this sense, those involved with the HGP worried about sharing per se, but they also worried about adverse effects on welfare that might result from ownership. Second, while the South Africa case revolves around a chronic disease condition with long-term needs, the avian influenza case is an acute public health threat calling for more short-term actions.

Whether these differences matter, and how they matter, is a separate question that must be addressed. Simply put, however, global disagreements over IPRs are
increasingly common and cover a broad spectrum of activities, from research to
diagnosis to acute illness to chronic disease treatment.

The attention given to these types of cases comes from many different
perspectives. Many call upon empirical social sciences, including historical studies,\textsuperscript{9} economic analyses,\textsuperscript{10} legal scholarship, and more general policy landscape examinations.

For example, in recent years, several major commissions have considered the
issue of IPRs and access. Some operated on a more “domestic” level, focusing mainly on
innovation and technological change (e.g., the U.S. National Academies 2003 report, 
\textit{Patents in the Knowledge-Based Economy} (Cohen and Merrill, 2003); the American
Association for the Advancement of Science’s 2002 “Science & Intellectual Property in
the Public Interest” Program\textsuperscript{11}). Others took a more global look at IPRs, such as the
United Kingdom’s Commission on Intellectual Property Rights (CIPR), whose 2002
report \textit{Integrating Intellectual Property Rights and Development Policy} examined how IPRs
might better enable economic development, including a chapter devoted to health

\textsuperscript{9} For two different perspectives, see (Chang, 2002) and (Choate, 2005).
\textsuperscript{10} For one example, see (Granville, 2002).
\textsuperscript{11} The AAAS-SIPPI program is mainly, though not wholly, domestic-oriented. See http://sippi.aaas.org/about/. Accessed 4 April 2007.
(Commission on Intellectual Property Rights, 2002). More recently, the World Health Organization’s (WHO) Commission on Intellectual Property Rights, Innovation, and Public Health (CIPIH) offered a report dedicated to considering the issue of IPRs, *Public health, innovation, and intellectual property rights* (Commission on Intellectual Property Rights, 2006). This report laid out an ambitious array of strategies for balancing innovation and access to medicines, diagnostics, and other health technologies with a focus on developing countries. Summarizing each of these reports and commissions is beyond the scope of this introduction; suffice it to say, then, that IPRs are currently under scrutiny.

Importantly, while all of these reports involve, or at least operate within, a set of normative assumptions, more specifically “normative” projects are relatively uncommon. Thus, the overarching goal of this thesis is to provide normative scrutiny of intellectual property rights in a specific context (access to medicines and related health technologies, such as vaccines), at a broad level (globally), and from a particular normative standpoint (distributive justice). Others have recognized the absence of

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14 For a notable exception, see (Drahos, 1996).
normative theorizing. For example, Barry Pakes, in commenting on the CIPIH report and some follow-on work in the *Bulletin of the World Health Organization*, said the following:

While their proposals are laudable, and they do cite articles on the ethical dimensions of their work, the unique, potentially guiding voice of ethical discourse is silent. (Pakes, 2006:341)

Taking Pakes’s comment seriously, this work aims to provide such a guiding voice.

### 1.2 The Controversy in Context: Inequalities in Global Health

Before proceeding further, it is important to emphasize the overall status of inequalities in global health that make the IPR/access issue so pressing. Were inequalities in global health not so extreme, the question of how IPRs impact access might be less important. Below, however, I give a brief overview of the reality of these inequalities, framed around inequalities in access to health care (the “health care services gap”) and access to the benefits of scientific knowledge (the “research gap”). The sheer magnitude of global health inequalities gives a first reason for considering the impact of IPRs on access to medicines and other health care technologies.

#### 1.2.1 Inequalities in Health Care Services

When considering global inequalities in health care services, a general theme emerges: Global health inequalities are severe and in many cases getting worse whether
organized according to different population groups, disease types, or availability of health care workers.

First, no matter which population group one might consider, global health inequalities are alarming. Overall, for example, life expectancy in many developing countries, such as those in sub-Saharan Africa (SSA), is not only far behind developed countries – in the mid-1980s, life expectancy in SSA peaked at just under 50 years, compared with well over 70 years for developed countries – but is also expected to roll back through 2010 to close to 45 years (World Health Organization, 2004). If one focuses on a particular illness in children, whereas rotavirus gastroenteritis causes 20-40 deaths per year in the United States, it causes over 600,000 per year in developing countries – in spite of the fact that second generation vaccines now exist (Roberts, 2004). Considering maternal and newborn health, the figures are equally striking: Lifetime risk of maternal death is 1 in 16 in SSA but 1 in 2800 in rich countries, with the mortality risk rising in some places (e.g., Malawi); neonatal infant mortality is 6.5 times lower in high-income countries as compared to low-income ones (World Health Organization, 2005b). Refugees, asylum seekers, and internally displaced persons, (“RAI”), not surprisingly, consistently fair worse than non-RAI persons (de Bruijn, 2006).

Second, the global burden of disease is strikingly unequal. Following the WHO CIPIH report’s classification, diseases fall into three general categories: Type I diseases
affecting both developed and developing countries (e.g., cardiovascular disease); Type II diseases affecting mainly developing countries (e.g., HIV); and Type III diseases affecting only developing countries (e.g., “neglected diseases,” such as leishmaniasis).

The unequal global disease burden is most obvious in relation to communicable or infectious diseases: In Africa 2 in 3 adult deaths are caused by communicable disease, whereas in developed countries, only 1 in 10 adult deaths are so caused (World Health Organization, 2003). Certain Type III diseases, such as leishmaniasis, trypanosomiasis, and Chagas disease simply do not occur in developed countries. Type II diseases, such as HIV, also predominantly impact developing countries. Of 39.5 million people living with HIV in 2006, 24.5 million were in sub-Saharan Africa, where 2.1 million of the 2.9 million deaths occurred (Joint United Nations Programme on HIV/AIDS and Organization., 2006). Nonetheless, in 2001, ischemic heart disease (a Type I disease) was the leading cause of death in low- and middle-income countries, just as it was in high-income countries, making it critically important around the world (particularly for developing countries in economic transition) (Lopez, et al., 2006).

Taken together, this means that many developing countries now face a “double burden” of disease – i.e., a burden of chronic disease (Yach, et al., 2004) shared with developed countries (Type I diseases) at the same time they continue to bear a large burden of Type II and Type III diseases.
Third, not only are health outcomes unequal, but so also is access to health care workers and services. In Africa, 2.3 health care workers (broadly defined to include many health workers, from physicians to nurses to community health workers) are available per 1000 persons; in the Americas, 24.8 are available (World Health Organization, 2006). Unfortunately, this glut of health care workers in the Americas exists in spite of Africa’s two- to three-fold disease burden. And to make matters worse, many of the trained health care workers in developing countries leave for the developed world – understandably so, given the salaries and opportunities available to them in these countries – thereby contributing the “brain drain” of human capital from the developing world (Martineau, et al., 2004, Saravia and Miranda, 2004).

In sum, vast inequalities exist in health outcomes and access to health services. Many of these inequalities are worsening, providing additional motivation for those wishing to understand and mitigate them.15 Unfortunately, global inequality runs deeper yet.

15 I do not discuss in detail the many other indicators of poverty and overall deprivation affecting the world, as any United Nations Human Development Report or WHO World Health Report will attest. This is not because these other indicators are not important but simply for the sake of succinctness.
1.2.2 Inequalities in Research

I say “deeper yet” because of a second remarkable inequality in global health: access to research relevant to solving or alleviating some of the threats to health just mentioned. A general theme again emerges: Developing countries’ disease problems receive very little attention from global research and development (R&D) spending, and what research does occur is not conducted by them and might not be applicable to their circumstances.

The fact that developing countries do not share equally in global R&D is well established. Only 10% of health R&D spending goes toward 90% of the global disease burden, creating the so-called 90/10 gap.\textsuperscript{16} Not surprisingly, a related statistic suggests that few new medicines are developed for tropical diseases: From 1975-1999, 16 of 1393 new molecular entities were for tropical diseases or tuberculosis (Trouiller, et al., 2002). Hence, the term “neglected disease” is often used to describe such tropical diseases that receive little attention from overall global R&D.

Matters seem to be worse, however, on several counts. First, the 90/10 research spending gap translates to a much wider gap when it comes to medical information. In a study of the content of the prestigious New England Journal of Medicine from 1997-2004,

\textsuperscript{16} This common statistic traces originally to (Commission on Health Research for Development, 1990). The actual gap was, at the time, closer to 95/5; some sources now suggest that the gap is less than 90/10.
less than 3% of the major articles, review articles, and editorials addressed developing countries (Lown and Banerjee, 2006). Second, according to some estimates, 163 countries – including most of the developing world – account for less than 2.5% of global scientific output as measured by publication output (eight OECD countries account for 85%; (King, 2004)).

Connecting these two facts, the importance of conducting scientific research that is both within, and relevant to, developing countries takes on new import: Scientific information from the developed world might not apply to the developing one. Certain vaccines, such as the polio vaccine, for example, require different dosing strategies to be effecting in the developing country setting (Roberts, 2004). Thus, clinical trials in those settings are more likely to discover such differences.

To conclude this all too brief section, in light of such vast inequalities, global health is receiving increased attention from the academic community, state leaders, activists, and other involved with national and international organizations. This is probably a result of increased recognition of these inequalities, as well as the recognition that many health threats (such as HIV, SARS, and pandemic avian influenza) are global in scope. Whatever the motivation, “global health” is now fashionable, with major

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17 Not all estimates are this extreme and reveal important inter-journal differences. See (Raja and Singer, 2004).
universities and institutions in the United States beginning to devote substantial resources toward both academic scholarship and positive change.

1.3 The Controversy in Context: Globalization of IPRs

If the presence of vast inequalities in global health gives one reason for being concerned about IPRs and access, the globalization of IPRs gives a second.

Intellectual property rights, traditionally conceived of as patents, copyrights, trademarks, and trade secrets, are increasingly becoming “globalized.” By becoming globalized, I do not mean that a global patent office now exists, though such a proposal is not infrequently discussed. Instead, I mean two different points: first, that international standards for the protection of intellectual property, backed by the coercive power of the World Trade Organization (WTO) in concert with the World Intellectual Property Organization (WIPO, a specialized United Nations agency dedicated to promote the effective use of IP); and second, that many IPR owners frequently seek and enforce their IPRs in many different countries around the world.¹⁸ Neither is an entirely “new” development, though the scale seems to be. I discuss both briefly.

I start with the latter because seeking global IPR protection motivated, in part, the quest for global minimal standards for the protection of IPRs. If one accepts that we

live in an increasingly globalized, knowledge- or information-based economy, then the drive to protect intellectual property – property in ideas or “products of the mind” – should not be surprising. Curtis Cook, in a book that describes from a business perspective how intellectual assets are the “new wealth,” how IP represents a new form of global currency, and that intellectual property is critical to the future of thought, presents the importance of IPRs in this way:

In many commercially driven societies around the world, billions of dollars are lost and gained on the basis of protecting these great ideas, catchy names, innovative designs and inspiring words. (Cook, 2002 3)

Or, from a different perspective, Keith Maskus suggests that increasing protection of IPRs serves to anticipate the importance of IPRs in supporting the high-technology, information-based economy of the new century. The world is increasingly characterized by the international exchange of information, technologies, and creative goods and services...Also important is the licensing of knowledge-based assets, including technical advantages, know-how, management skills, and reputation. (Maskus, 2000 2)

One finds similar statements in the introductions of most recent books and articles on intellectual property rights. In light of these two key features – the present economic importance of intellectual property, as well as its future significance or “anticipation” – the observation that pharmaceutical companies seek patents even in

19 Historically, the protection (or lack thereof) of intellectual property has always been important. The United States, for example, “stole” much intellectual property in the 18th and 19th centuries from abroad while seeking to protect its own citizens’ intellectual property by Constitutional mandate at home. See (Chang, 2002).
low-income countries who cannot manufacture their products is not altogether unexpected.20

Because of IP’s economic importance, the drive to protect intellectual property globally is not new, and is in fact older than many realize.21 Protection of intellectual property dates to at least 1474 (when Vienna passed a law protecting inventors’ right to prevent copying of their invention); Britain’s 1624 Statute of Monopolies similarly granted exclusive rights to inventors for a limited period of time. Up until the late 19th century, however, intellectual property law was exclusively a “national” endeavor (Drahos, 1997).22 In 1883 and 1886, this changed, however with the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works, respectively. These Conventions ushered in what Drahos (1997) calls the “international” era of intellectual property protection, where the conventions reflected international consensus but allowed substantial freedom for nations to craft their own intellectual property law (or none at all). The two bureau which administered

20 For an example of a letter from multinational pharmaceutical giant GlaxoWellcome to Cipla (an Indian generic company) involving claimed patent infringement in Uganda (a developing country), see http://www.cptech.org/ip/health/africa/glaxocipla11202000.html. Accessed 5 April 2007. The idea of “anticipation” perhaps explains why companies would seek patents in developing countries, who represent a miniscule portion of the global market, in the first place.
21 Here again, the history of IPRs is frequently repeated in most books and articles on IPRs. For one recent treatment, see (May and Sell, 2006).
22 The United States’ version of intellectual property protection was set forth in the 1787 U.S. Constitution to “promote progress in science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”
the Paris and Berne Conventions eventually become the World Intellectual Property Organization (WIPO) in 1967, and WIPO became a specialized U.N. agency in 1974. Among its many functions, WIPO administers the Patent Cooperation Treaty (1970), which allows inventors to file an international patent application simultaneously in a large number of countries.23

The modern “global” era of intellectual property, by contrast, reflects not simply international consensus but global minimal standards for IP protection. It is here that the WTO’s Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) becomes critically important. From 1986-1994 the Uruguay Round of trade negotiations led to the General Agreement on Tariffs and Trade (GATT), the creation of the WTO, and importantly for this context, the TRIPS Agreement. Two features of this shift in IPR policy to include the WTO are important.

First, a critical difference between the WTO and WIPO is the enforcement power of the WTO through trade sanctions and dispute resolution. This makes non-compliance with the terms of TRIPS potentially more costly to countries. Second, unlike the prior Paris and Berne Conventions, TRIPS

is a much less flexible regime for IP protection. It promotes universality in IP rights protection. Behavior that was once legal is now illegal. TRIPS requires states to adopt both civil and criminal penalties for IP rights infringement. The Paris Convention made

no mention of what items must be protected or the duration of protection to be offered. The TRIPS Agreement specifies obligations regarding the scope, subject matter, and duration of IP protection. (Sell, 2003 12)

To make this more concrete in the present context, TRIPS requires a 20-year patent term, the protection of pharmaceutical products, and the recognition of both product and process patents (among many other provisions). Given that many countries, prior to TRIPS, had no such provisions in their patent law (if they had patents at all), this is a remarkable shift.

To be sure, the implementation of TRIPS is stepwise: whereas developed countries needed to implement TRIPS in their national laws within 1 year of the agreement (i.e., by 1 January 1996), least developed countries were given until 1 January 2006 for implementation (and for pharmaceutical patents, until 1 January 2016). Nonetheless, many countries implemented TRIPS early; for example, India’s new pharmaceutical patent law took effect 1 January 2005, and Brazil’s in 1997. Nonetheless, the impact of these new global standards is worth emphasizing. For example, the absence of product patents enabled Shin Poong, a South Korean pharmaceutical company, to develop a more efficient process for manufacturing praziquantel (a treatment for the tropical disease schistosomiasis). This enabled Shin Poong to sell praziquantel for much less than Bayer (the original marketer) in countries where no product patent existed, including licensing the process to the Egyptian International
Pharmaceutical Industries Company (EIPICO) (Reich and Govindaraj, 1998). Clearly, some of the TRIPS provisions are important in light of cases such as this one.

The recognition that TRIPS, in some circumstances, could create barriers to public health resulted in the adoption of the Doha Declaration on 14 November 2001. The “Declaration on the TRIPS agreement and public health” declared that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.24 Doha thus reiterated the importance of certain TRIPS flexibilities, such as compulsory licensing, for the sake of public health. It also motivated what become known as the Paragraph 6 solution, which allows exports under compulsory license to countries that lack adequate manufacturing capacity to manufacture pharmaceutical products on their own.25

Much more could be said here regarding, for example, the impact of developed country interests on the content of TRIPS (Sell, 2003) or the import of the shift in IPR policy to the WTO. This all too brief summary simply suggests that IPRs are increasingly becoming globalized, and that this globalization is often controversial, particularly from the standpoint of public health and access to medicines.

1.4 The Controversy in Context: Global Distributive Justice and Human Rights

If inequalities in global health and the globalization of intellectual property rights provide two reasons for considering the impact of IPRs on access to medicines, increasing interest in global distributive justice and human rights provides a third.

Issues of distributive justice are a relatively recent, modern phenomenon ("modern" in the philosophical sense being the 18th century and after; see (Fleischacker, 2004)); consideration of global distributive justice is even more recent. Michael Blake, for example, dates serious consideration of international justice to only the mid-1970s (Blake, 2005). Like many, Blake recognizes Peter Singer’s “Famine, Affluence, and Morality” in 1972 as starting this trend. Singer famously argued, using the example of a drowning child in a pond, that if one is morally required to save the child so long as no sacrifice of comparable moral importance is required, then one is also obligated to make the same minimal sacrifice to save an impoverished foreigner, no matter how far away (Singer, 1972).

Since then, the interest in global justice generally, and global distributive justice in particular, has resulted in an explosion of literature on the subject.26 Battle lines are

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26 For one of the better recent reviews of the literature – though one that now needs updating – see (Jones, 1999). See also (Caney, 2004).
drawn between those who think moral obligations of distributive justice toward foreigners are more or less stringent than those toward co-citizens (i.e., whether national borders matter).

At the same time, the modern conception of human rights, starting with the 1948 Universal Declaration of Human Rights, has been in need of more systematic theorizing. That is, the moral basis of these rights, including their content and corollary obligations, required serious thought (rather than simply their declaration) – particularly in light of major objections to the human rights enterprise. Henry Shue (1980) provided perhaps the first philosophical treatment of the concept of human rights, and James Nickel’s (2007) recent, updated book Making Sense of Human Rights continues in the attempt to spell out the theoretical foundations.

Because issues of global distributive justice and human rights occupy Chapter 4, I do not delve more deeply into them here. Suffice it to say for now that the modern conception of human rights represents one example of moral cosmopolitanism, i.e., a moral view that acknowledges the fundamental importance of all persons, regardless of where they live. Moreover, the modern conception of human rights intersects global distributive justice, in so far as human rights provide a sort of basic minimum for a minimally decent human life (as Shue’s right to subsistence suggests).
Nonetheless, whether one accepts this view, it should be clear that the subject is currently receiving increased attention. This is true even for health, and even in relation to disagreements over intellectual property rights. For example, in 2005, seventeen non-governmental organizations appealed to Paul Hunt (the United Nations Special Rapporteur on the Right to Health), asking him to take a human rights stance on IPR provisions in free trade agreements thought to undermine access to generic medicines in Thailand.27

All three of these reasons, then, provide substantial motivation to explore issues of IPRs and access to medicines from a philosophical perspective: massive inequalities in global health, the globalization of IPRs, and increasing interest in global distributive justice and human rights.

1.5 Normative Analysis

In light of this, what ought one expect from a normative analysis of IPRs and global distributive justice? On my view, normative analysis ought to perform at least two functions: cutting through the rhetoric often present in this controversy and providing a normative basis for change.

1.5.1 Normative Analysis: Cutting Through the Rhetoric

What is normative analysis? In broad terms, normative analysis or “moral theorizing” represents (borrowing from Allen Buchanan’s characterization of it in international law):

…self-conscious, systematic moral reasoning, the attempt to produce an interrelated, mutually supporting set of prescriptive principles that will provide substantial guidance for at least most of the more important issues with which international law must deal…” (Buchanan, 2004 14-16)

To fill out this claim, normative analysis exhibits several virtues that deserve recognition. First, it helps clarify disagreements, particularly those covered by rhetorical flourishes: From what do the representative controversies arise? Mere disagreement over the facts of the matter, or something else? More to the point, normative analysis proves most capable at this first task by use of its second, the revelation of normative assumptions, which often create or manifest as value conflicts. Finally, in line with Buchanan, one goal of normative analysis should be to provide guidance, or a basis for institutional change, by relying on a justified set of principles. I discuss this guidance below in section 1.5.2.

To see an example of the first of these virtues, consider the ample rhetoric present in the debate over IPRs and access to medicines.

On the one hand, continual refrains of “patent piracy” or the “theft” of intellectual property are as normatively vacuous as “killing is murder.” Just as the
concept of murder implies unjust killing, the concept of theft already contains the idea of unjust taking. On the other hand, calls for a “human right to access to essential medicines” occur without due consideration of the difficulties involved with a theory of human rights, what counts as an essential medicine, or (most importantly) who should bear the duties associated with such a right. These are the very considerations at issue.

This rhetoric is potentially damaging in several ways. First, while politically useful, it is shortsighted. Arguments won by rhetoric are less likely to be convincing, even if the position defended is in fact the best available option. Achieving long-term gains requires, among other things, the justified normative principles just mentioned. Second, rhetoric short-circuits any sort of normative enterprise – not just one’s own. This is because as discussions turn to rhetoric, conflicts over deep-seated moral values do not rise to the surface. To obscure the moral values one holds is dangerous because it can contribute to real harm, harm that results from one’s moral commitments and not merely from uncertainty or accidental mistakes. Consider the history of medical paternalism in American medicine. To simply repeat the mantra “doctor’s orders” without any recognition of, or appeal to, principles obscures issues of autonomy, gender, and, most importantly, power, as they occurred in real-life medical conflicts. A refusal to acknowledge moral values and the belief structure that supported them may have contributed to the pervasiveness and perseverance of medical paternalism in
America. I discuss the role of normative theorizing in this example in more detail below, but one must admit that this sort of rhetoric is potentially damaging.

Returning to the IPR/access debate, rhetoric further operates to oversimplify the debate into “pro-IPR” and “anti-IPR” sides. In South Africa, for example, the pharmaceutical industry might be caricatured as “pro-IPR” whereas civil society might be caricatured as “anti-IPR.” The “pro-IPR” camp often calls upon rhetorical notions of “piracy” or the “theft” of intellectual property (Hull, 2003). The “anti-IPR” camp, on the other hand, often presents the IPR debate as an equally rhetorical choice between patents and patients (Associated Press, 2001, Billing, 2001). While politically useful in certain circumstances, both positions are grossly oversimplified. Even as a first cut, the so-called pro-IPR camp could actually divide into:

- Those who think there is a “natural right” to IPRs, understood in an almost absolute sense (as a “trump” right that cannot be violated except in very narrow circumstances - on this view, it would not necessarily matter how IPRs affect access to medicines); and
- Those who think IPRs simply do not hinder access to medicines as a simple, empirical fact; and
• Those who think IPRs might hinder access to medicines, but that the benefits of IPRs outweigh their costs.

Of these, the last position is probably the most common, and the most interesting. One reason for this interest results from the observation that, by admitting benefits and costs into the equation, one might thereby admit considerations of how to distribute these benefits and costs. And this makes the subject of IPRs a normative one—one involving distributive justice.

Similarly, the so-called anti-IRP camp could divide into:

• Those who think IPRs should not exist at all; and
• Those who think that IPRs should exist, but that they should be somehow limited in certain circumstance (such as if they were to limit access to medicines); and
• Those who think that IPRs should exist, but that the existing system of IPRs should not necessarily be the one used in the research and development of all medicines.
Here again, even on a first cut, different types of claims, both normative (the anti-property rights position) and empirical (some other system of research and development would, in fact, result in better access to medicines).28

How does a normative analysis help clarify these various claims? At the first instance, a normative analysis should systematically expose the claims, rather than allow them to be captured by the rhetoric of “pro-IPR” and “anti-IPR.” Second, normative analysis properly scrutinizes them, determining when they are questions of fact or questions of “value” (i.e., “normative” claims about the distribution of costs and benefits, or what counts as a cost or benefit in the first place). Third, where claims are normative, this kind of analysis ought to articulate, and where necessary, reject or reconcile different normative viewpoints. It is important to emphasize that where disagreements are normative, empirical data alone cannot settle the issue. Thus, at several points throughout this work, normative analysis will serve to translate rhetorical aspects of the IPR/access debate into normative disagreement worthy or scrutiny.

28 As Chapter 2 will explore, the normative and the empirical might not separate out this cleanly, but this distinction roughly applies. The question naturally arises about the nature of this distinction. For my purposes, I reserve “empirical” for questions of fact (the descriptive “is” and “are”) and “normative” for questions of value (the prescriptive “ought” and “should”).
1.5.2 The Power of Normative Analysis: Normative Change

However, the power of normative analysis does not solely reside in its ability to turn rhetoric into principled disagreement worthy of normative scrutiny. In addition, normative analysis ought to also provide a special kind of reason for change, namely, normative or “moral” reasons for change. This power of normative analysis is best revealed by two examples: the abolitionist movement and paternalism in medicine.

Regarding abolition, what becomes apparent is that the end of the slave trade and of the practice of slavery is not fully explained by economic, legal, or mere prudential matters. Instead, a radical normative shift occurred – one that saw all humans as having equal moral status, at least so far as slavery was concerned. This is best illustrated by recent scholarship on ceasing the British slave trade and, eventually, the abolition of slavery itself.

If Adam Hochschild’s recent book *Bury The Chains* is correct in its account of the abolitionist movement in Britain, normative (or “moral”) theorizing can be quite powerful (Hochschild, 2005). Not only did a normative shift regarding slavery occur independently of economic, legal, or prudential matter, but it also occurred in spite of them. In a span of just over fifty years, a small number of individuals successfully brought down slavery in Britain in spite of its entrenchment in the British economy, supported by statesmen, businesses, and most religious groups. For Hochschild, the
Quaker Thomas Clarkson, whose religious beliefs led him to oppose slavery,\(^{29}\) and several others (including the more well-known William Wilberforce) led what Hochschild considers the first grassroots human rights campaign. It started with Clarkson’s formation of the Committee for the Abolition of the Slave Trade in 1787 and culminated in the Slave Trade Act of 1807 (ending the slave trade) and the Slavery Abolition Act of 1833 (abolishing slavery).

Debate might exist as to the extent to which the this abolitionist movement truly involved the concept of “rights” or whether many abolitionists (especially Wilberforce) saw freeing the slaves a matter of “Christian duty” or “charity.” (At least for Clarkson, the language of “natural rights” is clearly evident along with the Christian notion of charity.) In addition, one must acknowledge that many of the white abolitionists did not see the African slaves and their white owners as perfectly equal, in spite of their campaign against slavery, as discrimination and racism continued well after abolition. Nevertheless, two points remain clear: First, abolition depended in large part upon a shift in normative thinking toward the fundamental equality of persons (for many abolitionists, fundamental equality before God – an idea that has become secularized in

\(^{29}\) His 1786 *Essay on the Slavery and Commerce of the Human Species* described in injustices of slavery.
modern human rights\textsuperscript{30}). Second, while many others believed in this idea (and, to Clarkson’s credit, he acknowledges them in his writings), Clarkson and the grassroots campaign human rights campaign of letters, boycotts, and even the involvement of slaves translated this normative ideal into action. Such can be the power of normative theorizing. This is true, even if normative theorizing alone cannot in all circumstances bring about change (the context of particular circumstances matter).

By no means does this lengthy analogy with the abolitionist movement intend to suggest that the present project is equally significant. To this end, considering a second analogy, which is both less weighty and yet more closely related to health, is important. The case I now consider is the end of paternalism in American medicine.

In earlier days of modern American medicine, medical paternalism – i.e., the deliberately limiting the liberty of a patient, often by withholding information or presenting false information, for the patient’s own good – was quite common. For example, in a 1961 descriptive study, nearly 90 percent of physicians withheld cancer diagnoses (Oken, 1961). Decades earlier, however, Joseph Collins wrote an essay in Harper’s, “Should doctor’s tell the truth?” which gave various justifications for why physicians ought not tell the truth in certain circumstances (e.g., cancer diagnoses,

\textsuperscript{30} See Allen Buchanan, “Moral Progress and Human Rights,” (unpublished paper), which discussed the abolitionist movement and its radical normative shift to considering all humans as having equal moral worth.
terminal illnesses, and so on (Collins, 1927)). Some of these included, for instance, the idea that in many cases furthering the health of the patient required not telling him or her the truth; the idea that fallibility in medicine meant that no diagnosis was absolutely certain and thus a wrong diagnosis of a terminal illness would be too much for a patient to bear; and the idea that patients who are seriously ill do not want to hear bad news in the first place (even if they say that they do). Such propositions were apparently widely accepted and used to justify outright lying to patients.

Did normative analysis help change this situation, if one thinks outright paternalism is no longer present (at least to the same extent) in contemporary medical practice? It did, on at least two separate fronts.

The first front assaulted the medical paternalist on his own terms by showing how the normative justifications offered for paternalistic actions are woefully inadequate, requiring as they do broad psychological generalizations about comparative harm (Buchanan, 1978). For example, withholding a terminal diagnosis on the grounds that a particular patient would be better-off living the rest of his or her life in ignorance of this diagnosis presupposes a great deal. It presupposes, for example, that a physician knows a patient’s life history, typical ways of coping with stress, and future aspirations, among other features of a patient’s life. Yet not only are contemporary physicians often
not in the best position to make such determinations, they are in even a worse position to evaluate them for the patient him- or herself (Buchanan, 1978).

This leads to the second front, which assaulted the paternalist from outside paternalism, rather than on its own terms. It did so because paternalism both dismisses the value of self-determination (or autonomy) and normatively privileges health above all other patient values (Goldman, 1998). Regarding the form, respecting self-determination implies that only that patient, and not the physician, is capable of making certain evaluative judgments about the patient’s life (such as whether, all things considered, it is better to know of a terminal diagnosis). Similarly, regarding the latter, the medical paternalist often proceeded as if a patient’s overall good reduced to his or her “medical” well-being. Collins (1927), for example, suggested that telling a patient of a terminal diagnosis could lead him or her to become depressed and thus exacerbate the illness. This could be true. But because one’s overall well-being does not reduce to health, all things considered a patient might like to know this diagnosis (if well-being reduced to health in this way, certain activities like drinking alcohol, skiing, or riding motorcycles without helmets would be less common).

Simply put, normative theorizing helped reveal these flawed assumptions and expand the normative debate to include other, non-health values. To be sure, just as abolition did not end racism (in spite of its commitment to the equality of persons), early
normative theorizing did not end paternalism. More recent scholarship suggests that these initial refutations of paternalism were less effective because they failed to take into account the institutional environment of American medicine, the role of the physician, and the physician-patient relationship (Buchanan, 2002). Nonetheless, the abolitionist movement and paternalism in American medicine provide useful examples of the power of normative theorizing to help facilitate change.

1.5.3 Normative Analysis and IPRs

Given the ability of normative analysis to cut through rhetoric, expose and reconcile normative disagreement, and create a normative basis for change, a normative analysis of intellectual property rights and global distributive justice takes on new import. Or, as Pakes writes

Incorporating a more explicit, systematic ethical analysis into policy documents may be a means to better clarify goals, identify common issues, and – most importantly – map common solutions. (Pakes, 2006 341)

This comment reflects a belief, which I share, that a normative void exists in the debate over IPRs and access to medicines. The idea is not so much that no normative stances are taken – in fact, as I argue in Chapter 2, they necessarily are. Instead, the idea is that many of the disagreements about IPRs could be helped, if not resolved, by a more systematic normative framework or the ironing out of normative disagreement. The rest
of this work, in line with Pakes’s comment, attempts to fill this normative void. In the final two sections of this introductory chapter, I explain a few important terms (1.6) and sketch the overall argument (1.7).

1.6 Definitions

Before proceeding, providing sketches of what I mean by “intellectual property rights,” “global distributive justice,” and “access to medicines” is necessary.

The traditional definition of IPRs, as alluded to above, is that they involve patents, trademarks, copyrights, trade secrets, and so on. Of these, patents attract the most attention the literature surrounding the effect of IPRs on access to medicines, diagnostics, and scientific knowledge. This is not surprising; at present, patents seem to occupy a critical place in the research and development of medicines and diagnostics. If they were not important, or if different factions did not consider them so important, there would be little to argue about.

However, it is essential to recognize that I consider intellectual property rights as functionally defined. What is the function of a property right? Quite simply, it is a right to exclude. The legal definitions of patents, copyrights, and trademarks illustrate this well. For example, a patent is a right to prevent others from making, using, or selling whatever the claims laid out in the patent cover. One part of this thesis considers the
justification of intellectual property rights (Chapter 3), but the reader should not equate this with necessarily justifying or undermining the specific legal doctrines of patents, copyrights, and trademarks. The conclusion is more general than this and would apply to anything that functions like an intellectual property right, i.e., anything that confers ownership on an “idea.”

An example of something this broader definition would capture – but that generally falls outside discussions of patents, copyrights, and trademarks – is “data exclusivity.” Data exclusivity refers to a privilege given to the safety and efficacy data file submitted by a pharmaceutical manufacturer when registering a product with a regulatory agency. This privilege prevents other manufacturers from using the data, during a set period of time (usually 5 – 10 years), to register an equivalent generic product. Data exclusivity is, in other words, a right to exclude, making it a form of intellectual property according to my functional definition. Others agree, considering data exclusivity “patent-like” intellectual property (Médecins Sans Frontières, 2004).31

Under many circumstances, data exclusivity does not apply, such as when the patent on the molecule extends beyond the 5 or 10 year data exclusivity privilege. But if the patent were to expire (or not exist) during this period, data exclusivity would serve as a barrier to competitive entry to the market, as competitors would have to provide their own

31 See (Drahos, et al., 2004) at page 249, stating “…protection of this data into an exclusive form of protection, creating in effect a type of property right.”
data. Not only would that be wasteful, but it would also be unethical: Repeating clinical trials with human subjects places human subjects at risk without any prospect of direct benefit to the subject or indirect benefits of discovering new knowledge (So, 2004).32

The idea of a “functional” definition of IPRs requires further elaboration, so as not to include any sort of “control” as a property right, but the overarching principle is relatively simple: When offering a normative argument that relates to intellectual property rights, whatever general conclusions one might draw (if any) should prima facie apply to anything that looks like an IPR or acts like an IPR. To make this point clearer, suppose one arrived at the improbable conclusion that no intellectual property rights should exist. If that were the case, it would seem inconsistent to apply this conclusion only to patents, copyrights, and trademarks, leaving “data exclusivity” in place, if we understand “data exclusivity” as a property right.

Having given at least a sketch of what I mean by IPRs, I turn now to an even more abridged sketch of what I mean by “global distributive justice.” Following Simon Caney and others, I use the term “global,” as opposed to international or transnational, for a very specific reason: to remain agnostic on whether the modern state system

32 Another example of property right-like “data exclusivity” is the U.S. Food and Drug Administration’s (FDA) new drug product exclusivity. The FDA grants 5 years of market exclusivity to products containing chemical entities never before seen by the FDA. An instance of this might be the U.S. marketing of Glucophage (metformin) by Bristol-Meyers Squibb (BMS). Although available in Europe since 1979, market exclusivity via the U.S. Food and Drug Administration gave BMS exclusivity in the U.S. from 1995-2000. See (Kesselheim, et al., 2006). I am thankful to Anthony So for point this example out to me.
should be the primary subject of distributive justice at the global level (Caney, 2004).

To treat the state as such risks ignoring the activities of many non-state actors, whether international (e.g., the United Nations or European Union) or non-governmental (e.g., Medicins Sans Frontieres and other non-governmental organizations and civil society active in this area). The activities of these groups should remain within the purview of moral theorizing. All this is not to say that the modern state system is unimportant, or that it might be the best available means of effecting “global distributive justice” for one reason or another (Buchanan and DeCamp, 2006). But we ought not assume that from the start.

Moving on, “distributive justice” deals broadly with the distribution of knowledge, goods, and services (Lamont, 2003). Exactly what falls within its scope, and to whom these resources are owed (e.g., individual persons, communities, or states), is a matter of great debate. In fact, some might object to the notion of “global distributive justice” from the start, arguing instead that principles of distributive justice, if they exist at all, apply only within particular political communities. Hence, Chapter 4 is devoted to this topic.

This project, while interested in these general questions of global distributive justice, is most concerned with a very specific kind of distribution: the distribution of

33 For a different view, see (O’Neil, 2004).
knowledge, goods, and services in so far as this distribution affects global inequalities in health. Moreover, it is concerned with how intellectual property rights (IPRs) impact the distribution of health-related knowledge, goods, and services around the world – in particular, pharmaceutical goods. Distribution in this sense is closely related to access, where access represents a reasonable opportunity to obtain a particular good (not an absolute guarantee). Therefore, this project positions itself within debates and movements known popularly as “access to medicines” and “access to knowledge,” and it endeavors to make a contribution to such debates.

In what follows, then, I discuss mainly “access to medicines” while acknowledging that the debate is much broader than this. It is broader because, in many cases, diagnostics – not medicines – are a limiting factor to treatment, thereby contributing to global health inequalities. In addition, it is broader because, in many cases, the absence of knowledge – not medicines – is a limiting factor to treatment, thereby contributing to global health inequalities. Yet the focus on medicines is both simplifying and strategic. On the one hand, it is simplifying because it does not require me to address diagnostics, knowledge, or any of the other numerous health care technologies that could come to bear on this issue. On the other hand, it is strategic because (as Chapter 4) will point out, the idea of essential medicines provides a “best case scenario” for the normative view I will advance (namely, one based on human
rights). The idea of an essential medicine turns out to be very important to the overall enterprise. I leave open the question of whether the analysis that follows applies equally well to these other areas, if a similar story can indeed be told for these other products.

1.7 General Argument

So what is the story that this project will tell? It proceeds in an exploratory manner. It starts with the observation that disagreement exists regarding intellectual property rights and global distributive justice. But what causes such disagreement? I examine three hypotheses in the chapters that follow: that the disagreement is merely about the fact, not about normative issues; that the disagreement relates to the nature of intellectual property; and that it reduces to deep-seated normative disagreement over global distributive justice. Each turns out to be an incomplete and mistaken explanation of disagreements over intellectual property and global distributive justice, but taken together, they yield important insights. I conclude with an examination of various IPR reform proposals in light of the normative analysis which immediately precedes it.

1.7.1 Clearing the Way for Normative Analysis of IPRs: Rejecting the “Empirical Data Thesis”

The next chapter, Chapter 2, clears the way for normative analysis by suggesting that the debate over IPRs is normative, not just empirical. That is, the sorts of
controversies which opened this chapter do not reduce to disagreements about empirical findings, as behind the data lie important normative judgments about, e.g., how much access is “enough,” how much profit is “deserved,” or whether issues about IPRs are unimportant as compared to issues of poverty, development, and ineffective local governments. I reject the “Empirical Data Thesis” – which claims that moral disagreement is not at the root of disagreements over IPRs – first because it is untrue (real normative disagreements exist) and second because it is risky: It allows normative judgments to masquerade as statements of fact, making them more likely to be accepted and less likely to be revised. It also shifts the priority from one of achieving normative agreement to one of collecting more or better data. All of these are counterproductive for an enterprise that is actually normatively based.

Thus, in Chapter 2, I identify and review several representative examples about patents and access to medicines where empirical studies and data are misappropriated in this way. The empirical data only make sense from a policy standpoint given certain normative assumptions – assumptions that these empirical studies often neglect to mention or do so only in passing. More than this, I also suggest several ways in which a better understanding of the normative issues at stake could better guide empirical studies in the first place. For example, a normative stance that take seriously the fundamental importance of individuals ought to be cautious about using empirical
methods that aggregate goods across populations or groups, in so far as such methods are distributionally insensitive (i.e., they are blind the question of “who” receives the benefits and costs). (This is not to suggest that such an analysis would be “unethical,” “immoral,” or “useless”; instead, it provides a relatively simple example of how the normative can impact the empirical.)

1.7.2 Theoretical Justifications of IPRs: The End(s) of Intellectual Property

If the IPR/access debate is normative as much as it is empirical, what normative issues come into play? In Chapter 3, I consider the normative justifications for intellectual property rights. That chapter simplifies the terrain surrounding the different theoretical orientations to IPRs by suggesting that all viable theories of intellectual property are “instrumental” or “social planning” theories. By this, I mean that IPRs are a means to some other end (“instrumental”), and that this end involves taking some kind of normative stance on what, in part, a just society looks like (“social planning”). Doing so requires rejecting so-called natural rights views of property rights and demonstrating the similarities among the other, competing view of property.

Unfortunately, this diversity of viewpoints toward intellectual property rights is often ignored. Instead, I suggest that the dominant paradigm in contemporary policy discussions and ways of thinking about the role of IPRs in medical R&D is that IPRs
serve only to “maximize innovation.” I call this thesis the Intellectual Property & Innovation Thesis. A different way of thinking about this thesis is to call it a “Develop First, Distribute Later” paradigm toward medical R&D. In other words, medical R&D asks, “How can we create the most new innovations?” – that is, “Develop First.” On this view, theories of distributive justice ask a second question, “How do we equitably distribute what we have, now that it’s been created?” - that is, “Distribute Later.” These two dimensions are reflected in the disjoint between literature on medical innovation and literature on distributive justice in health care.

The problem, as Chapter 3 points out, is that this paradigm is deeply problematic. The divide between medical innovation and distributive justice cannot hold, for two reasons. First, the ways new technologies and medicines are produced determines, in large part, who will benefit from these technologies and medicines (and what those benefits are). Second, in many cases, the best way to effect distributive justice is to alter the incentives under which new medical technologies are produced. A paradigmatic example of this is the U.S. Orphan Drug Act, which (among other things) provides market incentives for companies to develop products for conditions affecting less than 200,000 Americans. The failure to see the connection between medical innovation and distributive justice has contributed to “three distributive problems” – access problems as a result of monopoly pricing; problems in the types of innovation
produced by relying only on exclusive intellectual property rights to created incentives for medical R&D; and problems in the distribution of IPRs themselves. Global data reflect the gravity of these problems.

Returning to IP theory, what is remarkable is that the diverse ends of intellectual property, represented by the diverse theoretical approaches to IP, could have enabled us to see this all along. What IP theory tells us is that IPRs serve a diversity of ends, and that one of these might be distributive justice. In fact, IPRs and IPR regimes just are parts of distributive justice because IPRs place constraints on the feasible range of distributive outcomes. And given that IPRs are now globalized, this could involve global distributive justice – that is, if global distributive justice is even a possibility.

1.7.3 Global Distributive Justice, Human Rights, and IPRs

Chapter 4, then, takes on the idea that, even if the IPR/access debate is normative, and even if IPRs are involved with distributive justice, any attempt to modify IPRs for the sake of global distributive justice is thwarted by irresolvable disagreement about global distributive justice. This is the “Global Distributive Justice Disagreement Thesis.” Chapter 4 rejects this thesis in stepwise fashion.

First, I suggest that remarkable agreement exists among reasonable and diverse views of justice about two issues. One is the condemnation of present global inequalities in general, and global health inequalities in particular. Another is the acceptance of
basic human rights. In other words, cosmopolitan and communitarian (or “nationalist”) alike increasingly agree about the importance of fulfilling basic human rights. I argue, following many others, that a human right to a basic minimum of health does exist, and that access to essential medicines forms one part of this part.

Second, I recognize that in spite of this remarkable agreement, little has been done to alleviate these terrible inequalities in health. This represents a curious failure; after all, it is not often that such diverse interests agree, and one might think in view of such agreement that action would quickly follow. Why is this?

In answering this question, I suggest that part of the problem is a failure to fully appreciate the implications of basic human rights – namely, that basic human rights might suggest not only that something must be done to remedy the present state of injustice (i.e., the “underfulfillment of the right to health), but how. Here, I suggest several critical features of contemporary theorizing about human rights, the most important of which is its “subject-centered” view of justice, to use Allen Buchanan’s terminology.

Returning to the issue of IPRs and access to medicines, and taking into account the key features of human rights, I then make the following claims. The present medical R&D system, with its dependence on exclusive IPRs to generate incentives for medical R&D, results in the predictable and avoidable underfulfillment of the basic human right
to health (of which access to essential medicines is one part). This is illustrated by the “three distributive problems” of Chapter 3, whereby the present medical R&D regime creates barriers to affordable medicines (through the high prices enabled by monopolistic rights); produces preferentially a certain “type” of innovations (i.e., medicines for wealthy markets, rather than neglected diseases); and results in IPR ownership being located mainly in developed countries. All turn out to illuminate different aspects of fulfilling the right to access to essential medicines.

And while debate will undoubtedly exist as to the precise content of this right to health care. This is true, even if additional work remains in order to define, through institutionally-based deliberation, the content of “essential medicines” (as the present World Health Organization’s Model List of Essential Medicines turns out to be inadequate).

So what should be done - donation of the medicines to those who need them? Such a solution, while perhaps possible, fails to take seriously the concept of “subject-centered” justice embodied in human rights. Just as fulfilling other human rights requires addressing their structural causes, so to does fulfilling the basic human right to health. Donation alone would be a wrong approach, first because it does not solve the problem of generating the right kinds of medicines to fulfill this right; and second, because even if it could, it takes the wrong normative stance toward the subjects of
justice. In particular, it encourages dependency and suggests that individuals are objects of charity, not subjects of justice. This is one example of how a human rights approach might tangibly contribute to “how” these rights are fulfilled. The real upshot of this chapter, however, is the elaboration of a normative basis for change: Human rights offer a plausible account of what is wrong with the present system of medical R&D and suggest not only the reform is required, but also how it might be accomplished.

1.7.4 How Normative Analyses Contribute to IPR Reform Strategies

In the final chapter, I return to more empirical issues by illustrating how the normative analyses just conducted might contribute to real world IPR reform strategies. First, I elaborate several different reform strategies that vary according to whether they can work within existing IPRs (e.g., drug donation programs; advance market commitments to purchase vaccines; and other) or whether they might require directly changing IPRs (e.g., by using prize funds, rather than exclusive rights, to reward innovation).

Next, I discuss some relevant normative criteria by which one might analyze different reform strategies. These include the “three distributive problems” of access to medicines; access to particular types of medicines; and a more equitable distribution of property rights themselves (understood on my view to relate to capacity building in
developing countries – not the further expansion of IPRs). It also includes political feasibility, cost distribution, whether new institutions are required, and whether it respects the “subject-centered” focus of human rights. Using these criteria, I evaluate the proposals, and come up with a few tentative conclusions.

One is that reforms should be skeptical of proposals that address the problem in the wrong way. Drug donation programs – while surely necessary to some extent – turn out to be the most prominent example of this. Not only is donation likely to be ineffective and limited to whatever the current R&D system produces (or dependent upon serendipitous veterinary or cosmetic uses), but also it fails to respect subject-centered justice. It does so by seeing the issue of access to essential medicines as one of charity, not justice.

Another conclusion relates to an overall skepticism toward one-size-fits-all solutions or any single, best IPR reform plan. What becomes clear is that few, if any, of the present IPR reforms under consideration can increase access to currently existing essential medicines, produce new essential medicines, and ensure that these are reasonably available with the costs of producing them equitably shared. Recalling this is
important in so far as many become personally invested in particular reforms and attempt to push them forward.34

A final conclusion is the continued need for capacity building so that developing countries might eventually be able to research and solve their own medical problems. Any reform proposal that fails to address this issue to some extent – particularly because capacity building, too, is a human rights issue – is surely flawed.

In the end, all this must be kept in perspective. Medicines, diagnostics, and access to health care services are important, but might not be the most important determinants of health. Other issues, from basic sanitation to education, could be even more important in some cases. More than that, global poverty itself must be alleviated. Nonetheless, reforming intellectual property rights by modifying current institutions or creating new ones provides one concrete, feasible, and normatively justified way to better fulfill a basic human right. That alone should motivate action.

34 It is here that a global medical R&D treaty could make the most sense by recognizing the need for a diversity of proposals. See http://www.cptech.org/workingdrafts/rndtreaty.html (accessed 5 April 2007) and (Jack, 2005).
CHAPTER 2. Clearing the Way for Normative Analysis of IPRs: Rejecting the “Empirical Data Thesis”

2.1 The Empirical Data Thesis Introduced

Before proceeding to more substantively normative issues, clearing the way for normative analysis is necessary. By “clearing the way,” I mean refuting a view that many endorse, if only tacitly; namely, the Empirical Data Thesis. Roughly, the Empirical Data Thesis states:

Disagreements about IPRs and access to EMs reduce to an empirical question that can be resolved by collecting the right empirical data.\(^1\)

According to the Empirical Data Thesis (EDT), the debate over IPRs, or the answer to the question, “Do IPRs hinder access to essential medicines?” is merely empirical. By collecting and examining the right data, we can answer this question once and for all. Below (section 2.3), I give several prominent examples in the area of IPRs where the EDT is apparently at work. Although no one explicitly endorses the Empirical Data Thesis, the hypothesis that they assume it to be true explains the character of the literature.

This chapter seeks to refute the Empirical Data Thesis, first because empirical data in this area are frequently – if not always – normatively-laden, and second because

\(^1\) This these might be more general, covering any empirical studies. For my purposes, however, I only wish to suggest the EDT false in the area of IPRs and access to essential medicines. I leave this broader normative-empirical project to others.
even if they were not, translating these data into policy conclusions requires a normative judgment. Not only does the EDT fail for these two reasons, but it is also risky (in ways I will discuss later) as a result of unarticulated or unacknowledged normative commitments.

Refutation of the EDT is not solely a negative enterprise. In the course of discussing the EDT, I also clarify the relationship between normative theorizing and empirical data. More specifically, while many acknowledge the ways in which empirical data can constrain theorizing in general (not just the normative type), the reverse is less often explored. Thus, at the end of this chapter I suggest how a firm understanding of systematic normative thinking might guide empirical studies and better resolve disagreements about IPRs and access to medicines. At least in the area of IPRs, this is seldom acknowledged.

As a preview, the kinds of normative issues obscured by the EDT in the debate over IPRs and access include: the determination of costs and benefits (i.e., what counts a relevant “cost” or “benefit”); how to weigh different costs and benefits (e.g., in the short-term versus the long-term); and how these costs and benefits are distributed (i.e., issues

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2 A temptation exists to use the phrase “normative theory.” Some might object to the use of the word “theory” in the normative context. From my perspective – and in agreement with Powers and Faden (Powers and Faden, 2006 x-xi) – my use of the term “theory” suggests Nagel’s “loose framework for deliberation,” perhaps with the caveat that one should not interpret “loose” too “loosely” (Nagel, 1979 167-7). Chapter 1 explains more about the role and power of normative theorizing.
of distributive justice). Frequently, if not always, proponents of the EDT and others performing empirical work in this area fail to acknowledge the normative stances they take in interpreting their empirical data. This chapter seeks to help remedy this error.

2.2 Empirical Data En Vogue

Examples from two other fields of philosophical inquiry help illustrate what I mean by the relationship of philosophical or conceptual work (of which the normative is just one part) to empirical work. The use of empirical data is presently en vogue in philosophy, and particularly so in the philosophy of mind and the philosophy of biology. Each illustrates important themes surrounding the relationship between normative theorizing and empirical data.

2.2.1 Philosophy of Mind

The first important theme is this: one’s conceptual orientation often determines, in part, the type of empirical research one carries out (or supports others to perform). The relationship between conceptual work in the philosophy of mind empirical brain science illustrates this theme nicely. Consider three broad theoretical approaches to mental events: the behaviorist approach, the neural process approach, and the cognitive approach (Bechtel, 1988).
Philosopher Wilfrid Sellars defined behaviorism as the attempt to explain “psychological events in terms of behavioral criteria” (Sellars, 1963:22). The specifics of behaviorism are unimportant for present purposes. What is important, however, were the implications the behaviorist theoretic orientation had on empirical science. Behaviorists conducted experiments meant to verify their hypotheses about the connection between psychological events and behavior (often using a rat behavior model), organized professional societies and scientific journals, and pushed behavior therapy in psychology (Graham, 2005). Noted psychologist B.F. Skinner even wrote of Walden Two, a fictional account of what society would look like if governed by behaviorist principles (Skinner, 1948).

Now largely discredited, behaviorism had an impact, for a time, on empirical work, to the point of founding entire research programs. More recent (and more accepted) theoretical approaches to the philosophy of mind reveal similar themes. The connection between the philosophy of mind and empirical neuroscience is nowhere more evident than in Patricia Churchland’s Neurophilosophy (Churchland, 1986). Her idea of the co-evolution of philosophy of mind and neuroscience is an “eliminative materialist” approach. She (and others) explain psychological events in terms of neural processes. To this end, neural imaging modalities, such as electroencephalography or
functional magnetic resonance imaging – not behavioral observation – become the focus of empirical work.

To some, the tight connection between philosophy of mind and empirical investigation is only a recent development (Bickle, et al., 2006). Others suggest that this connection has always existed; for example, William Bechtel mentions the

…close interaction between philosophical claims and empirical research efforts such that those engaged in an empirical investigation frequently assume, consciously or unconsciously, a particular philosophical stance.(Bechtel, 1988 3)

Similarly, Alvin Goldman’s *Philosophical Applications of Cognitive Science* recognizes that “issues in the philosophy of mind are often closely intertwined with choices of research strategies in cognitive science (Goldman, 1993 63).” Nonetheless, for both Bechtel and Goldman, the predominant direction explored is from empirical research to philosophical stances. Philosophy dutifully serves its role as the Lockean handmaiden to the sciences. They acknowledge, but neglect, the claim about how philosophical stances impact empirical research.

In more recent years, philosophical or conceptual work has assumed a more prominent role in cognitive neuroscience. For example, this author’s own institution, Duke University, offers an interdisciplinary training program that includes philosophy in its Center for Cognitive Neuroscience.3 Much more could be said here; suffice it to

say that the interaction of philosophical work with empirical investigation is a fruitful one. Most importantly, this interaction reveals how one’s philosophical orientation underlies, and in at least some cases impacts, empirical work.

2.2.2 Philosophy of Biology

The prior section suggested that philosophical orientations underlie empirical work and in some cases impact it. This section makes more concrete the latter claim about how conceptual work in philosophy impacts empirical work using an example from the philosophy of biology. Two themes emerge: first, in some cases, philosophical distinctly steers the direction of empirical research (more than merely underlying it). Second, in cases where one has the “wrong” philosophical approach, one is also apt to misinterpret empirical data as evidence for that same “wrong” approach.

Many examples present themselves from philosophy of biology, or science more generally. A relatively recent and interesting one on which to focus is the acceptance of “group selection.” Group selection is the idea that natural selection occurs via the differential fitness of groups, not just individuals, and in spite of its Darwinian origins, it has had a tumultuous history (Sober and Wilson, 1998). In evolutionary biology,

4 I owe this example to Robert Brandon.
5 A good summary of this history is in the first two chapters of Elliot Sober and David Wilson’s Unto Others. What follows draws heavily on their work. Sober and Wilson examine altruism because, from an individual selection point of view, altruism should not evolve. Paradigm cases of altruism – the honeybee that uses its
where one stands on this so-called “level of selection” debate has profound implications for explaining the evolution of certain behavioral traits, such as altruism, in animal populations.

According to Sober and Wilson, in the 1960s, group selection fell out of favor with biologists. For example, biologist G.C. Williams’ 1966 book *Adaptation and Natural Selection* assaulted group selection, asserting that group behavior reduces to the collective actions of individuals – and nothing more (Sober and Wilson, 1998 10). In the past several decades, however, group selection has re-emerged as a viable explanation for certain traits. Here again, the details are not as important as the reason for the return of group selection as an evolutionary force in addition to individual selection.

Why did Williams oppose group selection as a viable explanation for the evolution of certain traits? One reason, among others, was parsimony (Sober and Wilson, 1998 38). Because of his commitment to a theory of individual-only selection, he sought to reject group selection by studying empirical data about sex ratios.

The ratio of the number of females to the number of males born in human populations is about 105:100. Individual level selection, acting alone, favors an even sex ratio, whereas group selection acting alone favors a heavily female-biased sex ratio.

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stinger to protect the hive, thereby killing the bee – are problematic at the individual level for the survival of the fittest. They then seek to explain such traits by noting that groups of altruists (or with altruists) will better succeed evolutionarily (i.e., produce more offspring) than groups of non-altruists (Sober and Wilson, 1998 4). This is true even if one accepts that altruism is evolutionarily costly for the individual altruist.
Because the observed sex ratio in humans (and other organisms) is frequently close to one, Williams concluded that group selection did not occur. Group selection therefore fell out of favor, “comparable to the rejection of Lamarckism” (Sober and Wilson, 1998 39-40). Williams’ theorizing about levels of selection led him to consider empirical data, which confirmed his theory of individual selection.

Most interesting, however, was a paper appearing in Science one year later, W.D. Hamilton’s “Extraordinary Sex Ratios” (Hamilton, 1967). Hamilton documented a large number of female-biased sex ratios among species and used the concept of a species’ average fitness to help explain each ratio. In doing so, Hamilton recognized that two forces work to create this average: female-biased sex ratios increase the size of the population (group selection), but even sex ratios are evolutionary advantageous for individuals within that population (individual selection) (Sober and Wilson, 1998 41).

Unfortunately, others did not recognize this, nor connect it with Williams’ earlier study using sex ratios to help resolve the level of selection debate. In fact, they mistakenly interpreted Hamilton’s work as evidence in favor of individual selection alone. Sober and Wilson lament

At the very time that group selection theory was entering its dark age, the empirical evidence that should have counted as evidence for group selection was accepted as a triumph of individual selection theory! (Sober and Wilson, 1998 42)
If this all too brief history is correct, it implies that conceptual or theoretical work in the philosophy of biology – in this case, conceptual work on an alternative, group-level selection when the concept of individual selection was deeply entrenched in biology – was influential in encouraging empirical studies (e.g., Hamilton’s sex ratios) in order to help resolve the level of selection debate. More than that, it also implies that individuals engaged in this sort of empirical work were apt to interpret those results in ways consistent with their prior theoretical commitments.

### 2.2.3 Returning to IPRs and the Access Debate

In sum, philosophical work impacts empirical work in three main ways: first, because empirical work often presupposes some kind of philosophical stance; second, because these philosophical stances might direct or partially determine the kind of empirical work performed; and third, because one’s philosophical stance might, under certain circumstances, influence how one interprets the empirical work itself (a sort of “confirmation bias,” in psychological terms).⁶

Even at this early stage, then, we have reason to doubt the Empirical Data Thesis. If any or all of the above statements are true, it is unlikely that the IPR/access debate

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⁶ Some might object to the move from consideration of “conceptual” work to the consideration of “normative” work, citing a significant disanalogy. However, my discussion of “conceptual” work is only meant to illustrate the potential impact of philosophical work on empirical studies and debates. Thus, the analogy is not essential to my general argument.
reduces to disagreements over empirical data. The challenge will be the flesh out these three distinct levels of impact in the area of IPRs and access to essential medicines.

At this point, one might wonder why I emphasize the move from the philosophical or conceptual to the empirical, rather than vice versa. The rationale is simple. First, the impact of empirical work back on the philosophical or conceptual is widely accepted. Numerous examples come to mind in the sciences and in medical ethics. In science, for example, theorizing about the sun’s movement around the earth became meaningless when empirical work dismantled geocentrism. In medical ethics, the normative (and paternalistic) claim that terminal cancer patients do not want to hear their diagnosis rings hollow once empirical surveys show that, in fact, they do (Alfidi, 1971).

Second, and more importantly, because my eventual interest is in showing how normative analyses might move forward the debate over IPRs and access to medicines, my emphasis here is similarly aligned.

The rest of this chapter clears the way for normative theorizing about IPRs and access to medicines. In section 2.3, I make the case that popular and influential empirical studies often mask normative claims within empirical studies; that is, they mistakenly assume the Empirical Data Thesis. For each example, I give clear and

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7 For a review of the various ways in which empirical research impacts medical ethics, see (Sugarman and Sulmasy, 2001).
concise examples of normative claims that are unacknowledged. In section 2.4, I explain in more general terms why the EDT is false, as well as why it is risky. And finally, in section 2.5, I offer suggestions about the way in which normative theorizing can contribute to empirical studies in the area of IPRs and access to medicines – just as conceptual theorizing has already done for philosophy of biology and philosophy of mind. Good normative work can positively impact good empirical work and is essential to translating empirical work into policy.

2.3 Intellectual Property Rights and Access to Essential Medicines: Normative, Not Just Empirical

A comprehensive survey of all the empirical work in the IPR/access debate is well beyond the scope of this project. Instead, in the following subsections, I focus on three prominent areas of recent empirical scholarship: the debate about patents and access, focusing on where medicines are patented; the debate about the role of patents as incentives for pharmaceutical research and development or innovation; and the debate over intellectual property rights and foreign direct investment.

As a preview, the conclusion of this section is that each debate, as framed in the empirical literature, is severely truncated by neglecting the normative claims either embedded in the data or necessary to translate the empirical research in question into
policy solutions. Each debate does this in a way that is normatively instructive, a topic that I take up in section 2.4.²

2.3.1 Patents and Access to Medicines

In two oft-cited articles, Amir Attaran (with Lee Gillespie-White in one article) asks essentially, “Do patents constrain access to medicines in developing countries?” The answer, according to Attaran, can be found by empirically examining what medicines are patented where: If antiretrovirals and other essential medicines are unpatented in developing countries, then patents cannot be the main barrier to treatment access. Here then might be two good examples of the Empirical Data Thesis at work.

2.3.1.1 Attaran and Gillespie-White: Patents and ARVs

In the first influential article, Attaran and Gillespie-White examined 15 antiretrovirals (ARVs) for HIV/AIDS treatment in 53 African countries from October

² In the debates the follow, I distinguish between the normative issues at play and the potential conflicts of interest also at work. For example, many criticize empirical studies supporting industry positions on IPRs because the industry funded those particular studies (and those conducting them would like continued industry support, leading them to misinterpret their studies or conduct them in certain ways). Many also criticize empirical studies opposing industry positions because those involved are anti-corporate interests. The conflict of interest issue is critically important. However, my goal is to interpret these studies from the standpoint of, “What normative assumptions are needed to allow interpretation of the empirical study in this way?” As such, what follows operates somewhat orthogonal to the conflict of interest debate.
2000 – March 2001 (Attaran and Gillespie-White, 2001). Their principal findings and conclusions were as follows:

- In 795 possible instances of patenting\(^9\) (53 countries times 15 ARVs), only 172 (21.6% of the total) actual patents existed (Attaran and Gillespie-White, 2001 1887).

- Several of the “strongly recommended” highly active anti-retroviral therapy (HAART) regimens by the US Department of Health and Human Services (HHS) were unpatented in 52 of 53 countries (Attaran and Gillespie-White, 2001 1887).

- Notable exceptions to this overall low percentage of patenting include South Africa (where 13 of 15 ARVs were patented) and the behavior of individual companies (e.g., GlaxoSmithKline’s Combivir, patented in 37 of 53 countries) (Attaran and Gillespie-White, 2001 1887).

- Although the current level of patenting is low, the authors acknowledge that yet-to-be-developed antiretrovirals might be another matter, and their study could not address these.

\(^9\) In their article, Attaran and Gillespie-White actually refer to “exclusive rights,” which includes patents (whether on product, process, or mode of treatment) or market exclusivity. For simplicity, I use the term “patent” broadly here.
• They also acknowledge that it is wrong to cite their study as proof that patents never affect access, though other factors might be more important (such as overall financing, availability of infrastructure, inefficient drug regulatory agencies, or high tariffs) (Attaran and Gillespie-White, 2001 1890).

• Finally, Attaran and Gillespie-White propose and an “equitable balance” between respecting patent laws and patent holders themselves supplying medicines to the poor without profit (Attaran and Gillespie-White, 2001 1891).

The article’s findings evoked a strong response from many activists and those involved with administering HAART in these settings (e.g., Médecins Sans Frontières, or MSF).10 To a large extent, however, the responses took the authors to task on empirical grounds.

One empirical response reinterpreted the data by looking beyond simple “patents versus country” totals and examining patents against other metrics, such as

10 See the MSF response (with several other NGOs) at http://www.accessmed-msf.org/prod/publications.asp?scntid=171020011428553&contenttype=PARA. Accessed 10 April 2007.
percentage of HIV patients on the African continent or GDP. James Love and Michael Palmedo performed that analysis and found the following:\textsuperscript{11}

- Countries with patents on 6 or more ARVs have 46\% of the HIV patients.
- In terms of GDP, 68\% of the group’s GDP is located in countries with 4 or more ARV patents.
- Combining per capita income with infection rate revealed that 82\% of per capita income times infected persons is located in countries with 6 or more ARV patents.

In other words, patenting-by-country analyses miss a simple empirical fact: Patents in a single country might be critically important if that country has a high infection rate or high per capita income (indicating ability to pay for the medicines).\textsuperscript{12}

A second empirical response focused not just on individual countries, but also on individual treatment regimens. Boelaert et al (2002), in a response published in the same journal, noted that certain triple therapy combinations – such as zidovudine/lamivudine/nevirapine – were considered better for developing countries.

\textsuperscript{11} Their data, calculations, and explanations can be found at \url{http://lists.essential.org/pipermail/ip-health/2001-October/002010.html}. Accessed 10 October 2006.
\textsuperscript{12} This point is also well-developed by Kritina M. Lybecker (Lybecker, 2003).
and yet were blocked by zidovudine patents in 33 of 53 countries and nevirapine patents in 25 (Boelaert, et al., 2002 840).13 Those working in-country supported this claim by explaining that in South Africa, where all treatments were patented, the price of two of the necessary drugs in combination (GSK’s Combivir) was three times more expensive than generic medications (Goemaere, et al., 2002). Therefore, Attaran and Gillespie-White’s broad empirical claims fail to recognize individual treatment opportunities blocked by certain patents.

One other empirical rebuttal concentrated on future predictions about patenting as a result of recent WTO Agreements (i.e., TRIPs) and trade negotiations. The main concern here was that, even if Attaran and Gillespie-White’s analysis were correct in 2000-2001, future antiretroviral medicines and improvements on older ones would be more likely to be patented as more African countries are required, or decide, to adopt pharmaceutical patenting (e.g., through the African Growth and Opportunity Act) (Consumer Project on Technology, et al., 2001). If true, this counterargument suggests that even if Attaran and Gillespie-White’s analysis were correct for the period studied, the analysis would not predict future behaviors and so would be a shaky guide for policy.

13 In their response, Attaran and Gillespie-White further questioned the clinical utility of this combination and recommended another, less frequently patented one (Attaran and Gillespie-White, 2002). For my purposes, the details of the argument are less important than the observation that it is an empirical disagreement.
Common to all three of these empirical responses was how each took the authors of the original *JAMA* study to task on its own terms, i.e., empirically. Such a reaction is critical to ensure that, as much as reasonably possible, the empirical facts are straight when making policy decisions.

 Nonetheless, some of the (less well-publicized or recognized) responses to Attaran and Gillespie-White hint at a disagreement occurring at a different – and perhaps *normative* – level. For example, at one point in the joint NGO response, critics assailed the two co-authors for assuming too much about the status quo of the rapidly globalizing IPR regime. They remarked that the suggestion that countries can make do with the US and European offers of concessionary prices does not deal realistically with the factors that lead to those price decreases (*threats* of compulsory licenses, *extraordinary and unsustainable* NGO and UN pressures, the existence of a competitive market for ARVs created by Brazil14), nor does it recognize the substantial price differences that still exist (Consumer Project on Technology, et al., 2001) (*emphasis added*).

 Restated, these groups take issue with a system of IPRs that requires *threats*, *extraordinary and unsustainable* measures, including mass political mobilization, to encourage that kind of voluntary price reductions that made Attaran and Gillespie-White’s analysis even possible. To make the matter even more concrete, others point out that, until the year 2000, the high cost of ARVs (up to $10,000 per year) made almost any

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14 Part of the reason for Brazil’s competitive market was the fact that Brazil did not recognize pharmaceutical patents until 1996.
drug treatment in Africa infeasible (Boelaert, et al., 2002). To this, one might also worry that the delay in the development of fixed dose combination (FDC) pills was at least partially a result of competing firms’ ownership over different medicines necessary to produce such a FDC pill. Importantly, all these concerns reflect dissatisfaction with the IPR system, that it is perhaps unfair and ought to be different. And to suggest this is to suggest a normative, not an empirical, disagreement.

A somewhat more obvious normative disagreement is evident in the response of bioethicists Michael Selgelid and Udo Schuklenk (Selgelid and Schuklenk, 2002). Two of their points are worth emphasizing here. First, they worry that the Attaran-Gillespie-White findings “are likely to be misrepresented by pharmaceutical lobbyists...with the aim of blocking proposed TRIPS agreement amendments that weaken pharmaceutical patent protection in developing countries.” One wonders if this alone makes it incumbent on Attaran and Gillespie-White to recast their findings, rather than relying on what Selgelid and Schuklenk (2002) call “carefully qualified conclusions” about, for example, the importance of South Africa, individual companies, or future ARVs to the analysis. And although Attaran has himself criticized the media for its selective reporting of his work (Attaran, 2003), whether these ex post facto efforts were sufficient to prevent spurious uses of the JAMA piece is another matter.
Their second point is that Attaran and Gillespie-White are wrong to suggest that if patents are not the only, or even the primary, access barrier, then they require no attention. In other words, the fact that something is not the only, or the main, access barrier says little about whether it is a barrier that should be removed or modified. Selgelid and Schuklenk give the following thought experiment (recalling that Attaran and Gillespie-White had identified poverty and lack of international aid as the primary barrier):

Imagine that the poverty problem in Africa’s poorest countries had already been somewhat alleviated via international aid. More patents would have been sought, drug prices would have increased, and aid money would purchase fewer drugs than would have been possible if it were not for intellectual property protection. If this retrospective analysis is correct, then it is misleading to claim that poverty rather than patents pose barriers to care (Selgelid and Schuklenk, 2002).

What these bioethicists say implies not only that it is a normative judgment to consider something a “significant” barrier, but also that the two barriers in question here (poverty and patents) are inextricably linked. The simple fact that something is described as being or possibly is a barrier encourages us to ask whether it is one that might be removed. The question is whether it is a barrier, not the only barrier.

Before proceeding to a second highly influential empirical study by Amir Attaran, one other preliminary normative claim is worth noting. This judgment – a major conclusion of Attaran and Gillespie-White – translates their findings into the
policy statement that patent owners’ voluntary action to supply ARVs at a “no profit” price should be sufficient for supplying medicines to the poor.

To this end, and given the current state of affairs, voluntary action to supply drugs at zero profit might never be sufficient. More importantly, certain institutions (like the currently globalizing system of IPRs) might act to unduly inhibit this voluntary action. Just as NGOs considered the pressures necessary to lower ARV prices extraordinary and unsustainable, waiting on voluntary action in this way might prove equally challenging. What we do know is that at the time of this controversy, certain pharmaceutical companies (e.g., then GlaxoWellcome – now GSK) that held a large number of patents in countries (e.g., Uganda) wrote letters to generic companies (e.g., Cipla) to protect their IPRs. Moreover, we have reason to be skeptical of whether this has substantially changed (Hartsough, et al., 2006).

Much more systematic normative work remains on this important controversy. I take this up below in section 2.3.1.4, after explaining two related examples of the EDT.

2.3.1.2 Attaran, Patents and Essential Medicines

The prior example about ARVs and patents might not have been so noteworthy had the same controversy not erupted again, three years later, among the same

individuals. In 2004, Amir Attaran performed a similar analysis, expanding beyond ARVs to look at 319 essential medicines (as defined by the World Health Organization’s Model List of Essential Medicines16). This time, he found the following: only 17 were even patentable, with an overall low patent incidence (1.4%) heavily concentrated in large markets (Attaran, 2004b). Other major findings and conclusions included:

- Of the 969 total “patentable” cases (where patentable case equals a particular essential medicine in a particular country), companies did so 31% of the time (300 cases). Only 186 of these were fundamental, in the sense that the patent actually served to block generics (Attaran, 2004b 158).
- “Patents cannot cause essential medicines to be inaccessible in ‘many’ developing countries because they do not exist 98.6 percent of the time; similarly, patents cannot be a ‘global’ necessity of pharmaceutical business because companies forgo them 69 percent of the time (Attaran, 2004b 159).”

• Again, Attaran concludes that poverty – not patents – are the problem, though appropriate “out-licensing”\footnote{\textit{Out-licenses}, for Attaran, are voluntary, non-exclusive licenses from a pharmaceutical patent holder to a generic company to sell one of its patented products in developing country markets in exchange for some royalty amount (e.g., 5\% of sales). For more, see (Friedman, et al., 2003).} of patents might help the pharmaceutical industry’s image and perhaps improve access.

Responses to this article were equally quick and equally empirically-minded. James Love suggested that patented medicines were often excluded from the WHO Essential Medicine list because the list takes cost-effectiveness measures into account (i.e., because of the high cost of patented drugs), thereby biasing the results (Hubbard and Love, 2004). Eric Goemaere et al. (2004) again noted that certain patents can have dire consequences – for example, GSK’s patent on 3TC (an ARV) blocked the availability of the simplest and most affordable AIDS treatment available—the WHO-recommended fixed-dose combination of d4T/3TC/NVP (Goemaere, et al., 2004). He also noted that such patents were likely to increase because of increasing harmonization of IPR law through TRIPS and bilateral trade agreements.

On the other side of the empirical debate, Eric Noehrenberg of the International Federation of Pharmaceutical Manufacturers Association lauded the article. But he also
suggested that a general policy of voluntarily out-licensing essential medicine patents was unnecessary (Noehrenberg, 2004).18

Fewer normative-sounding responses followed this second Attaran analysis. One example, from the electronically published eLetters to Health Affairs, echoed the earlier worry that one ought not infer from the extent of poverty that the patent barrier is therefore unimportant or does not require systematic changes. Connie Liu and Sanjay Basu stated “to acknowledge that there are several blockages in the pipeline between better research and better patient outcomes does not logically render one important blockage less obstructive.”19

As I did above, I hold off on the normative theorizing from this section until after discussing one final, less well-known, example of an empirical study in the patents/access debate.

2.3.1.3 Borrell and Watal: Patents and ARV Access

This last example is notable, first because it is a more complex analysis of patents and access to ARVs, and second because it reaches a somewhat different empirical

18 Attaran’s response to these criticism in Health Affairs expressed frustration at both sides. For example, he implied both sides demonstrated “exaggeration” and “histrionics.” And toward the pharmaceutical industry side, he noted the “…stunning incognizance that price reductions have barely improved the industry’s battered public reputation. Intransigence is not the way for the drug industry to win friends.” See (Attaran, 2004a).
conclusion. In the latest revision of their paper, Joan-Ramon Borrell and Jayashree Watal use pharmaceutical sales data from 1995-99 in 34 low and middle income countries to examine how two primary forces (drug pricing and market introduction\(^{20}\)) impact whether, or how, patents affect access to ARVs (Borrell and Watal, 2003). They call the net effect of these two factors an “empirical question” (Borrell and Watal, 2003 5), thus implying some degree of commitment to the EDT.

Their findings include the following:

- Patents appear to increase availability of the drug (because innovators might have an incentive to introduce a drug sooner) but decrease the sales of the drug (because of higher prices). The net effect is 34% fewer sales (Borrell and Watal, 2003 2).

- According to their model, switching to a “no-patent” regime would increase annual treatment doses in some areas (e.g., South Africa, Thailand) but reduce it in others (e.g., Central America, Indonesia) (Borrell and Watal, 2003 21-2).

- Overall, the switch to a “no-patent” regime would increase the number of patients treated for HIV/AIDS in these countries, but only from 0.88% to

\(^{20}\) “Market introduction” acts as a positive force in this analysis. It implies that having patent protection encourages a company to introduce a product into a particular country.
1.18%, still leaving 98.82% of HIV/AIDS patients without treatment (Borrell and Watal, 2003 5).

Based on this, the authors conclude that “patent rights do matter but patents cannot be blamed for the lack of access of the vast majority of patients in developing countries” (Borrell and Watal, 2003 21).

In several ways, their results agree with Attaran and Gillespie-White’s. For example, patent status might have a different impact in different countries, depending on the country’s overall income, income inequality, and many other factors. And like Attaran and Gillespie-White, they seem to conclude that patents “cannot be blamed” for the lack of access to ARVs.

Another point of agreement is the use of so-called “static” analyses to draw policy conclusions.21 The methodology used in these studies frequently does not adequately take into account external changes – social, political, and otherwise – that might arise as a result of seemingly minor policy changes. Before the year 2000, for instance, when HIV treatment cost over $10,000 per year, international aid funding would not have been geared toward treatment of HIV as much as its prevention, and justifiably so. At the time, one might have been tempted to suggest that lowering HIV

21 I owe this point to Anthony So.
drug prices would have little effect on access, because so little aid funding went toward treatment programs. Clearly this neglects that fact that lowering prices might cause a shift in the allocation of aid funding, once treatment became cost-effective. Therefore, we ought to be wary of empirical analyses that are limited in this “static” way.

Of course, empirical limitations are just as evident in their work as in the prior analyses. The authors freely admit that they focus only on retail sales, ignoring major, free distribution programs such as those in Brazil and Thailand. This is significant, given recent estimates that Brazil treats upwards of 130,000 individuals through its government-funded HIV treatment program. In developing countries, the use of retail sales data as a proxy for access might be particularly suspect, particularly in cases where a nation’s IPR strategies undermine retail sales. My emphasis here will not be on these empirical issues, however; instead, I focus on the normative ones.

2.3.1.4 Normative Issues

Having spent some time explaining the above three examples, it is time to make good on my promise to examine more systematically their normative dimensions.

Some of the normative issues in these examples mirror those suggested by my prior examples from the philosophy of mind and philosophy of biology. To reiterate, earlier I suggested that philosophical work impacts empirical work in three main ways: first, because empirical work often presupposes some kind of normative stance; second,
because these normative stances might direct or partially determine the kind of empirical work performed; and third, because one’s normative stance might, under certain circumstances, impact how one interprets the empirical work itself. Examples of all three are evident in examining the above debate over patents and access to essential medicines.22

Consider first the idea that empirical analyses often presuppose some kind of normative stance.23 For the patent/access debate, what counts as a “significant” number of patents (particularly for Attaran and Gillespie-White) appears to be unacknowledged and certainly not defended. What is it about 1% of essential medicines under patent that allows us to conclude that patents are therefore unimportant, versus 2%, 10%, or more (or less)?

Similarly, on what basis do Borrell and Watal conclude that patents are not significant barriers to access (even though, unlike Attaran, they do conclude that they are barriers)? Is this because “only” thousands of additional individuals (as opposed to the millions who are HIV positive) would have had access to treatment, were no patents in

22 What follows is, in some respects, speculative, but this does not render it uninstructive.
23 A different way of stating this would call to mind the work of Elizabeth Anderson in feminist epistemology. As she notes, feminist epistemology is the daughter of Quine by understanding observation as “theory laden,” i.e., observation only makes sense against some background theoretical assumptions. Yet feminist epistemology, according to some, goes further in suggesting the important role value (or “normative”) judgments play in empirical projects. I am in agreement on both points. See (Anderson, 2007). I thank Alex Rosenberg for pointing out this point.
place? Perhaps they assume something about how cost effective it would be to change the patent system for the sake of those individuals, but they do not articulate this clearly normative view. In fact, a normative view that takes seriously the right of all individuals to access essential medicines might come to a different conclusion based on these same data. For example, on a human rights-centered view, the benefits accruing to these thousands of individuals might weigh more strongly in the decision about whether to honor patents in particular countries, particularly if the main cost is a small decrease in profits among corporations.24

In short, the answer to the seemingly empirical question “Do patents constrain access to antiretrovirals?” could be yes or no, depending on one’s normative stance. This is because the idea of “constraint” appears to operate as a normative term, more like “unreasonably constraining” or “unduly hindering.” Different people might disagree about what counts as an unreasonable constraint, making this at some level a normative dispute.

Consider second the idea that one’s philosophical or normative stance might direct or partially determine the kind of empirical work performed. In his analysis, Amir Attaran fails to consider seriously the observation that certain seminal patents might be critically important to medicine access. Might this result from a normative

24 I do not advocate such a view here but simply note it to highlight the difference.
stance that places primacy on the aggregation of data across different countries, drugs, and patent systems, rather than one that takes seriously the distributional differences among and within these countries?

Finally, recall the critically important notion that one’s philosophical stance might, under certain circumstances, impact how one interprets the empirical work itself. Fulfilling this third way in which a philosophical or normative stance affects empirical data could be Attaran’s emphasis on poverty and voluntary out-licenses. Could it be that Attaran’s normative view that poverty is the most important barrier to access blinds him to evidence that reliance on voluntary out-licenses might be insufficient or infeasible, given how actors (like multinational pharmaceutical companies) are likely to behave?

In fact, the dearth of international aid and the extent of poverty, as emphasized by Attaran, would overwhelm almost any factor in the access debate: Why worry about patents if the problem is poverty? Why worry about medicine delivery systems if the problem is poverty? Why worry about training health care workers in developing countries if the problem is poverty? Taking this line of reasoning one step further might lead us to the strange claim that we ought not worry about medicine prices if poverty is the real problem. If access to medicines awaits a general solution to the problem of poverty, this takes off the table almost any targeted policy.
The reason this is a strange claim is because poverty – understood as a lack of available funds to purchase medicines – is linked with whether medicine prices are affordable in the first place, and medicine prices are linked to available generic competition and the way IPRs are governed. Higher prices in a situation where health budgets are limited reduce access. Stated a different way, poverty might be a problem in affording medicines, but so might be the high prices enabled by monopoly pricing. In Thailand, for example, estimates suggest that the use of compulsory licensing could reduce the cost of second-line HIV therapy by 90%, thereby reducing its future budgetary obligations by $3.2 billion through 2025 and cutting by over half the cost per life saved (from $2,145 to $940) (Revenga, et al., 2006 169).

Perhaps the chief normative assumption to emphasize from the above debate is to the false either/or choice between a “patent” (with or without voluntary out-licensing) system to a “no patent” system. Such an assumption ignores alternative institutional arrangements, or changes to patent rules themselves, that might facilitate better access to medicines. These alternatives could be based on empirical facts, normative judgments, or both. Attaran, Gillespie-White, Borrell, and Watal all fail to ask whether more subtle changes might be made; if so, what kind of changes; and why we ought to make these changes for the sake of access. All of these issues are normative as much as they are
empirical. What is most remarkable is that those who make the above normative assumptions do not defend them, even though they might be contestable.

2.3.2 Patents and Incentives to Innovate (R&D)

Having examined the patent/access debate and exposed some of its normative elements, I now move to a second contentious area within intellectual property rights and access to essential medicines: IPRs and incentives to innovate. Normative claims are no less evident in this area, though they differ in instructive ways.

Few question the importance of IPRs (and more specifically, patents) to the pharmaceutical industry. In a frequently cited survey conducted from 1981-83, Edwin Mansfield found the pharmaceutical industry to be most reliant on patent protection. Respondents suggested that 60% of inventions would not have been developed and that 65% of inventions would not have been introduced without patent protection (Mansfield, 1986 175). More recent work by Frederic Scherer (noted by the Commission on Intellectual Property Rights) confirms a continued perception that IPRs necessary for research and development (R&D) and technological innovation (Commission on Intellectual Property Rights, 2002 29-30). Simply stated, the reason is that the cost of innovation is high – topping $800 million, by some recent estimates (DiMasi, et al., 2003) – while the cost of imitation is low.
Others are not so sure about the high cost of pharmaceutical innovation. James Love questions the $800 million figure as being inflated by suspect opportunity cost of capital amounts or clinical trial costs (Love, 2003 3-5). And even those who agree with the average figure question the use of such an average in making policy decisions. For example, Adams and Brantner performed a similar analysis using publicly available data from a different database (Adams and Brantner, 2006). While they confirmed the overall result, they noted that the actual total cost can vary by therapeutic drug class and firm (perhaps reflecting a particular firm’s strategic decisions). The total cost range, based on their analysis, was $500 to $2,000 million.

Thus, there is an empirical disagreement about the costs of drug development and hence the magnitude of the incentives needed to spur R&D (and who will bear the costs of those incentives). As a recent example, consider a roundtable discussion about the patenting of cumulative pharmaceutical innovation published in the Bulletin of the World Health Organization in 2004 (Correa, 2004). In his anchoring article, Carlos Correa notes several facts:

- Pharmaceutical innovation is stimulated both directly and indirectly by public sources, with estimates in the 1999 UN Human Development Report suggesting governmental involvement in 70% of drugs with therapeutic gain (Correa, 2004 784).
• Citing data from the National Institute for Health Care Management (NIHCM)\textsuperscript{25}, only 35\% of US Food and Drug Administration approved applications for new drugs involved products with \textit{new} active ingredients (Correa, 2004 785).

• During the same period, NIHCM data indicate that only 153 of the 1035 (15\%) applications were both new and of significant clinical improvement to deserve “priority” new molecular entity status from the FDA (Correa, 2004 785).

Another familiar figure used in this context (though not cited by Correa here) is that from 1975-1999, only 16 of 1393 new molecular entities were for tropical diseases or tuberculosis (Trouiller, et al., 2002). Correa suggests in his piece that these facts are a direct result of a flawed policy that allows patenting of minor, cumulative innovations that restrain competition and delay generic entry, presumably hindering both innovation and access.

\textsuperscript{25} The NIHCM is “a non-profit, non-partisan group that conducts research on health care issues. The Foundation disseminates research findings and analysis that promote and enhance access to health care and the efficiency and effectiveness of health care services and delivery.” Its board of directors is composed entirely of CEO’s from major private insurers, such as Blue Cross Blue Shield. See http://www.nihcm.org. Access 10 October 2006.
In their contribution to the roundtable, Harvey Bale and Boris Azais dispute these facts. They put forth the following counterclaims (Bale and Azais, 2004):

- Governments are not involved in drug development: The US NIH reported in 2001 that for the 47 prescription drugs whose sales exceeded $500 million per year, the NIH was involved in only 4 (Bale and Azais, 2004 788).
- The NIHCM statistics exclude over 130 important vaccines and biotechnology products, skewing their numbers (Bale and Azais, 2004 789).
- Finally, FDA “priority review,” according to the FDA itself, is “not intended to predict a drug’s ultimate value” (Bale and Azais, 2004 789). It is therefore an inappropriate indicator from which to draw conclusions about innovation.

After disputing these facts, Bale and Azais finish by concluding that patenting of cumulative innovation is absolutely necessary. This is because it prevents generic entry of similar but slightly advanced products that would otherwise diminish the incentives for creating the product in the first place.

In this case, the authors use facts to support or reject the claim that patent standards should be tightened to reduce the number of patents on cumulative innovations. But is this argument just about the facts, as the Empirical Data Thesis
would suggest? The answer, of course, is no. Several normative issues arise in this debate over IPRs and innovation.

First, the authors disagree about the role of government in the development of pharmaceuticals. Correa implies that government funding is involved in most products, either directly (through basic research or funding) or indirectly (through tax credits and other incentives). Bale and Azais suggest that, in the US, the NIH is involved in a relatively small number of medicines (less than 10% by their count). The general normative issue at stake, then, is whether and to what extent the amount of governmental contributions to pharmaceutical development should matter when it comes to setting IPR policy. Stated a different way, this is an example of a more general issue, namely, the appropriate division of labor between public and private development of pharmaceuticals. And this issue, while relying on facts, is normative – not just empirical.

Specifically regarding this example, one reason for their disagreement could be a reliance on different data sets. Correa uses data from the UN Human Development Report that are not cited there (and not original to the report); they appear trace back to the 1993 book *Making Medicines, Making Money* (Drake and Uhlman, 1993). The analysis utilizes a now-defunct FDA classification system of “Important Therapeutic Gain – 1A,” “Moderate Therapeutic Gain – 1B,” and “Little Therapeutic Gain – 1C” to judge
therapeutic importance. The 70% figure refers to products from the 25 largest pharmaceutical companies during the period 1981-1991, not the entire data set. Bale and Azais, on the other hand, focus on sales data for drugs that sell over $500 million per year.

But here again, the issues are not merely empirical, because beneath these facts and figures is a normative disagreement about what counts as a worthwhile drug. Is it the US FDA’s determination of therapeutic importance, or drug sales data (implying perhaps the “wisdom of the market”) that should determine the value of a given drug to society? The value of a medicine to society is thus a normative, not just an empirical, issue.

Related to this is a third normative disagreement: the authors disagree about the patents / innovation debate not merely because they disagree about the facts of the matter, but also because they disagree normatively about whether current innovations are the right kind of innovation. In other words, they disagree about whether the current system of IPRs is structured to produce the right kinds of medicines for society. This is why the low percentage or medicines for tropical diseases and tuberculosis from 1976-99 is significant. For Correa, it represents a failure of the current system and perhaps reveals that, at present, the IPR system does not adequately differentiate between

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26 During that time period, 16% of the new drugs approved by the FDA fell into category 1A (Drake and Uhlman, 1993).
“good” and “bad” innovations from a social perspective. And while Bale and Azais might concede this point, they would argue that this alone does not require changing the patent system. To make either argument involves a normative claim, not just an empirical one.

A final normative issue falls directly from the last few lines of the Bale/Azais article:

Therapeutic advances historically delivered by the private sector would cease without the protection of the patent system. Some generic producers might benefit in the short term from such a temporary windfall, but in the end, neither they nor patients would experience a healthy future. (Bale and Azais, 2004 789)

To be sure, these final words are somewhat overstated, particularly in reference to Correa’s article (which did not advocate for abolishing the patent system, but instead refining it in a specific way). However, Bale and Azais express at least two separate ideas.

One idea hints at what might be called the “But For the Patent System” Argument. This argument suggests that we cannot criticize the current IPR system from an access standpoint because the medicines made created via the patent system would not have otherwise existed. In other words, we would not even be discussing access to ARVs were it not for IPR system’s ability to stimulate innovation into ARVs in the first place. This argument is taken up later in this project (Chapter 3).
A second idea calls upon the distinction between short-term and long-term benefits. According to Bale and Azais, we ought not give up the patent system because the short-term gains (from their perspective, to generic manufacturers, but also in terms of lower prices and increased access) are not worth the long-term cost (an absence of new innovation). The proper balance between short-term benefits of “access now” and long-term benefits of “new products,” however, is not simply an empirical issue. It is also a normative one that could be framed as “access now versus access later,” and as such it brings up interesting issues of distributive and intergenerational justice.

To summarize this section before proceeding to a final example: The seemingly empirical debate about patents and the incentives to innovate is normative in at least three important ways. First, the division of labor between public and private efforts to spur innovation – and more specifically, whether and to what extent public support of innovation entails conclusions about how IPRs should be structured – is a normative issue. Second, how one determines the value of a medicine to society (e.g., through sales data or by the determination of regulatory bodies) and whether the current IPR system generates a sufficient number of “valuable” medicines is a normative issue. And third, the tradeoff between access now and access to (different medicines) later is normative, not just empirical, involving as it does intergenerational justice and other distributive issues.
2.3.3 IPRs and Foreign Direct Investment

The last example of a seemingly purely empirical, but in fact significantly normative, issue in the debate over IPRs operates at an intriguingly different level. The first example – IPRs and access to ARVs or essential medicines – examined a direct, microlevel tension between patents and short-term access to medicines. The second example – IPRs and innovation – examined a more macrolevel tension between patents and long-term access, not to mention long-term access to the right kind of medicine. This third example looks at a much broader macroeconomic issue, namely, the impact of IPRs on foreign direct investment (FDI).

FDI, according to the annual UN Conference on Trade and Development’s World Investment Report, involves private capital flow with management control from an entity in one country (the “source” or “home” country) to an acquired or established subsidiary in another country (the “recipient” or “host” country). Conventional economic wisdom suggests that FDI is a good thing for economic development. So, according to the Empirical Data Thesis, if IPRs stimulate FDI, and if FDI is a good thing, then IPRs ought to be established in countries where they are not (or perhaps

strengthened in those where they already are). And whether IPRs stimulate FDI is solely an empirical question.

As in the prior examples, substantial disagreement exists about the empirical evidence on IPRs and FDI. On the one hand, several pieces of empirical evidence suggest that IPRS do stimulate FDI. Edwin Mansfield and Jeong-Yeon Lee, using a survey methodology similar to their 1986 work on patents and innovation, found that, for U.S. firms, amount and composition (e.g., sales and distribution outlets versus R&D facilities) of FDI correlate positively with the perceived strength of the host country’s IPR system (Lee and Mansfield, 1996). Keith Maskus offers further support of the positive impact of IPRs on FDI, particularly for industries that depend heavily on intellectual property protection (Maskus, May 2000, Maskus, 1998).

To be sure, Maskus emphasizes IPRs as an important, but by no means the only, determinant of FDI or its benefits within a broader policy context. But many are less convinced of the overall empirical picture. Correa, for example, cites examples where FDI in the pharmaceutical industry increased in Italy after pharmaceutical patents were first recognized in 1978 and increased in Brazil after pharmaceutical patents were abolished (Correa, 2000 28). The overall economic environment, not the strength of
IPRs, is likely to impact FDI most\(^{28}\) – particularly in least developed countries, and particularly after most countries become TRIPs compliant (and thus adhere to similar IPR standards, leveling the playing field). From this empirical uncertainty, Correa suggests that FDI does not necessarily follow from strengthening IPRs.

At this point, then, we seem to be at an empirical impasse. However, the debate over IPRs and FDI is just as normative as it is empirical. One empirical study is worth mentioning in this regard, because it provides a transition to revealing normative elements of this example.

In a 2001 paper, Feinberg and Majumdar examine technology spillovers\(^{29}\) (one proposed benefit of FDI) from foreign direct investment in the Indian pharmaceutical industry (Feinberg and Majumdar, 2001) during the 1980s and early-1990s. The Indian pharmaceutical industry is an interesting example for several reasons: the historical presence of multinational pharmaceutical companies; the emphasis on pharmaceutical R&D; and the interesting set of policies in India on pharmaceutical product patents (which were not honored until January 1, 2005), drug price controls, and limits on

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\(^{28}\) This is, in an interesting sense, a mirror argument to the patent/access argument presented earlier. Here, instead of saying, “Patents are not the only, nor the most important access barrier, therefore we ought not change them,” the idea is that, “IPRs are not the only, nor the most significant determinate of FDI, but we therefore ought to create them.” Those arguing for increased IPR protection seem to be putting forth both arguments at the same time.

\(^{29}\) Also called “R&D spillovers,” technology spillovers represent unappropriated benefits of R&D activities. They are social benefits occurring as a result of innovative activity but not captured by the return on private investment. Examples might include knowledge about cutting-edge technology, processes, or institutional structures.
multinational ownership of indigenous firms (Feinberg and Majumdar, 2001 422-5). The intent of these policies was to develop the domestic industry and make medicines available to the poor.

Feinberg and Majumdar essentially conclude that the net effect of these policies was to encourage technology spillovers only between multinational companies within India, but not between Indian companies (nor between multinational companies and Indian companies). For the authors, this is a problem: Firms’ incentives to create new knowledge in this environment were limited (because it would rapidly become public), and “the weak intellectual property regime must also mute incentives for successful Indian firms to undertake significant local technology development” (Feinberg and Majumdar, 2001 433).

This article is illustrative because it leads naturally to critical examination of two clearly normative questions. First, how significant are the benefits of FDI? And second, how are the benefits of FDI distributed? Understanding both of these questions would shed light on whether we thought the benefits of FDI were enough to justify changes to IPRs.

In their article, Feinberg and Majumdar appear critical of India’s policies toward IPRs and FDI because they reduced incentives for local technology development and technology spillovers. This, however, should not be viewed as an empirical fact.
Rather, it is a normative judgment that potentially ignores the tradeoff between local technology development and improving access to already developed technologies (such as medicines) for the poor – the other stated goal of India’s policy. In other words, it is a normative issue to decide whether the benefits of FDI are significant enough to outweigh the costs, if one of those costs might be reduced access to certain technologies.

Of course, not all FDI is created equally; in their article, Feinberg and Majumdar appear critical of a certain kind of FDI policy: one that imposes restrictions on foreign investors to which domestic firms are not subject. Presumably, Feinberg and Majumdar are advocating for a freer, more liberalized policy on FDI, in spite of the historical fact that most developed countries did not apparently get to where they are now through “freer” FDI in this sense (Chang, 2003).

But the fact that not all FDI is created equally implies a second normative issue: Development policy is not simply about increasing the quantity of FDI, but also about increasing its quality (Bernal, et al., August 2004). For example, some believe that the kind of FDI utilized in African mining operations has not necessarily led to the promised development benefits for African countries (though it has led to benefits for source countries) (United Nations Conference on Trade and Development, 2005). In the IPR/FDI debate, the distinction between quality and quantity is sometimes lost.
Finally, a third important normative issue in this case is distribution of the costs and benefits of FDI. While the Indian pharmaceutical example discussed different kinds of benefits (access for the poor versus local technology development), understanding that the benefits and costs of pursuing FDI might accrue to different individuals is crucial. FDI might increase wages in the host country overall, but in an unequal fashion—perhaps favoring skilled workers over unskilled (Velde and Morrissey, April 2002). If this consequence is true, it is important: Policies regarding IPRs (such as India’s noted above) might seek to help the poor, e.g., through lower prices to medicines, while policies regarding FDI might end up helping the already-skilled workforce or local business owners. Simply put, the policy options do not help (or harm) the same people, making the policy choice a normative one that implicitly requires taking a stand on deeply contested issues of distributive justice—not just an empirical question about “how much” benefits and costs exist.

In sum, then, at least three types of normative issues arise in relation to the question of how IPRs impact FDI: (1) what kinds of benefits are important; (2) whether those benefits must be traded against other benefits; and perhaps most importantly, (3) how the benefits and costs of alternative policy choices are distributed. Because these issues are fundamentally normative—even if they involve empirical elements as well—

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30 The resemblance to Rawls’ criticism of utilitarianism on the basis of the separateness of persons is striking. See (Rawls, 1971 19-24).
they suggest that the EDT cannot be true. Empirical data alone are not capable of resolving the debate over IPRs and essential medicines.

2.3.4 Some Caveats

A couple caveats are worth mentioning at this point, as a dedicated proponent of the EDT is not likely to feel satisfied by the above sections.

The first caveat is that my selection of empirical studies and questions is obviously limited in depth. Any real empirical expert on these three topics is certain to both view my summaries as inadequate and also suggest several more crucial empirical studies the further refine or, in his or her mind, put an end to the debate. While the former point about refinement is true, the latter point is not. In fact, I avoid depth for the very reason that discussing these examples in general terms is likely to reveal the general normative elements involved. I suggest that normative elements apply, no matter the study involved nor the eventual conclusion reached.

The second caveat is that my selection of empirical studies and questions is obviously limited in breadth. Why focus on these three issues and neglect, for instance, the normative issues involved in claiming that IPRs help technology transfer or diffusion? My response is that this list of studies is meant to illustrative, not exhaustive, and additional areas of empirical debate will almost assuredly reveal some similar normative issues and some potentially new ones. As noted in the prior section, my
examples are meant to operate at three different levels of analysis, thereby representing a range of normative issues.

Therefore, the key point is that neither breadth nor depth is critical to my overall argument against the Empirical Data Thesis. In so far as any of the above examples really do reveal normative issues, the EDT is false. I now turn to a summary of these normative issues.

### 2.3.5 Exposing the Normative, or, the Failure of the EDT

Sections 2.3.1-4 gave three examples of ongoing debates surrounding IPRs with emphasis on the pharmaceutical industry. For each, I uncovered several normative issues that arise in conjunction with the empirical debate. All this suggests that the Empirical Data Thesis is false.

One obvious way in which normative issues are at work acknowledges that facts alone do not entail normative conclusions about what we ought to do, or how policy ought to be, absent some normative premise that translates this fact into a policy imperative. For example, the simple fact that intellectual property rights appear to increase foreign direct investment does not translate into the idea that a developing country ought to adopt strong IPRs unless FDI is a “good” thing (as measured by what it does and by whom it affects). Whether FDI is a “good” thing, therefore, is not simply an empirical question.
The idea of requiring normative premises with empirical data to reach policy conclusions, however, is not particularly novel (even if it is often overlooked). Thus, it is worth emphasizing how the normative-empirical interaction I envision runs much deeper. A simple way of thinking about this, in agreement with my prior examples from the philosophy of mind and the philosophy of biology, suggests that the normative assumptions affect what empirical work gets done, how it gets done, and how it gets interpreted.

In terms of what gets done, it seems clear that researchers have normative reasons for pursuing the types of questions they do. This appears true both motivationally and regarding content. Motivationally, for example, Carlos Correa’s work on incremental innovation patenting (section 2.3.2) appears motivated by a sense of unfairness in the current system. The same might be said – though from a sense that the current system is not inherently unfair – of Amir Attaran’s work (section 2.3.1).

Normative views similarly impact the content of what gets done. Correa’s claims about whether the kinds of medicines currently produced by IPRs represent significant therapeutic advances indicates a normative view that IPRs ought to produce medicines that are “innovative” in some normative sense. Bales’ criticism of Correa and his invocation of a metric using more than $500 million in U.S. sales as an indication of
“innovation” is similarly a normative one. Both agree, however, that IPRs ought to stimulate innovation; they differ regarding what innovation matters most.

*How* the empirical work gets done also involves normative issues. A strong presumption favors economic analyses that aggregate data across many different medicines, countries, and years. This only makes sense within a normative framework that places primacy on this level of analysis (e.g., Attaran and Gillespie-White’s continent-wide view of Africa) rather than one that looks at lower levels (e.g., country-by-country, drug-by-drug, or even the individual level). The normative assumptions at play here involve distributional issues, in so far as aggregation obscures how what is aggregated is distributed.

Finally, in terms of *how* empirical data get interpreted, the normative dimension is no less apparent. Recall that the empirical finding that X% more individuals would have received treatment under a “no patent” regime. This makes sense when phased as “only” X% (as the authors themselves phrase it) “only” if we understand them to be saying that X% is not worth the cost of changing to such a system; is not an efficient use of resources; is not worth the future losses to innovation; or some other unacknowledged normative viewpoint.

Beyond this, however, two broad normative themes emerge in the debate over IPRs and access to essential medicines.
For one, many of the normative issues in question fall under the more specific category of *distributive justice*. So, for example, I noted critical issues surrounding: the tradeoff between different social goods (e.g., access to already developed medicines versus greater technology development in the Indian pharmaceutical study); the issue of how the benefits and costs of a particular policy are distributed (e.g., FDI); and the issue of access to medicines now versus access to innovations later. These distributive issues are sure to play a major role as this book proceeds, though as I later point out, they cannot be the only normative issues considered.

The second theme worth noting is a worrisome normative assumption present in most of these studies: the idea that IPRs should be evaluated to see that they *do not impede*, as opposed to *actually improving*, access to essential medicines (Westerhaus and Castra, 2006). This is seen most clearly in the Attaran work cited earlier, where the issue at stake seems to be whether or not patents “hinder” access. Might it be a fundamentally different question to suggest that IPRs ought to *improve* or better enable access to essential medicines, rather than simply not hindering it? The Commission on Intellectual Property Rights report puts the difference this way:

> Such rights must therefore be closely monitored to ensure that they do actually promote healthcare objectives and, above all, are not responsible for preventing poor people in developing countries from obtaining healthcare (Commission on Intellectual Property Rights, 2002 30).
Together, understanding these themes and their particulars indicates that the Empirical Data Thesis should be rejected. Yet this is not the end of the story. In the next section, I give several reasons why assuming the EDT is risky. I then follow it with an examination of how normative work might actually help empirical work, much as conceptual work did in the philosophy of biology and philosophy of mind.

2.4 The EDT: A Risky Thesis

Some readers might accept the argument until now, with an important qualification. What I might call “weak” proponents of the EDT might say, “Yes, these normative elements are surely present, but they do not tangibly impact the questions at hand.” In this section and the next, I suggest why this is incorrect.

The major reason this weaker EDT is incorrect stems from the risks inherent to assuming the EDT – risks that might be mitigated by understanding the normative elements I am proposing.

Recall that I earlier suggested how empirical studies are “normatively-laden,” not in a spooky social constructivist sense, but in the sense that normative elements are inextricably linked with the empirical ones. Empirical work might presuppose a normative stance, for example, because it assumes (i) that the aggregate benefits of FDI are more important than issues of equity for helping the poor, or that (ii) FDI is desirable, but without taking into account the effects of policies used to promote FDI by
strengthening IPRs. This, in turn, might determine that researchers spend a great deal of
time and effort uncovering and modeling these benefits using economic measures.
Finally, depending on the results, they might recommend certain policy solutions in
accord with their findings. In the meantime, only rarely (if ever) does anyone articulate
that this empirical enterprise continually depends upon normative elements.

In fact, the nature of the data under study make the normative elements critically
important. The simple reality is that the economic data about access to medicines are
exceedingly complex. They are also almost always incomplete, requiring us to make
decisions with a high level of uncertainty. The combination of complexity and
incompleteness raises the first risk of the EDT: that without an understanding of the
normative issues at stake, or perhaps of normative commitments, translating one’s
recommendations into policy runs the risk of being overly conservative.

By overly conservative, I mean less willing to accept change for the sake of
collecting just a few more data points to lower uncertainty even a small amount more.
To make this point more concrete, consider the issue of racial and ethnic disparities
within the U.S. health care system. A 2003 IOM report, Unequal Treatment, examined this
issue in some empirical detail (Smedley, et al., 2003), including a chapter devoted to an
ethical analysis of when and how such disparities matter from the standpoint of justice
(Powers and Faden, 2003). In a published response to this report, two authors criticize
the report’s findings, partially on the grounds that no high quality studies had yet established causation (as opposed to mere correlation). They then suggest that more detailed empirical studies are needed before changes are made to the existing health care system (Satel and Klick, 2005).\textsuperscript{31}

But are racial and ethnic disparities in health care simply an empirical question, one that must be answered with ever more certainty before changes are recommended? From a normative perspective, the answer is almost certainly no: The history of unequal treatment of racial and ethnic minorities in the U.S. might suggest that action needs to be taken even before all the empirical data are in and full causation is established. Or, for a more egregious example, imagine if anti-abolitionist forces had continued to push for more empirical analyses on the economic effects of ending slavery, further delaying emancipation. The point is that the normative reasons for change were a primary motivator for change.

In the IPR/access realm, advocates of even this weaker version of the EDT fail to understand that data in the area of global economics are perhaps uniquely complex and incomplete. Thus, decision-making necessarily involves uncertainty, which can never be zero, at least at reasonable cost. If this is true, the combination of uncertainty plus the

\textsuperscript{31} They also suggest that health care outcomes – not health care access – ought to be the measure of disparity. This, too, is an important normative difference with empirical consequences for how disparities are studied and what type of changes might be required to the health care system. However, this difference is not critical to the point I am now making about the risks of the EDT.
gravity of the decisions made regarding globalized IPRs (because they potentially affect millions of people) might place greater emphasis on the normative aspects of the debate. Aside from this, one also worries that the overly conservative potential of the EDT advocate is self-reinforcing, because those involved are usually interested in collecting and analyzing data as part of their careers.

A second risk of assuming the EDT (i.e., a risk of failing to acknowledge the normative aspects of the debate of IPRs and access) is this: By presenting the answers to these difficult questions as supposedly pure “facts,” an unjustified aura of certainty surrounds them. For example, many paraded around with Attaran and Gillespie-White’s article about patents and ARVs, considering the debate settled and hoping to convince others of this on the basis of a very limited set of facts that might obscure deeper normative disagreements.32 These disagreements are what I examine in the remaining chapters.

Ironically, the flipside of this risk is that, by concealing normative commitments, one runs the converse risk of having her normative stance seemingly overturned by a change in the facts. To again draw an analogy with the abolitionist movement: Suppose one’s normative belief is that the fundamental equality of persons makes slavery wrong, but instead of pursuing this normative argument, she decides to fight slavery by arguing

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32 For an example of this, see http://world.phrma.org/ip.access.aids.drugs.html.html, where little is made even of Attaran and Gillespie-White’s own qualification of their results. Accessed 20 October 2006.
that whether the institution of slavery is economically profitable. Should the data come out that slavery is profitable, much ground has been lost in fight to end slavery for normative reasons. This lesson should not be lost on those in the IPR/access debate, as a well-grounded normative framework might both strengthen one’s empirical case and make it more resilient to empirical change.

The final reason I consider the EDT “risky” is that it unduly constrains the overall debate over IPRs and access to essential medicines. The constraint occurs in at least two ways. First, the use of standard economic analysis appears to isolate IPRs and compare them to only one or another variable at a time (e.g., IPRs and FDI; IPRs and technology transfer; IPRs and GDP, etc.). This runs the risk of ignoring a more complex array of social, economic, and political factors that could impact the IPR/access debate. And second, the emphasis on economic and empirical analyses as the only way to address this debate makes the mistake of assuming that the only human good that IPRs serve is an economic one (innovation, development, or otherwise). As I suggest in the next chapter, IPRs might serve other human goods as well, goods that are less easily measured by econometrics.

More generally, then, the EDT constrains the debate over IPRs and access by short-circuiting normative theorizing itself. By pretending that the debate is merely empirical, we are unable to either reveal or resolve what might be deep-seated
normative disagreements about intellectual property rights. The remainder of this project seeks to expose those normative roots.

2.5 Normative Contributions to Empirical Studies

The time has finally come to consider the more positive portion of my analysis of the EDT. In this section, I conclude with three preliminary suggestions of how a better understanding of the normative elements can tangibly impact empirical work. They are “preliminary” because the bulk of the real normative work in this book yet remains.

The first area of impact connects directly with the prior section. Acknowledging the normative issues and stake, and the normative stances taken, might directly mitigate the risks of the EDT. Exposing the normative underpinnings for why and how one pursues, analyzes, and draws conclusions from a particular empirical study might prevent the overly conservative, fact-masquerading, debate-constraining aspects of considering this to be “only” an empirical issue. Moreover, where these normative underpinnings result in psychological biases in the interpretation of the data themselves (as alluded to in my philosophy of biology example, and speculatively in several of the IPR examples), disclosure of normative issues might foster better accountability. This might, in turn, aid policymakers as they consider policy changes on the basis of “mere facts.”
The use of the term “disclosure” is no accident, as the analogy to recent conflict of interest debates is telling. While I do not imply that one’s normative framework amounts to a conflict of interest, I do suggest that disclosure of normative issues is at least a start to better understanding empirical research. And as the prior chapter has suggested, normative issues are pervasive.

A second area of impact intersects directly with whether an empirical study is actually a valuable contribution to the policy debate. Here, I would suggest that a better understanding of the normative issues at stake might call certain types of empirical studies into question. To begin with two different analogies that have figured prominently in this book, consider the cases of the abolitionist movement and racial and ethnic disparities. For the former, one might question the empirical study of “who owns which slaves where” unless that study somehow contributes to the overall slavery debate. And when one understands that debate as involving the fundamental equality of persons, such an empirical study seems questionable. For the latter case of racial and ethnic disparities in health care, one might question empirical studies that continue to narrow the confidence interval of the inequities present, again unless those studies somehow contribute to devising policies for alleviating those disparities.

33 The literature here is vast. For a readable review of the negative side of the conflict of interest debate, see (Kassirer, 2004). For the official voluntary policy of the industry, see (PhRMA, 2002)
34 I owe this general point to Anthony So.
The general reason this is important is that such studies are wasteful, particularly when considering the gravity of the issues at stake. This is obviously so in the area of global health inequalities, so we should expect the same reasoning to apply here. Do studies of who owns which patents where contribute to the overall policy debate? If so, how? And what are the normative issues involved with such a study?

Finally, better normative clarity in this area should contribute not just to whether a study is performed, but how. As I alluded to earlier, this is most evident in terms of what I call the “level of analysis.” If one is fundamentally concerned with whether individuals have access to medicines, does it make sense to aggregate data across multiple communities, countries, or even continents? In the debate over IPRs and access to ARVs, does it make sense to draw conclusions on the basis of raw population, or of population taking into account disease burden and income? The choices here are normative as much as they are empirical, and so acknowledging the normative issues at stake should help guide the “right” empirical studies.

To be sure, there are risks of the kind of normatively-grounded study I envision. The most obvious falls directly from the complex and incomplete data available in this area (ironically, the same complexity and incompleteness that helped motivate the normative discussion). Will normatively-grounded empirical studies allow one to “cherry pick” the data that best support one’s normative stance? In response, I suggest
that this risk is not new, and is probably more of a risk with the EDT itself (where the normative is completely excluded from the start). Moreover, as I noted above, disclosure and discussion of these issues are at least a start, enabling more complete debate of the normative and empirical issues themselves.

2.6 Conclusion

This chapter set out to refute a particular view of the debate over IPRs and access to essential medicines, one that sees this debate as merely empirical. This view, which I called the Empirical Data Thesis, is tempting because the data are inextricably complex and incomplete. I have shown this be false – normative issues arise in conjunction with the empirical ones, from the decision to carry out empirical studies, to their implementation, to how they are translated into policy imperatives. Simply put, these disagreements are not just “about the facts,” and acting as if they were is detrimental to the overall debate. Demonstrating this leaves open the possibility of examining normative reasons for change in the IPR/access debate that operate somewhat independently of the empirical ones. The next two chapters begin the task of more systematically examining these normative elements.
CHAPTER 3. Theoretical Justifications of IPRs: The End(s) of Intellectual Property

3.1 The Intellectual Property & Innovation Thesis Introduced

Chapter 2 suggested that the debate over IPRs and access to medicines is normative, not just empirical. More positively, it gave several examples of the normative issues in question; for example, whether the benefits of modifying the current IPR regime are worth the costs (and what those costs and benefits are – see 2.3.2.3). It also offered general ways in which normative analysis might aid empirical research (e.g., by using normative considerations to better target empirical studies to answer policy questions).

The present chapter considers the justification of intellectual property rights. By “normative justification,” I mean the value or values to which one appeals – or how they are weighed – in justifying the existence or the extent of IPRs. Just as Chapter 2 broadened the IPR/access debate by arguing that it is inextricably normative and empirical, Chapter 3 further broadens the debate by recognizing the different normative justifications that exist for IPRs.

Doing so requires attention to theories of intellectual property rights. This is not, however, pursuing theory for theory’s sake. Neither is the goal to canvass every theory of IPRs. Instead, I offer a focused analysis driven by the presumption that a better
understanding of intellectual property rights’ normative underpinnings could yield valuable insights into how IPRs might be structured.

To better understand where this chapter is headed, its main conclusions can be listed as follows:

First, the terrain of IPR theory is unnecessarily complicated by theories of different “types.” In place of various typologies discussed by others, I suggest that all viable IPR theories are instrumental theories. This requires rejecting the main competitor of instrumental theories: natural rights (sometimes, “labor dessert”) (see section 3.5). In other words, all viable IPR theories see IPRs as a means to foster some socially desired end or – perhaps more importantly – socially desired ends (as at present little reason exists to expect IPRs to serve only one end).

Second, as a whole, even the best instrumental theories of IPRs fail to acknowledge fully the distributive impact of IPRs. In other words, they fail to acknowledge that, given certain background conditions, IPRs can limit the range of feasible distributive outcomes for what IPRs cover. This fact makes the choice of IPRs and IPR regimes a matter of distributive justice.

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1 It seems to me that not all labor dessert theories need be natural rights theories. It could be, for example, that IPRs represent “just dessert” for pursuing innovation. If this is the case, it would seem that labor dessert theories of intellectual property are instrumental theories.
Finally, to make both of these points more concrete, I explain how the dominant way of thinking about IPR theory involves what I call the Intellectual Property & Innovation Thesis (IPIT):

Intellectual Property Rights (IPRs) are normatively justified by their ability to maximize innovation.2

The Intellectual Property & Innovation Thesis is a commonly held view of the normative justification for IPRs. It correctly views IPRs as *instrumental*, but it truncates the IPR debate by assuming – in opposition to my first major conclusion, drawn from theories of IPRs – that maximizing innovation is the *only* normative justification for IPRs. It also assumes, contrary to my second major conclusion, that IPRs operate separately from questions of distribution. This results in a “Develop First, Distribute Later” approach to medical innovation, an approach that leads to three distinct distributive problems (distribution of what IPRs cover; distribution of what IPRs create; and distribution of IPRs themselves, as I articulate in section 3.6). Recognizing this has important implications for my view of global distributive justice in Chapter 4.

This chapter proceeds as follows. I first explain why the study of intellectual property theory is important (3.2). In the next section (3.3), I clear some ground for

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2 This is the strongest possible version of the Intellectual Property & Innovation Thesis, because it includes the term “maximize.” If it did not, we could reasonably ask, “What other values or ends should constrain pursuit of innovation?” And asking that question would be perfectly in line with the rest of this chapter. Beginning with the strongest possible version is merely a useful starting point.
theorizing about IPRs by noting that the extent of analogy or disanalogy with chattel property does not solve IPR problems, even if it is occasionally employed. I also reinforce the idea of “functional” intellectual property rights as the subject matter of this dissertation (see also Chapter 1).

In sections 3.4 – 3.6, I examine the theories underlying IPRs to draw out the conclusions noted above. Section 3.4 simplifies the complex terrain of IPR theory by arguing that all of the major IPR theories are either instrumental theories or natural rights theories. The limitations of each type of instrumental theory suggest that we ought not seek a single “correct” theory of IP. In fact, the only IP theory worth rejecting outright is the natural rights theory (section 3.5), in spite of its popular appeal. All this culminates in section 3.6, where I return to the IPIT and criticize its “Develop First, Distribute Later” paradigm of medical innovation or R&D by noting the three distributive problems it creates. This leads naturally to Chapter 4, which will argue that efforts to modify the present IPR regime for the sake of solving these distributive problems is supported by well-justified views of global distributive justice and basic human rights.

This is a complex chapter that covers a lot of ground. At its core, however, it suggests that the only well-justified views of IPRs are instrumental views. The question then becomes, “Instrumental to what end or ends?” And because I argue below that

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3 I also note that Locke – often regarded as the theory’s originator – might not have agreed with how recent authors construe his view and actually himself presents a more instrumental view.
IPRs might serve a diversity of ends, but that one end it should serve is global
distributive justice (the topic of Chapter 4).

3.2 Why Study the Theory of Intellectual Property?

As previously noted, few systematic analyses of the justification of intellectual
property rights exist (Drahos, 1996 1). This is in spite of the fact that many analyses of
property rights in physical objects exist. Whether such analyses translate directly to
what Drahos (1996) calls the “abstract objects” of intellectual property is, for now, an
open question (see below, section 3.3.1). But why study the theoretical underpinnings of
intellectual property rights in the first place? There are several distinct reasons.

First, the system of intellectual property rights falls under what Rawls considers
the “subject of justice”:

For us the primary subject of justice is the basic structure of society, or more exactly, the
way in which the major social institutions distribute fundamental rights and duties and
determine the division of advantages from social cooperation…Thus the legal protection
of freedom of thought and liberty of conscience, competitive markets, private property in
the means of production, and the monogamous family are examples of major social
institutions. (Rawls, 1971 6)

IPRs, which form part of the regulation of competitive markets and private property in
the means of production, are therefore a subject of justice. This is particularly important
in light of the fact that IPRs have become increasingly regulated at the global level,
implying something of a “global basic structure” (Buchanan, 2000) roughly analogous to
Rawls’ primary (domestic) basic structure. Intellectual property, therefore, requires justification from the standpoint of justice.

A second, and related, reason is noted by Adam D. Moore in his theoretical work on intellectual property. He links the theoretical justification of intellectual property with the coercive power of globalized IPRs:

To be justified—to warrant coercion on a worldwide scale—systems of intellectual property should be grounded in theory. (Moore, 2003 193)

For Moore, because IPRs operate in an increasingly global “coercive” environment (where coercion means regulated by the power of law, such as through the World Trade Organization), they stand in need of some theory. Why? One answer would be that a well-grounded theory of intellectual property could give those affected (“coerced”) by its rules special reason to endorse or even support the institution of intellectual property.

Finally, and perhaps most importantly, one should expect any viable theory of intellectual property to yield important insights into how IP policy ought to be structured (Fisher, 2001 194). As William Fisher notes, attention to IP theory might reveal novel solutions to intellectual property problems, such as whether IP law ought to
hinder or promote price discrimination⁴ (Fisher, 2001 196-7). In addition, because a theory of intellectual property sheds light on which end(s) IPRs ought to serve, it should also give us some idea of how to reach these ends while at the same time suggesting measures for whether these ends are actually achieved. That is, theory itself might provide the basis for accountability and even direct the types of empirical studies needed to demonstrate this (see Chapter 2). For example, if some IP policy is justified theoretically by its ability to “maximize innovation,” and if it can be shown that current IP policy does not, in fact, maximize innovation, we would have reason to question or change the policy. (We might also question the theory; such facts could provide the opportunity for rethinking and revising the theory.)

3.3 Theories of Intellectual Property: Preliminary Points

With a sketch of why theorizing about intellectual property rights is important, the remainder of this chapter seeks to establish two separate, but related, ideas: First, IPRs should be understood instrumentally – as a means to some end – and that little reason exists to suggest that IPRs need be instrumental to only a single end (contra the Intellectual Property & Innovation Thesis). Second, recognizing this gives strong reason

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⁴ “Price discrimination” is the sale of goods or services at different prices in different markets but by the same seller. In the pharmaceutical industry, price discrimination could be important as a way to sell the same drug at different prices in different countries, thereby increasing overall access.
for us to consider distributive “ends” to IPRs – that is, that IPRs ought to take into account distributive justice, especially because how IPRs are structured has distributive implications. Before proceeding, however, a few additional introductory points are worth noting.

3.3.1 Property in Ideas versus Property in Objects

Because what follows draws upon a rich philosophical history involving property in objects, one might question whether this is a fruitful endeavor. More specifically, one might argue that theorizing about property rights in objects offers nothing useful regarding property in ideas because the two are fundamentally different.

This is a debate that John Duffy terms intellectual property “exceptionalism” or “isolationism” (Duffy, 2005b 1089). IP exceptionalism is roughly the claim that intellectual property – property in ideas – is fundamentally different than chattel property – property in physical objects. If true, we might expect that the normative justifications of intellectual property, or the policies that govern IPRs, should not derive from justifications of physical property. If false, we might expect the justification of intellectual property to fall more or less directly from justifications of physical property.
Simple examples of exceptionalist or isolationist views show how little one gains by strictly pursuing either strategy.⁵

Consider two examples of IP “exceptionalism” meant to argue against IPRs in general. In the first, property in ideas is fundamentally unique because information is a “public good.” A public good is generally understood to mean non-rivalrous in consumption (i.e., my use of an idea does not prevent your use – the idea is not “used up”) and non-excludable (i.e., once an idea becomes known, I cannot prevent you from knowing it). A paradigmatic “public good” is national defense. It is both non-rivalrous (my “use” of national defense does not preclude its use by other co-citizens) and non-excludable (national defense cannot be provided to me without providing it to other co-citizens, at least at reasonable cost). According to Duffy, some commentators argue that information is a public good and that it therefore should be left in common (i.e., not appropriated as private property through IPRs).⁶

For Duffy, the problem with this argument is obvious: Not all information is a pure public good, at least not in the same sense as national defense.⁷ Not only is

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⁵ Duffy himself thinks that IP should be viewed as a subspecies of physical property. See (Duffy, 2005b).
⁶ See (Duffy, 2005a), citing (Benkler, 2000).
⁷ The use of the word “pure” here reflects a spectrum between pure public goods and pure private goods. Recognition of this spectrum merely implies that more argument is needed to translate an entity’s position on this spectrum to how we ought to treat it.
information at least partially excludable8 for a limited period of time (e.g., patents), but it can also be rivalrous in certain circumstances. For example, to show how some information is rivalrous, Duffy cites a famous case, *Salinger v. Random House, Inc.*, where J.D. Salinger’s enjoyment of his unpublished letters would decrease if others read ("consumed") them (Duffy, 2005a 14-15). In short, not all information is a pure public good, so little follows from the “exceptionalist” view that information is unique in being a public good.

A second example of IP exceptionalism often used to argue against property rights in information is that IP (unlike physical property) uniquely creates undesirable monopolies. Because free market advocates usually seek to avoid the waste associated with monopolies, we should be wary of IP – perhaps to the point of drastically limiting it. According to Duffy, the problem with this argument is that, construed broadly enough, “all property rights involved trade-offs between individual monopoly benefits and social welfare.”9 Even a narrow definition of monopoly – defined as “anti-trust” – might not help, because the mere existence of one or more patents does not necessarily create a monopoly (assuming substitutes exist in the market)(Duffy, 2005a). The anti-

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8 The type of excludability I have in mind is not some metaphysical exclusivity, but rather excludable at some reasonable cost or effort. Patents, it would seem, effectively exclude at some reasonable cost.
9 See (Duffy, 2005a), quoting (Khan, 1995 92).
monopoly argument therefore fails either to uniquely differentiate intellectual property or justify restricting it for the sake of limiting monopolies.

Interestingly, IP “exceptionalism” is not attractive only to those seeking to restrict intellectual property. Others who advocate for strong property rights in ideas similarly claim the uniqueness of IP in a failed attempt to support their arguments.

Frequently, for example, one hears that the crucial feature of ideas is their “declining average cost.” Simply put, once someone has invested a fixed amount to create or discover an idea (the “fixed cost”), the cost of each additional use of that idea is very low, if not zero (“zero marginal cost”). In the context of drug development, pharmaceutical R&D (as mentioned in Chapter 2, some hundreds of millions of dollars) represents a high fixed cost whereas the cost of copying an effective drug, once developed, is very low or close to zero. Because of these unique economic features, the argument goes, IPRs should be very strong to protect innovators from free riding copiers.

As Duffy notes, however (Duffy, 2005a), this situation is neither unique to intellectual property nor prescriptive for how to deal with such situations. For one, the situation is much like “natural monopolies,” i.e., situations where high fixed costs (such as in digging subway tunnels or laying electrical cable) in conjunction with low to zero marginal costs (such as in extra lengths of subway or electrical cable) makes it more
efficient for one firm to provide the service rather than many (McEachern, 2005).10

(Imagine the inefficiency of two companies competing to dig subway tunnels for the
same busy commuter routes.) Declining average cost or the possibility of free riders,
then, are not unique to intellectual property.

Moreover, Milton Friedman already recognized in 1962 (Friedman, 1962) that the
mere fact of declining average cost gives a government three options, which Duffy
frames as:

(1) unlimited private rights, which will lead to private monopoly; (2) partial private
property rights, which include governmental limitations ranging from price regulation;
and (3) public ownership, either with or without public subsidies. (Duffy, 2005a 22)

And although Duffy argues for some version of (2), what should be clear is that the
simple fact of declining average cost does not alone suggest how governments ought to
act, or how policy ought to be.

A second, remarkably simple attempt to justify strong property rights in ideas
bases its conclusion on the observation that the supply of good ideas is infinite whereas
the supply of physical property is not. Because the supply of good ideas is infinite, we
ought to protect ideas as much as possible to stimulate creating more of them, drawing
on their infinite supply. In economic terms, ideas are not scarce, unlike physical

10 (Mill, 1848) discusses the same concept regarding railways in Book I, Chapter 9, of Principles of Political
Economy.
property, so what harm could come to anyone as a result of someone’s taking of a single idea from an infinite resource (Kinsella, 2000)?

The strength of this argument depends, in part, on defining a relevant baseline for harm (see below, section 3.5.2). However, the appeal to ideas as an infinite resource seems to be weakened by several considerations: First, while the realm of ideas might be infinite, the resources they cover, and that they require to be instantiated or used in physical form, are not. The idea of an HIV vaccine does not prevent HIV; the vaccine itself does, and if only one effective vaccine were available, it will be of little solace to those who might be infected by HIV that the set of ideas is infinite (Sterckx, 2005 185).

Second, continuing to focus on pharmaceutical R&D, even though the set of ideas might be infinite, access to these ideas is not. Pharmaceutical R&D requires specialized skills and infrastructure that not everyone has, and so practically speaking, the set of ideas is not infinite to the majority of individuals. Related to this is a third consideration: intellectual property rights are not just about property in ideas, they also govern relations among individuals. As such, they must take into account the dynamics of power involved with conferring and executing these rights – dynamics not
adequately addressed by their “infinite” nature, if different individuals have differential access to this “infinite” pool.11

Finally, the most ironic part of appealing to the infinite stock of ideas as part of a justification for strong intellectual property rights is that, when it comes to physical property, an infinite stock serves as a reason to have no property rights. For many property theorists, it is only in the context of limited resources in the state of nature that property rights are necessary. Were the stock of ideas truly infinite, no property rights would be necessary in the first place.

In sum, arguments about the “exceptional” nature of intellectual property – property in ideas – are not convincing either in favor of or against “strong” intellectual property rights. This is mainly because property in ideas does not appear to have any single, unique characteristic that distinguishes them from property in objects. One upshot of this is that, while no necessary link exists between theorizing about physical property and theorizing about intellectual property, the interchange can be fruitful. Another is that much work remains in terms of theorizing and justifying intellectual property; were we to consider intellectual property “just like” physical property, or “just unlike” it, the present task might have been easier.

11 The attention to power is best captured by “social relations” theories of property, which I discuss more below. See (Munzer, 2001).
3.3.2 Patents, Copyrights, and Trademarks, Oh My: A Functional Definition of IPRs

A second preliminary point outlines the general scope of this discussion: What exactly is theorizing about intellectual property rights about? Typically, one considers theorizing about IPRs to include patents, copyrights, trademarks, trade secrets, or other discrete legal entities falling under property law.

As discussed in Chapter 1, I wish to break from this tradition. In what follows, it is essential to recognize that I consider intellectual property rights as functionally defined. What is the function of a property right? Quite simply, it is a right to exclude. For example, a patent is a right to prevent others from making, using, or selling whatever the claims laid out in the patent cover. Thus, while this project considers the justification of intellectual property rights, the reader should not equate this with necessarily justifying or undermining the specific legal doctrines of patents, copyrights, and trademarks. The conclusion is more general, and would apply to anything that functions like an intellectual property right, i.e., anything that confers ownership on a piece of intellectual property.

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12 This is not necessarily new. In 1964, Charles Reich (Reich, 1964) argued that welfare benefits should be seen as a species of property (to prevent unjust governmental intervention) and that licenses from the Federal Communication Commission should be seen as a form of property right. My functional “property rights” are less expansive and are not articulate in reference to preventing governmental coercion. For a recent article on Reich’s vision for property rights, see (Bussiere, 2004).
An example of something this broader definition would capture – but that generally falls outside discussions of patents, copyrights, and trademarks – is “data exclusivity.” Data exclusivity refers to a privilege given to the safety and efficacy data file submitted by a pharmaceutical manufacturer when registering a product with a regulatory agency. This privilege prevents other manufacturers from using the data, during a set period of time (usually 5 – 10 years), to register an equivalent generic product. Data exclusivity is, in other words, a right to exclude, making it a form of intellectual property according to my functional definition. Others agree, considering data exclusivity “patent-like” intellectual property (Drahos, et al., 2004: 249, Médecins Sans Frontières, 2004 4-5).

Of course, under many circumstances, data exclusivity does not apply, such as when the patent on the molecule extends beyond the 5 or 10 year data exclusivity privilege. But if the patent were to expire before this period ends, this data exclusivity would serve as a barrier to competitive entry to the market, and any potential competitor would have to provide its own data. Moreover, when clinical trials are involved, such protection might require repeating clinical trials with human subjects –

13 As Drahos et al. explain, “…protection of this data into an exclusive form of protection, creating in effect a type of property right” (Drahos, et al., 2004).
yet such duplicitous clinical trials are themselves unethical, putting human subjects at risk without any prospect of discovering new knowledge (So, 2004).14

The idea of a “functional” definition of IPRs requires further elaboration, so as not to include just any sort of “control” as a property right,15 but the overarching principle is simple: When offering a normative argument that relates to intellectual property rights, whatever general conclusions one draws (if any) should prima facie apply to anything that looks like an IPR or acts like an IPR. To make this point clearer, suppose one arrived at the improbable conclusion that no IPRs should exist. If that were the case, it would seem inconsistent to apply this conclusion only to patents, copyrights, and trademarks, leaving “data exclusivity” in place, if we understand “data exclusivity” as a kind of property right.

Practically, looking at “data exclusivity” through the lens of property rights could be important for international negotiations of IPR policy. This is because it could push issues such as data exclusivity more transparently into property rights forums rather than, for example, drug regulation forums (data exclusivity often arises in discussions of drug regulatory agencies, like the U.S. FDA). Therefore, considering data

14 For some relevant research ethics guidelines, see (Council for International Organizations of Medical Sciences (CIOMS), 2002), requiring that “…the risks of research be reasonable in the light of the expected benefits.” Available at http://www.cioms.ch/guidelines_nov_2002_blurb.htm. Accessed 15 November 2006.
15 In fact, one follow-on task from this analysis might be to better elaborate what precisely looks and acts like a property right.
exclusivity a type of property right adds a new dimension to these discussions, bringing to the surface what might otherwise go unnoticed. The notion of “TRIPS-plus” – i.e., intellectual property provisions, often negotiated in bilateral agreements, that go beyond the WTO TRIPS agreement’s minimal requirements – increasingly recognizes the connection between data exclusivity and property rights (Correa, 2006b).

3.4 Theories of IPRs Distilled into Two Major Types

With these preliminary points in hand, in the following sections I engage theories of intellectual property for two main reasons. The first reason is to suggest that typologies of IPR theory are unnecessarily complicated, and that this unnecessary complexity has several unfortunate consequences (such as a tendency to seek one single “end” in intellectual property rights). In place of these typologies, I propose to differentiate “natural” and “instrumental” theories of IPRs. The second reason is to point out the paucity of distributive justice in theories of IPRs – not in terms of how IPRs are distributed, but in terms of how IPRs impact the distribution of the tangible products tied to them.

The purpose here is not to review every possible typology or species of IPR theory. Instead, I review several recent and instructive ones that focus on specifically normative issues.
3.4.1 Sterckx: Truncating Distributive Justice and Consequentialism

The first example of a typology of IPR theories comes from Sigrid Sterckx and her article, “The Ethics of Patenting – Uneasy Justifications” (Sterckx, 2005). She notes that

Attempts to justify the patent system can be based on three grounds: (1) natural rights; (2) distributive justice; and (3) consequentialist (economic) arguments. Every single one of these is in many ways problematic. (Sterckx, 2005 178)

I set aside for now the question of “natural rights” until section 3.5, when I show that they are perhaps the most problematic justification of intellectual property. Instead, allow me to focus on her other two grounds, beginning with (3), consequentialist arguments. Examination of her discussion of consequentialism is important because it reveals how an unduly narrow view of consequentialism equates consequentialism with traditional economics (as she explicitly does above). This in turn limits the consequences to which one might appeal in justifying IPRs, both in type (by ignoring non-economic consequences, which Sterckx neglects) and in principle (by ignoring distributive consequences, a matter that Sterck takes up in (2) above).

First, to summarize the exposition of consequentialist (economic) justifications: Sterckx draws the long history of consequentialist arguments for intellectual property, beginning with a quote from Jeremy Bentham – “he who has no hope that he shall reap will not take the trouble to sow” (Bentham, 1785 71). She then moves quickly into more
modern justifications. These include what she (and others) terms the “incentive to innovate” (David, 1993) and “incentive to disclose” arguments. Both appeal to the idea that patents are justified because their net economic consequences are positive (namely, the “good” creation and diffusion of ideas and inventions outweigh the “bad” allowance of deadweight loss associated with a patent monopoly).

So why, according to Sterckx, are these justifications “in many ways problematic”? Similar to my own concerns in Chapter 2, Sterckx notes that empirical evidence is lacking to sufficiently justify the consequentialist (economic) claims about IPRs. This is not a new revelation, and Sterckx is aware of this. In an oft-cited 1958 study, Fritz Machlup noted that

The literature abounds with discussions of the “economic consequences” of the patent system, purporting to present definitive judgments, without even stating the assumptions on which the arguments are based, let alone submitting supportive evidence for the actual realization of these assumptions. No economist, on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss upon society. (Machlup, 1958:79)

Sterckx would argue that this situation persists. What can be said of her rejection of the consequentialist justification without delving into the entirety of this literature?

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16 For a recent review of the “incentive to disclose” argument, see (Andersen, 2004:434-8). This argument might also be called the “social contract” or “avoiding secrecy” argument, because it minimally suggests that having ideas out in the open is preferable to having them held in secret. So, government awards a patent in exchange for disclosure of the invention.
Sidestepping the specific empirical parts of the debate, several interesting themes emerge.

First, to a certain extent, Sterckx appeals to current patenting practices to refute the theoretical justifications for IPRs, rather than seeing these as deviations from theory that require explanation or even correction. For example, in her discussion of the “incentive-to-disclose” argument, Sterckx notes that “it needs to be stressed that the requirement of sufficiency of disclosure is often not taken seriously by patent granting authorities” (Sterckx, 2005 199). This point does not dispute the “incentive-to-disclose” argument; instead, it would require patent granting authorities to take sufficient disclosure more seriously.

Second, the incompleteness of empirical evidence regarding the impact of IPRs on innovation and disclosure creates, at best, a stalemate over whether to change the IPR system. Incomplete evidence does not entail that we have the wrong IPR system; it simply means we do not know if it is the right system. Of course, other non-economic (or even normative) reasons might exist to change the system, and to this extent, Sterckx endorses something like the Empirical Data Thesis of Chapter 2 (and all of its failings).

Finally, Sterckx conflates consequentialist arguments with economic arguments for intellectual property rights. In other words, she misses the critical point that some consequences of IPRs might not be adequately captured by economic analyses, either in
principle or in the way they are currently carried out. Consequentialism, understood broadly as the idea that “normative properties [i.e., whether something is morally right or wrong] depend only on consequences” (Sinnott-Armstrong, Spring 2006), might surely involve more than economic consequences. For example, IPRs might foster personal creative activity or greater equity in access to new technologies, and if either is an important part of human welfare not adequately captured by economic analyses, we could view it as part of consequentialism more broadly construed.

In sum, then, Sterckx’s analysis of consequentialist justifications for IPRs is revealing because of what it neglects: By focusing solely on economic consequences, narrowly construed, Sterckx unduly constrains the debate about whether there is a sound consequentialist justification for IPRs from the start. Below, in sections 3.4.2 and 3.4.3, I examine two typologies that do not make this mistake, and I explain how a richer conception of the normative justifications for IPRs would improve the IPR debate.

Returning to her criticisms of (2), distributive justice, reveals the same truncating error, but in a different context. For Sterckx, appealing to distributive justice to support intellectual property rights means “that it is only fair that inventors are rewarded because they do society a service. Society is obliged to guarantee that reward (Sterckx, 2005 188).” She proceeds to examine the difficulties with determining the amount of such awards and to whom they should be given. Briefly, she notes that IPRs might
create unequal access to use of the information covered by such rights, but in general, she focuses on the distribution of rights to inventors. She eventually concludes that the patent system overemphasizes the private interests of inventors, rather than public good, and implies (but does not further specify) that something ought to be done about this.

What is strange in this distributive justification is that it should only, or perhaps primarily, be concerned with how IPRs are distributed to inventors – how much, how long, etc. Yet this is surely a narrow view of distributive justice that ignores broader questions, such as who owns how much intellectual property, whether the deadweight losses associated with intellectual property might be unequally distributed, and so on. Just as in the above discussion of consequentialism, Sterckx avoids these broader questions, even though they might come to bear on the debate.

To be sure, Sterckx’s analysis is brief – only the length of a book chapter – and most of the difficulties she points out are real. However, her analysis (and that of Penrose, who adopts a similar typology (Penrose, 1951 19-41)) is a symptom of common error in IPR theory; namely, the attempt to justify IPRs from severely truncated perspectives, whether “economic,” “distributive,” or otherwise. Viewing IPRs within a vacuum, focused only on the inventor, the invention, and the right itself, neglects other
relevant social considerations that affect – positively or negatively – the justification of IPRs.

Fortunately, a few individuals engaged in theoretical debates seem to recognize this. Unfortunately, they appear unduly pessimistic about the ability of these other considerations to affect the practice of intellectual property rights.

3.4.2 William Fisher and “Theories of Intellectual Property”

Unlike Sterckx, William Fisher’s (Fisher, 2001) survey of IP theory covers a great deal more territory. Building on Sterckx, this venture into surveys of different theories of intellectual property teaches two major lessons. First, Fisher’s own view of intellectual property, the so-called Social Planning Theory, ought to make us realize that all theories of IP are to some extent Social Planning views (see section 3.4.3, where I also decide to call these instrumental views). Recognition of this is important, in so far as some remain skeptical of social planning views because they appear “too burdensome” compared with other, more preferably minimalistic ones. Second, even though some IP theorists like Fisher recognize the potential connection between IPRs and distributive justice, they are pessimistic about the prospects for substantial agreement about distributive justice (see section 3.4.4). This makes them reluctant to commit to involving distributive justice
in IP policy, even though any IP policy, given certain background conditions, entails certain conclusions regarding distributive outcomes.17

Before discussing this in more detail, briefly discussing Fisher’s characterization of IP theory is helpful. Fisher delineates four types of IP theory and suggests what each theory might entail for answering questions about IP policy.

1. Natural Rights Theory. Fisher notes, in line with Sterckx, the natural rights view based on the idea that an individual has a “natural property right to the fruits of his or her efforts – and that the state has a duty to respect and enforce that right (Fisher, 2001 170).” He identifies Robert Nozick (Nozick, 1974) as the major modern proponent of this view. As in my discussion of Sterckx above, I postpone discussing this view in detail until section 3.5, below.

2. Utilitarian Theory. Roughly analogous to Sterckx’s “consequentialist” view, Fisher sees the utilitarian justification for IP – for him, the “maximization of net social welfare” (Fisher, 2001 169) – as one of the more popular ones. He identifies William Landes and Richard Posner’s work on copyright and trademark, as well as William Nordhaus’ exposition of patent law, as modern expressions of this theory, though of

17 This becomes most evident when I more fully explain the “Develop First, Distribute Later” assumption in the latter sections of this chapter.
course many others exist.\footnote{Fisher cites (Landes and Posner, 1989); (Landes and Posner, 1987); and (Nordhaus, 1969) as relevant articles. He also notes their philosophic indebtedness to (Bentham, 1785) and (Mill, 1862).} For utilitarian theorists of IP, the critical question becomes how one defines social welfare and how to construct IP policy to maximize it. One might define social welfare, for example, by wealth maximization criteria or other, more narrowly defined metrics. (For Fisher, these might include maximizing incentives to innovate, optimizing patterns of productivity, or reducing the waste of rivalrous invention.) Of note, however, Fisher does not make the same mistake Sterckx does in equating utilitarian (or consequentialist) theory with economics, as his discussion of social welfare points out.

3. Personality Theory. The third theoretical orientation to intellectual property derives roughly from the views of Kant and Hegel (and in particular, Hegel’s Philosophy of Right). As Fisher describes it, based on modern views developed by Jeremy Waldron (Waldron, 1988), Margaret Jane Radin (Radin, 1993), and Justin Hughes (Hughes, 1988), Personality Theory implies that IP might be justified either on the ground that they shield from appropriation or modification artifacts through which authors and artists have expressed their ‘wills’ (an activity thought central to ‘personhood’) or on the ground that they create social and economic conditions conducive to creative intellectual activity, which in turn is important to human flourishing. (Fisher, 2001 171)
For personality theorists of IP, the critical question then becomes, “Which human needs or interests, among those important to ‘human flourishing’ ought to be promoted by properly structured IPRs?” Here, Fisher notes several possibilities articulated by Jeremy Waldron, such as privacy, self-reliance, self-realization, and personal identity, among others (Waldron, 1988). Fisher also mentions that personhood theories require a fully articulated view of human nature and thus provide little practical guidance.

4. Social Planning Theory. Lastly, Fisher describes a view that IPRs can and should be shaped so as to help foster the achievement of a just and attractive culture... This approach is similar to utilitarianism in its teleological orientation, but dissimilar in its willingness to deploy visions of a desirable society richer than the conceptions of ‘social welfare’ deployed by utilitarians. (Fisher, 2001 172)

Fisher places himself in this camp and himself gives it the name, “Social Planning Theory.” He attributes the intellectual pedigree of Social Planning Theory to Thomas Jefferson (Jefferson, 1972), the early Karl Marx (Marx, 1964), legal realists such as Morris Cohen (Cohen, 1927), and more recently, Neil Netanel (Netanel, 1996). For the Social Planning Theorist, the critical question becomes which vision of a just and attractive culture to foster. Much as in Personality Theory, Fisher is again pessimistic because the range of “visions” is so broad that practical guidance is lacking. Fisher suggests that

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19 Netanel develops his interesting view based on the idea that James Madison and others saw (narrowly defined, short-term) copyright as essential to forming a democratic society. See (Netanel, 1996).
these visions might include consumer welfare, distributive justice, semiotic democracy, or respect. But he concludes:

The possibilities are endless...[Regarding distributive justice], [it] is plainly implausible that theorists of intellectual-property could resolve controversies of this scale in the course of analyses of copyright or patent doctrine. (Fisher, 2001 193)

Thus, Fisher’s own preferred view appears to require a great deal more work to become helpful in policy debates about intellectual property rights and how they ought to be structured.

One could, at this point, launch into a detailed discussion about each theory of intellectual property, its different versions, and weigh their merits to come to the “correct” or “best” theory, all things considered. Such a strategy would be unhelpful for several reasons.

First, it would be impractical. Reviewing all seemingly plausible theories of IP would be (deservedly) a project all its own and thus fall beyond the scope of the present one.

Second, choosing one “best” theory obscures the observation that intellectual property might serve these different functions at different times. For example, protecting a celebrity’s public image or persona as intellectual property – a policy that appears most justified by Personality Theory – might not fare well from a more Utilitarian approach (if net social welfare is increased by not protecting a celebrity’s
image). While this might point toward a need to change IP policy for the sake of a Utilitarian end, it might also imply that IP need not serve one and only one end. In fact, the assumption that IPRs ought to serve only one end (namely, innovation) is an assumption that I question later in this chapter.

Third, creating different typologies of theories and analyzing them in such manner reinforces the mistaken idea that only one correct theory of IP exists. To explain what I mean by “one correct theory,” consider an analogy with the old and now rejected approach to found ethics on a single overarching principle (e.g., of utility, virtue, practical rationality, etc.). This approach was rejected for ethics more generally and ought to be rejected for IP theory as well. So while some theorists like Fisher (Fisher, 2001) and David (David, 1993) seem to lament the hodgepodge of different theories, keeping in mind the diversity of approaches could be a good thing.

In saying this, however, I do not imply that we need to keep in mind all of these theories and add on some sort of “metatheory.” Quite the opposite. Indeed, maintaining different types of theories and expanding these typologies contributes to the very errors just noted. What this points to, instead, is a need to simplify the typology articulated by Fisher.

3.4.3 Collapsing IP Theories: Natural Rights and Social Planning (or Instrumental)
Having summarized Fisher’s description of theories of intellectual property, and continuing with the intuition that simplification might be in order, I now draw out the first important lesson about IP theory: Typologies of intellectual property theories are unnecessarily complicated. In fact, IP theory can be distilled into two major types: natural rights (which I set aside until section 3.5) and, for now, “Social Planning Theory.”

To get to this point, we need to collapse Utilitarian, Personality, and Social Planning Theories into one type of theory. Practically speaking, this collapse is important; one consequence would be that concerns over the “personality” dimensions of IP, or the seemingly vast possibilities for “distributive” justice and IP, cannot be ignored by simply appealing to a so-called pure utilitarian theory. This is because all of these theoretical approaches are better framed as instrumental theories – that is, they see IPRs as a means to some end, though they differ on what those ends are. Because the natural rights view appears to be the only non-instrumental theory of intellectual property, I discuss this approach on its own in section 3.5.

Allow me to begin by collapsing Personality Theory with Social Planning Theory. Notice that Fisher elucidates two quite different justifications for Personality Theory. One is that IP is justified because it is through IP that authors and artists “express their wills” in a Hegelian sense; another is that IP creates social and economic
conditions conducive to human intellectual activity, which is critical to “human flourishing.”

**Expression of the Will.** Interestingly, the “expression of the will” justification actually sounds more like the Natural Rights Theory’s appeal to individuals having a natural right to the fruit of their labor (in this case, their mental labor). So, one might suggest that this justification actually collapse into the Natural Rights view – one of the two types of theories of IPRs I am now proposing. Alternatively, one might suggest that IP is necessary for – i.e., a means to – the expression of the will, in which case the justification collapses into one form of the “human flourishing” view, which I consider next.

**Human Flourishing.** The “human flourishing” justification emphasizes the role of human creativity in human flourishing by creating the kinds of social and economic conditions conducive to human intellectual activity. In doing so, it can easily be reframed as a type of Social Planning Theory. Why? Because this version of Personality Theory states basically the following: “Human intellectual activity is a key part of human flourishing. Social and economic institutions ought to be structured to facilitate human flourishing. One such institution is the institution of intellectual property, which is necessary to facilitate human intellectual activity. Therefore, intellectual property ought to be structured to facilitate this.”
To be sure, many questions arise in relation to this statement. Is IP necessary for creative activity, or might other social arrangements do a better job at this? For now, however, this is not the issue. The key point is that this Personality Theory view of intellectual property is a type of Social Planning view because it instantiates one particular vision of a desirable society; namely, one where individuals have access to property rights in their own intellectual works as protected by social and economic institutions. Is this not a “vision of a desirable society,” as Fisher characterizes Social Planning Theory?

Fisher might retort that it is not, because the vision is not “as expansive” as Social Planning Theory. However, one might reasonably question what counts as expansive. To some, the idea that IP be structured to allow individuals to “express their wills” or to encourage “human flourishing” could appear very expansive. This could be because of (i) the “expansive” institutions necessary to support such “limited” IPRs (e.g., patent offices, courts, etc.) or because of (ii) the idea that an institution ought to encourage human flourishing in this way is itself quite expansive (as opposed to a view whereby institutions are only justified if they do not violate individuals’ rights, if they have such rights). In other words, based on how one defines the human flourishing of Personality Theory, and the institutions needed to foster it, no clear reason exists to consider Personality Theory less expansive than Social Planning Theory.
The same can be said for Utilitarian Theory. Here, Fisher’s contrast between the concept of social welfare in Utilitarian Theory and the vision of a just society in Social Planning Theory appears most stark. This is because of a sense of false simplicity in Utilitarian Theories of IPRs. I say “simplicity” because, as Fisher himself notes, Utilitarian Theory might justify IPRs because they “maximize incentives to innovate,” i.e., they maximize the creation of new ideas. This appears simple enough, and moreover, it appears minimalistic, particularly as compared to Social Planning Theories. “Who could argue with maximizing innovation? Certainly fewer than would argue with Social Planning Theory’s attempt to create a ‘desirable’ society,” or so the story would go.

The problem is that this is simplicity by omission, and hence it is false simplicity. It omits, for example, the idea that the attempt to “maximize innovation” would have little regard for Personality Theory’s emphasis on individuals having access to IP as part of human flourishing (and in fact, it would suggest that individuals would necessarily trade this, if doing so maximizes innovation). It further omits to consider whether the system maximizes innovations of certain types, as not all new ideas might be created equally in terms of their usefulness. Lastly, it neglects to consider whether various expansive institutions might be necessary to foster maximizing innovation, or whether these institutions impinge on other aspects of social welfare. For example, it fails to
address whether the same institutions utilized to maximize innovation might create barriers to the dissemination of such innovations (or, it assumes that society will create other institutions to facilitate this dissemination). For a view that claims to be “less expansive” than Social Planning Theory, even the simplest Utilitarian view thus assumes a whole lot about how society ought to be structured. And as Utilitarian views become more complicated, so might the Utilitarian view of a just or desirable society. Thus, Utilitarian Theory, on my reading, collapses into Social Planning Theory.20

In sum, then, these 3 “different” theories can all be seen as Social Planning Theories because they all instantiate some vision of a just and desirable society (though of course they do not portend to be the whole of a just and desirable society).21

Moreover, it is not clear the extent to which any of these different theories are “more” or “less” expansive in their view of such a society. Recall that Fisher questioned the practical implications of Social Planning. Part of his skepticism relates to the controversial nature of different social visions, which perhaps really implies a skepticism using coercively-backed legal measures to create such a vision. As my discussion of Utilitarian Theory suggests, endorsing a seemingly simple purpose of

20 The collapse of utilitarianism with social planning is noted by Adam Moore (Moore, 2003 200).
21 In fact - although this is not critical to my overall argument because I reject natural rights theory in section 3.5 – Natural Rights Theory, too, instantiates a vision of a just and desirable society. For this theory, a just and desirable society is one in which individuals are given property rights in the fruits of their labor, subject only to minimalist constraints that appear to discount potential harms to others that could have been avoided through alternative institutional arrangements. Clearly, this might be a sort of “Social Planning.”
intellectual property – e.g., maximizing innovation – is in two respects “expansive”: first because it could require many of the same (or potentially, even more) coercively-backed legal measures, making it no less intrusive on individuals; and second because its falsely minimalistic vision actually takes a somewhat expansive stance on a desirable society (e.g., one that is distributionally insensitive).

This collapse is not without beneficial consequences. First, it prevents us from being lulled into thinking that certain views are preferable because they are minimalistic. One ought not conclude, for example, that because Social Planning Theories are so expansive we ought to adopt a Utilitarian Theory to “maximize innovation.” Instead, understanding all three “different” theories as a type of Social Planning Theory compels us to ask the same question for each: What sort of vision for society does this view instantiate or ask us to consider?

This is the second benefit of the collapsing strategy: It brings to the surface certain background assumptions about a desirable society that would otherwise go unchecked. Finally, a third benefit is that understanding the relatedness of these (not so) different theories reminds us that concerns over Personality – understood as the importance of human intellectual activity to human flourishing – or distributive justice, among others, are not washed away because we decide that Utilitarian Theory is the “true” IP theory. All of these considerations, and any other values which intellectual
property might foster, together help constitute intellectual property theory, even if by
omission. This relatedness requires us to keep these considerations in mind when
translating IP theory into IP practice.

Nearest to this kind of unification is the broad Instrumentalism of Peter Drahos
(Drahos, 1996). Drahos describes his instrumentalist view as requiring a

strongly articulated conception of the public purpose and role of intellectual property.
Under instrumentalism intellectual property would be located in the context of some
broader moral theory and set of values (Drahos, 1996 223).

In line with the view I am developing, he writes that, “An instrumentalist theory of
intellectual property would be a normative theory” (Drahos, 1996 220).²² From my
standpoint, then, Drahos’ Instrumentalism is effectively a Social Planning Theory of
intellectual property.

Therefore, at this juncture I wish to change my terminology. Rather than
continuing to use Social Planning Theory – which carries terminological baggage
relating to its (falsely) “expansive” view and the connection to a line of theorists defined
by William Fisher – I will now use instrumental theory (though I consider social planning
and instrumental to be roughly equivalent). By instrumental theory, I mean the basic
idea that intellectual property serves social and economic ends. The use of plural “ends”

²² For Drahos, Instrumentalist theory is at least partially defined by what it is not: Proprietarian theory,
which roughly corresponds to the natural rights view I criticize in section 3.5.
is critical, because as I have articulated above, little reason exists at the outset to suggest that IP should serve only one end (though it might), or what end(s) it ought to serve. In adopting the term instrumental, we should not forget that any IP theory (and by extension, any IP policy) is “social planning” in the sense that it instantiates some vision of a just and desirable society.

Peter Drahos does not fully articulate the implications of his Instrumentalist theory by arguing for more specific content to the “public purpose” or the “ends” of intellectual property. Unlike Drahos, I seek to draw out the implications of an instrumental view in a very narrow context with a particular value, social vision, or instrumental end in mind: distributive justice.

3.4.4 IP Theory and Distributive Justice: Theoretical Approaches and Their Distributive Implications

For my initial foray into the intersection of intellectual property theory and distributive justice, I return briefly to Fisher’s essay on theories of intellectual property. The reason for this is his pessimism over the ability of IP theory to accommodate social planning for, say, distributive justice or other social value areas where widespread disagreement exists. Put in my terms, he questions the ability of intellectual property to serve the end of distributive justice. Recall the following quote, with one additional sentence at the beginning:
What sort of society should we try, through adjustments of copyright, patent, and trademark law, to promote? The possibilities are endless…[Regarding distributive justice], [it] is plainly implausible that theorists of intellectual-property could resolve controversies of this scale in the course of analyses of copyright or patent doctrine. (Fisher, 2001 193)

Examining this quote is helpful, first because it seems to preclude considering distributive justice in relation to IP theory and second because it reinforces my claim that all IP theories and practices assume some vision of a just and desirable society, even if they do so by omitting certain normative considerations.

Why the pessimism about distributive justice? Fisher implies that it is because “the possibilities are endless” or because “controversies of this scale” could not be resolved through intellectual property analysis. He must have in mind conflicts between egalitarian, welfare, dessert-based, and libertarian views, among others. However, this pessimism is unwarranted. Even if possibilities are endless, this does not exclude what might be well-justified, widely agreed upon views of a basic minimum or sufficiency view of distributive justice. Such a view could acknowledge endless possibilities and yet recommend that a basic minimum exists. And in fact, in Chapter 4, I argue that regarding global distributive justice, a well-justified and agreed upon view of human rights might represent such a basic minimum. In addition, one need not ask IP theory to “solve” all disagreement over distributive justice, but to simply take them into account. Fisher therefore overemphasizes both the “endless possibility” and “controversy” involved.
What about the idea that all IP theories and practices instantiate some (partial) vision of a just and desirable society? To argue that IP could never accommodate distributive justice is tantamount to arguing that intellectual property somehow operates independently of distributive justice. This is far from true; instead, intellectual property theories and policies actually do take stands on distributive issues. Returning to Fisher’s typology of theories helps reveal this. (To differentiate them from my conception of broadly instrumental theory, I now call them “approaches” to suggest that an emphasis on a particular value would have the following distributive implications.23)

**Utilitarian Approaches.** Utilitarian approaches to intellectual property are, classically, “distributionally insensitive.” This is because a utilitarian approach that seeks to maximize innovation, for example, will prefer whatever distribution of property rights best maximizes innovation. Such a system would judge a system of single property right holder compared with a system of multiple property right holders by the same standard: Which maximizes innovation?

Yet this is not the only way in which a utilitarian approach at maximizing innovation is distributionally insensitive. It is also distributionally insensitive in the sense that such a system leaves open the question of how the innovations produced are distributed. Or, stated in a slightly more positive way, a system whose only goal is to

23 I borrow this use of “approach” from (Munzer, 2001).
maximize innovation perhaps assumes that other social structures are in place to deal with the distribution or dissemination of innovations. In this case of pharmaceutical patents, this would include the tangible products covered by a patent (i.e., medicines).

*Personality Approaches.* Unlike a pure utilitarian approach, the personality approach takes quite a different stand on distributional issues. Because intellectual property rights and the human creativity fostered by them are a major contributor to human flourishing, the personality approach would appear to value everyone having access to IPRs. How much access, and whether individuals could forfeit this access, are difficult questions; but surely the personality approach (unlike the utilitarian one) would be highly critical of a system involving only one or a few major property rights holders. Quite possibly, it would also be critical of a system where individuals turn over their intellectual property rights to an institution (as is commonly the case with IP today, for example, in the university setting).

Personality approaches might also imply certain things about distribution in the second sense, i.e., distribution of the products covered by intellectual property. In so far as these products are deemed essential to human flourishing, or essential to human creativity, personality approaches would imply that these ought to be available to all.

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24As I note below in section 3.6, the structure that is presently assumed is the market.
Examples here might include minimally sufficient supplies of food, minimally sufficient housing, or access to a basic set of health care services or essential medicines.

Already, however, a tension arises: individuals might be in a situation where their fulfillment of these basic human needs in some way conflicts with their access to intellectual property rights (understood by personality approaches as themselves a basic human need). Suppose, for example, that an IPR system maximizing innovation did a better job at getting food and shelter to those in need, at the expense of giving those in need access to IPRs (which is important from a personality approach).

While this requires resolution, at this point I am merely suggesting that each approach has distributive implications that that can be reasonably predicted given the nature of each theory. This alone is important because I continue to build a case that IP theory ought to take into account distributive justice – contra Fisher’s pessimism – in part because IP theory and practices have distributive implications.

*Social Planning Approaches.* Of the three instrumental approaches to intellectual property – utilitarian, personality, and social planning – the last requires minimal discussion of its distributive implications. This is because at least some social planning approaches could explicitly accept distributive justice as one of the ends the IPR system should promote (though Fisher is unduly pessimistic of this attempt).
However, one particular approach to property that falls under the rubric of social planning appears to have interesting distributive implications. This is the social relations approach, defined in part by the idea that

Differences in power influence the relations among human beings and the property rights that result...Variations in power and the distribution of property enable some persons to limit the freedom of, or even to coerce, other persons...The reform of institutions sometimes requires changing basic rules of property law (Munzer, 2001 41-3).25

Because a social relations approach emphasizes how property rights impact power and freedom, it would appear to be an example of a social planning approach. In addition, one might reasonably conclude from this line of thinking that, because property rights both result from and create differences in power (thereby limiting others’ freedom), we should be concerned with how intellectual property rights are distributed. In other words, all things considered, a more equal distribution of property rights might be preferable to an unequal one in order to mitigate the coercive effects of property rights. This places social relations approach somewhat in agreement with the personality approach in its limitations on how property rights are distributed.

This section has helped better specify my claim that all instrumental IP theories (and policies based on them) help instantiate some vision of just and desirable society

25 A full social relations theory also includes ideas about the self as socially constructed. However, it is not clear that one has to accept any particular view of the self to recognize the importance of the power relations discussed in social relations theory.
generally, and that they do so by implicitly taking a stand on distributive issues. None of the individual IP approaches acknowledge this point. I can also state this in a different way, relating back to the discussion of William Fisher’s skepticism of the intersection of IP theory and distributive justice: Far from dismissing the attempt to utilize intellectual property to effect distributive justice, because all intellectual property theories appear to take a some sort of stand on distributive issues, we should recognize that intellectual property is simply part of distributive justice (though of course not the whole of it).26

Earlier, however, I mentioned that these distributive issues or outcomes typically occur against certain background social and institutional arrangements. For example, recall that when discussing one version of a utilitarian approach to “maximize innovation,” I implied that this was distributionally insensitive; as stated, it includes nothing about how those innovations were distributed. It could be, however, that in the real world institutional arrangements exist to ensure that innovations are distributed equitably. Whether or not such arrangements exist, and how amenable they are to change, requires a more practical (rather than theoretical) approach. I begin considering this practical issue in section 3.6, where I return to the Intellectual Property and Innovation Thesis currently dominating discussions of IP. As a hint of what is to come,

26 Importantly, this claim appears valid whether one accepts my view that all approaches to IP collapse into instrumental theory.
there I will argue that, at present, such arrangements do not exist. In addition, I suggest that certain normative components of IP theory (e.g., personality, social relations) imply that modifying intellectual property rules themselves – rather than creating such institutions – could be a better way of dealing with this institutional problem, rather than by creating new institutions to remedy this distributional insensitivity.

First, however, I must finally acknowledge a line of thinking that runs counter to the instrumental view presented here. I owe those readers persuaded by a natural rights view of property some acknowledgement. In the next section, I explain why a natural rights view of property is untenable. Readers who do not need such convincing may proceed to section 3.6.

3.5 Natural Rights for Intellectual Property Rejected

Addressing natural rights theories of property is necessary for two reasons. First, from a theoretical standpoint, natural rights to intellectual property seem to preclude any real consideration of distributive justice. This is true, even though in a certain sense the institutions needed to support natural rights might be “expansive” and even though they take a stand on distributive issues (i.e., by suggesting that an individual has no clear responsibility to “share” what he or she creates and therefore owns). Moreover, natural rights views are non-instrumental; it is not that the right serves some greater social end, but that an individual deserves the right as a result of
intellectual labor or some other natural characteristic. The second reason is that, from a very practical standpoint, natural rights views of property have popular appeal (see section 3.5.1).

The writings of John Locke (Locke, 2003; 1690) – in particular, passages from Chapter V, Book II of the Two Treatises of Government – are regarded as the paradigmatic natural rights view of property. Locke’s view reads something like this:

God gave the Earth to all mankind in common. Given this, how can individual property rights in parts of the earth arise out of this commons, and without the express agreement of the other co-owners of the commons? “Every man has a property in his own person,” says Locke, including “the labour of his body, and the work of his hands,” so that whenever he mixes his “labours” with part of the commons, it becomes his property (Locke, 2003; 1690). This newly minted property right is justified if the following two constraints are satisfied: first, so long as “enough and as good” remains in common for others to appropriate (the so-called Lockean proviso of Robert Nozick (1974)); and second, so long as the property is not wasted or allowed to spoil (Locke says, “Nothing was made by God for man to spoil or destroy” (Locke, 2003; 1690)).

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27 For Locke, the invention of money does eventually allow one to justly accumulate property beyond which one can “use” without spoilage. See (Locke, 2003; 1690)
To be sure, many difficult interpretive questions arise here. These involve both Locke’s general view of property, as well as the extent to which Locke’s view applies to intellectual property.

Regarding property, for example, different interpretations claim that Locke justifies radical free market capitalism (Macpherson, 1962), some form of socialism, and everything in between (Sreenivasan, 1995, Tully, 1980, Waldron, 1988). Regarding intellectual property, different interpretations claim that Locke’s view could justify either strong IPRs (Moore, 2003, Nozick, 1974) or only weak IPRs (Shiffrin, 2001). Some even suggest a reading of Locke that implies he was to some extent an instrumentalist about property, seeing it as a way to encourage otherwise lazy men into labor (Hughes, 1988).²⁸

Yet interpretation is not the critical issue for me. Thus, although engaging in Lockean exegesis appears obligatory for any discussion of property rights, and while what Locke meant is an important historical, philosophical, and contextual question, I am not interested in this per se. Rather, I wish to use this (traditional) Lockean view and some of its followers as representatives of a non-instrumental view of property rights.

²⁸ If the function of property rights is to encourage labor, it sounds more like the incentive-based utilitarian theories discussed earlier. And if one accepts this utilitarian dimension of property, it would open the door for many others (such as those based on distributive justice). Thus I consider more purely “natural rights” views. The observation that natural rights views often cannot help but appeal to such dimensions of property could be telling.
This view is “non-instrumental” because, at least on the traditional reading, property rights do not promote an end in anything like the ways I noted previously. The non-instrumental view I consider, therefore, is analogous to “labor dessert” views of property – i.e., the idea that property rights are rewards justly given for the fruit of one’s labors. It is also analogous to the “natural rights” views (a term also commonly applied to Locke). Natural rights views emphasize the pre-social status of certain rights. For example, in the above paraphrasing of Locke, the natural right to property seemingly justified by the Lockean “as much and as good” proviso arise in the state of nature, before mankind enters into society. Once mankind enters into society, society continues to honor these rights.29 Thus, in what follows, I will use the terms “non-instrumental” and “natural rights” views somewhat interchangeably.

The purpose here will be to ask the more general question of whether such a non-instrumental, natural rights view is tenable – not whether Locke’s own view is tenable. I conclude that the natural or non-instrumental view most commonly appealed to in justifying (intellectual) property rights suffers from inconsistencies, explanatory difficulties, epistemic burdens, and practical inadequacies to which instrumental views are immune. Together, these make non-instrumental views of property untenable, both in theory and in practice. This might not amount to a knockdown refutation of non-

29 Another example of a “natural right” might be a circumscribed “right to life,” taking into account killing in self-defense and other potentially exceptions to such a right.
instrumental views. But it does give us good reason to consider, at least for now, instrumental views of property as the most productive avenue for thinking about property rights. Once rejected, I return to consider a specific form of instrumental theory currently popular – the “maximize innovation” thesis introduced in section 3.1 – in section 3.6.

3.5.1 Examples of Lockean Rights in Theory and Practice

Before proceeding, elaborating the popular appeal of natural rights views of property is important. Doing so underscores the need to scrutinize such views, as I do in the next section. But it also could be telling, in so far as tacit endorsement of natural rights views could help explain apathy toward modifying IPR policy: Understanding IPRs in a natural rights framework might, for example, cause one to eliminate any distributive justice constraints on IPRs from the outset. In other words, endorsement of natural rights-type views truncates the discussion about IPRs because discussion of the “ends” of intellectual property seems explicitly prohibited.

Where do we see such views expressed and endorsed? David Weder (Weder, 2005) suggests two popular examples. Consider first the popular fable, the Little Red Hen. In this story, a little red hen discovers a grain of wheat, sows and reaps a field of wheat, and then bakes the harvest into a loaf of bread. Her friends – a duck, a cat, and a dog – are unwilling to help with the labor, but when it comes time to eat the bread, all
are willing. The little red hen, however, denies them this and eats the bread herself (Galdone, 1973). The moral of the story? The little red hen’s labors justify her exclusive use and control of the fruits of those labors. This fable, which is told to many young children, seems to support a “labor dessert” view of property. It might also be seen as a natural rights or non-instrumental view, in so far as the story does not depend upon extent of social or political organization between the little red hen and her friends.

Weder’s second example is a quote from Tom Giovanett’s 2004 article in the Washington Times:

> Our lives have been made healthier, more pleasant and more productive because of the property-rights model of innovation, where those who invest their time, money, creativity and effort in developing new products and services get to direct their own efforts, own the results and profit from their inventions.30

This quote is interesting, because it appeals both to the “labor dessert” view of property (see “own the results”), as well as a more instrumental view (see “our lives have been made healthier”). Using the positive effects of a “labor dessert” view to justify its existence is, of course, inconsistent with a purely natural rights view. Doing so leaves open the possibility that were a different view of property to provide for greater net beneficial effects, we might prefer such a view. This inconsistency, however, might be lost in popular views of property.

30 Quoted in (Weder, 2005).
According to some, the rhetoric of “theft” and “piracy” – so pervasive in discussions of intellectual property – further reinforces a “natural rights” view. Over fifty years ago, Edith Penrose wrote

Similarly, the loose use of the word ‘stealing’ remains in most patent discussions to remind us of the natural property right conception of patents. Stealing could, of course, be given a narrower meaning: the appropriation of something which by law is granted exclusively to another. But it is used in a wider and vaguer sense to include the use by another of a man’s ideas even though they are not in fact patented or patentable under the law applying to him who uses them. Upon this concept all charges of ‘piracy’ are based when they are leveled against nations who permit their nationals to sue freely inventions patented elsewhere but which are not patentable under their own laws. (Penrose, 1951 24-5)

Do such sentiments ring true today? In a recent popular press article entitled, “Patent Piracy,” Gary Hull (Hull, 2003) compares compulsory licensing on several occasions to piracy or theft of intellectual property in the context of the pharmaceutical industry.31 Recall that compulsory licensing is “when a government allows someone else to produce the patented product or process without the consent of the patent owner” (World Trade Organization, 2005) but with remuneration to that owner.

Compulsory licensing is legal under international law and has been used by developed and developing countries alike in different circumstances. But it is “legalized theft,” according to Hull – a claim that only makes sense if one assumes a pre-legal, moral right

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31 For another example, see (Choate, 2005).
to intellectual property of the sort justified by natural rights views of property. Hull writes

We all marvel at the new drugs and medical devices that continually improve and lengthen human life. Yet nobody raises the alarm that patents – the moral and legal foundation of the industry – are under assault. …The right to patent secures a creator’s property right to his invention. We should not be fooled into thinking that it is ‘practical’ or ‘necessary’ or ‘humane’ to violate another person’s right, or a corporation’s right, to property (Hull, 2003).

In short, the popular appeal of a natural right to property, partially or mostly based on the fruit of one’s labors, is alive and well.  

This popular appeal trickles over into recent academic discussions. Were the natural right to property not an important view, we might not see recent essays (Shiffrin, 2001) and books (Murphy and Nagel, 2002) devoted to questioning it. Murphy and Nagel, for example, suggest that property in general is a legal convention and that natural rights views of property are tantamount to myths:

Any convention that is sufficiently pervasive can come to seem like a law of nature – a baseline for evaluation rather than something to be evaluated. Property rights have always had this delusive effect. Slaveowners in the American South before the Civil War were indignant over the violation of their property rights that was entailed by efforts to

\[\text{32 This is true not only in the developed world. Jason Cross, a Duke University PhD student in cultural anthropology, is examining the impact of natural rights views of property in developing countries (more specifically, Latin America).}\]
prohibit the importation of slave into the territories...But property in slaves was a legal creation...(Murphy and Nagel, 2002 8)

The feeling of natural entitlement produced by an unreflective sense of what are in fact conventionally defined property rights can encourage complacency about the status quo, as something more or less self-justifying. But it can also give rise to an even more confused criticism of the existing system on the ground that it violates natural property rights, when, in fact, these ‘natural’ rights are merely misperceptions of the legal consequences of the system itself. (Murphy and Nagel, 2002 9)

These passages are critically important, first because they imply an academic assault on natural property rights and second because they imply real dangers in failing to question such views. This questioning is exactly what I perform in the next section. And of course, the primary danger in failing to question natural rights views is that it might prevent us from recognizing the diverse ends of intellectual property rights (or, from my perspective, the intersection of intellectual property rights with global distributive justice).

3.5.2 Unique Problems with the Non-Instrumental or Natural Rights View

Exactly what problems exist for the natural rights view of intellectual property rights? One might simply adopt a view that excludes natural rights at the outset, recalling Jeremy Bentham’s famous quote that, “Natural rights is simple nonsense: natural and imprescriptible rights, rhetorical nonsense -- nonsense upon stilts” (Bentham, 1816). This scathing critique of the Declaration of Rights (written during the
French Revolution) boldly pronounced that “natural law” or “natural reason” (in Lockean terms) could create only imaginary rights, whereas real law creates real legal rights. For Bentham and his utilitarian followers, the issue of natural rights is trivial.

Yet one need not agree wholeheartedly with Bentham to appreciate the difficulties with natural rights views of property. In what follows, I suggest that natural rights views of intellectual property suffer from four major flaws, none of which are as apparent in instrumental views of property. Natural rights views are inconsistent; encounter explanatory difficulties regarding the shift from natural rights to social rights; suffer from severe epistemic demands; and, lastly, are practically useless given current social and political circumstances.

_Inconsistent._ Earlier, I suggested that natural rights theorists about property find it hard to resist appealing to more instrumental concerns in elaborating their views. The easiest way to make this point more clear is to consider the limitations such theorists place on property rights.

Take, for example, the Lockean proviso that “as much and as good” be left in common for others, as well as the claim that property rights are subject to a wastage constraint. Although one might plausibly read the “as much and as good” proviso as ensuring other individuals’ liberty in obtaining property rights (a seemingly non-instrumental concern), the “wastage” claim is more challenging. In fact, interpreting it
as anything other than an instrumental concern for the efficient or maximal use of resources – given that the “as much and as good” criterion is already satisfied – appears problematic from the standpoint of a “pure” natural rights, non-instrumental theory. Accepting the wastage criterion does, however, open the door for other limitations or modifications of property rights (such as, for example, those that seek a more just distributive outcome).33

Unfortunately, merely dropping the “wastage” criterion will not save this natural rights view, for several distinct reasons. The first is that almost all so-called natural rights theorists accept some limitations on property rights. A different way of putting this point is as follows: While there is widespread agreement that some “natural rights” (such as the right to life or basic civil and political rights) cannot be sacrificed for gains in overall welfare, few believe that the right to property, physical or intellectual, is one of these rights. Alex Rosenberg (Rosenberg, 2004) makes this point, and he cites Richard Epstein’s (Epstein, 1985) view of the state power to take physical property (as in use of eminent domain laws), but with compensation. (The parallels with the aforementioned compulsory licensing are striking.) And again, once these limitations are accepted, we must at least entertain the question of what other constraints might be placed on property rights.

33 Of note, Locke himself does not appear troubled by this inconsistency, nor need he be. It could be, after all, that Locke’s view of property rights is not a “natural” or “non-instrumental” as it is often read.
A second reason dropping the “wastage” criterion will not save the day is that the practical implications of a pure natural rights view just seem unreasonable. By definition, because natural rights arise prior to social and political arrangements, the legitimacy of national patent systems is shaky. Were IPRs a natural right, should it not be the case that a property right in a particular idea must be honored globally? Moreover, why should IPRs encounter any of their current limitations (e.g., time limited patent rights)? Pure natural rights views would seemingly require absolute and never-ending property rights in ideas. When taken to its logical conclusion, this would require asking every idea’s owner permission to use any idea ever created (a practice, for example, that would have made impracticable, because of transaction costs, the completion of this thesis).

To be sure, libertarian theorist Robert Nozick (Nozick, 1974) offers a non-instrumental explanation of time delimited intellectual property rights. On his view, patents are justifiably limited in time because others might have eventually discovered or invented the “substance” covered by the patent:

However, as time passes, the likelihood increases that others would have come across the substance; upon this fact might be based a limit to his property right in the substance so that others are not below their baseline position (Nozick, 1974 181).

What is surprising about this quotation, however, is that Nozick does not justify time limits on the basis of the liberty limitations on those who “would have come across
the substance” at a later time. Instead, he appeals to a “baseline position,” i.e., whether or not the others are made worse off by someone else’s property right in a substance. This is where the real trouble begins. By appealing to a “baseline position” of being worsened by a property right, Nozick implicitly brings in welfare-based concerns about the relevant baseline and what counts as worsening it. This falls from Nozick’s interpretation of the ambiguous “as much and as good” proviso, which is itself deeply problematic (as I articulate in more detail below).

In sum, I have hinted in this first section that most natural right or non-instrumental views of property suffer from inconsistencies by appealing to instrumental or welfare-based constraints. Instrumental views of property do not suffer from this inconsistency, of course, because they are happy to accept instrumental constraints on property (even if in practice they fail to fully do so). But even if one is not convinced by this “inconsistency” criticism of natural rights views, more trouble remains.

*Explanatory Inadequacy.* A second major flaw to natural or non-instrumental property rights theory is its explanatory inadequacy. By this, I mean the explanatory gap between a “natural right” to property and the social or economic property right that the natural right is supposed to entail.
This is perhaps similar to Bentham’s critique of natural rights, but it requires further elaboration. Edwin Hettinger (Hettinger, 1989) accomplishes just that in his discussion of intellectual property rights. Hettinger writes

There is a gap – requiring extensive argumentative filler – between the claim that one has a natural right to possess and personally use the fruits of one’s labor and the claim that one ought to receive for one’s product whatever the market will bear…In short, a laborer has a prima facie natural right to possess and personally use the fruits of her labor. But a right to profit by selling a product in the market is something quite different. This liberty is largely a socially created phenomenon. (Hettinger, 1989 40)

Hettinger reaches this conclusion by noting that market value is itself a socially created phenomenon, because

market interaction is possible only when property rights have been specified and enforced, and there is no ‘natural way’ to do this…The sorts of freedoms one may have in a marketplace are thus socially agreed upon privileges rather than natural rights. (Hettinger, 1989 39n.21)

Simply put, Hettinger argues that the natural rights appeal to a “labor dessert” theory of property – the idea that one justly deserves the fruits of her labors in a property right – is flawed. Such a view says that the laborer deserves something – perhaps a property right, but perhaps a prize or some other reward – but it does not suggest which of these socially created goods it deserves. Whichever it is falls in the domain of social policy.34

34 As in note 32 above, here again Locke might have originally acknowledged this gap and thus appears not quite as non-instrumental as on first glance. Citing sections 129 and 138 of the Second Treatise, Jacqueline
In this regard, a more instrumental approach to intellectual property has the distinct advantage of starting with a socially constructed right. It therefore does not require bridging Hettinger’s explanatory gap between “natural” and “social” rights, even though it might recognize some prima facie claim to a “natural” right of ownership. For example, in patent law, this might be recognized by continuing to place the inventor’s individual name on the patent, even if the property right itself is assigned to an institutions (as is common practice). The terms of the patent, however, are a different matter – one for social policy.

*Epistemically Demanding.* A third critical flaw in the natural rights or non-instrumental theories of property rights involves their epistemic demands. By “epistemic demands,” I mean the knowledge requirements needed for a theory to be adequately specified, or the way in which a theory deals with such requirements. What makes natural rights or non-instrumental theory overly demanding from an epistemic standpoint breaks down into three different problematic areas: labor apportionment, justifying time delimited patent rights by the “would otherwise have invented” criterion, and most importantly, explaining the “as much and as good” proviso itself.

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Stevens notes that Locke himself might have believed that natural rights do not translate directly into social rights, depending upon the “laws made by the society.” See (Stevens, 1996 440).

35 I owe this important concept to Allen Buchanan.
The first problematic area – labor apportionment – is a well-known criticism of the Lockean idea of “mixing one’s labors” to create a property right. The major issues involve determining (i) what counts as labor and (ii) how much of it justifies a property right, and in what. For example, Robert Nozick’s (Nozick, 1974) famous rhetorical example asks whether pouring a rightly owned can of tomato soup into the ocean results in him owning the ocean, or simply losing his can of tomato soup.

In this case, the answer might seem easy: surely that amount of labor and mixing is not sufficient for a property right of that magnitude. But the general problem of determining the amount of individual labor – critical for labor dessert or natural rights theories – that justifies a property right in an idea is not. The idea here is that, below some critical threshold, one’s labors no longer deserve in a property right. But where should this threshold be? For the labor dessert or natural rights theorist, what an individual laborer deserves should be proportional to the amount of individual labor expended.

Hettinger (Hettinger, 1989) discusses this, though he does not characterize it as an epistemic problem. The problem, as he sees it, is that

Given this vital dependence of a person’s thought on the ideas of those who came before her, intellectual products are fundamentally social products...Separating out the individual contribution of the inventor, writer, or manager from this historical/social component is no easy task. Simply identifying the value of a laborer’s labor adds to the world with the market value of the resulting product ignores the vast contribution of others. A person who relies on human intellectual history and makes a small modification to produce something of great value should no more receive what the
market will bear than should the last person needed to lift a car receive full credit for lifting it (Hettinger, 1989 38).36

Is there evidence to suggest that this epistemic problem – determining the amount of an individual’s labor contribution and rewarding it accordingly – is a serious one? Practice reveals the difficulty of this component of labor dessert or natural rights theory. For example, the typical criteria for patenting – the novelty, non-obviousness, and utility criteria – do not take into consideration the degree of effort exerted by the laborer, but rather the laborer’s results.37 Thus, in practice, labor is not rewarded based on the effort expended, but by the results of the labor.

One might respond to this by suggesting that a fixed patent term (e.g., 20 years from the date of filing) over-rewards some inventions requiring miniscule labor inputs, under-rewards others requiring massive labor inputs, and gets some just right. Overall, then, patents do reward individuals based on their labor expenditure, but for simplicity the one-size-fits-all standard is used. This response acknowledges the epistemic demands of determining individual labor contributions but proposes a solution to this demand.

36 This epistemic problem has a close analogy in medical ethics: the debate over individual and social responsibility for health. See (Wikler, 2002).
37 See (Hettinger, 1989 42n.25), citing (Becker, 1977).
The response is problematic. First, it appears ad hoc, sidestepping one of labor theory’s main requirements. For an analogy, suppose an instructor announced to her introductory philosophy course that student assignments would be graded based on the quality of the work contained in them. But, because this is hard to determine, all students will simply receive the same, “average” grade in the course. Can it really be said that students are rewarded based on the quality of their work? Second, and perhaps more importantly, a simpler explanation exists for both the patenting criteria discussed above and the just mentioned fixed patent term: Society chooses to assign property rights based on criteria that evaluate the results of labor, and in a way that serves as an adequate reward and stimulus for the types of labor that produces such results.

This more parsimonious explanation would be an instrumental one. Thus, just as instrumental theory presents no inconsistency and leaves no explanatory gap, an instrumental theory provides an escape from this first epistemic quandary. Instrumental theories that see intellectual property rights as a means to some end need not be concerned with the amount of individual labor; rather, it is concerned with whether IPRs, however structured, adequately serve the end(s) they are meant to (e.g., innovation, human flourishing, and so on). Instead of a vantage point from labor to property rights, instrumental theory looks from property rights to the labor required in
creating something deserving of them. On a more instrumental view, little reason exists
to parse out amounts of labor so long as the end(s) are being served. Why add in a
level of theory when no such level is needed?

The second major epistemic demand of labor or natural rights views of property
hearkens back to Nozick’s justification for time delimited patent rights. Recall that an
apparent problem with natural rights-oriented views is explaining any limitation of the
property right in question, or perhaps even minimalist ones (just as an individual’s
natural right to life cannot be sacrificed except in extreme, clearly delineated
circumstances). Nozick’s response in *Anarchy, State, and Utopia* (1974) is that, as time
passes, it becomes more likely that someone else would have come up with that
invention. At that time, the second individual’s liberty could be harmed, should a
property right already exist covering his independent invention.

Putting the “would have invented” condition into practice again creates
enormous epistemic demands on this theory. The process of innovation remains
incompletely understood and the subject of much study in business schools. Can we

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38 Part of this might involve rewarding individual laborers, perhaps by assigning them property rights or
naming them as inventors on a patent.

39 A similar counterargument arises when considering the notion of “independent invention.” According to
pure natural rights theories (including Nozick’s), independent invention – where two individuals
independently create the same thing – requires honoring both inventors. And yet the high epistemic
requirements of proving this lead modern patent systems to reject independent invention. (The point is not
the fact that they do reject it but why they reject it.)
reliably determine when a particular invention would have occurred? The appeal to a
general “would have invented” rule, such as a twenty-year patent period, is also
problematic here. The rapid pace of technological change (such as in the computing
industry) would suggest short “would have invented” periods. In addition, many
technological innovations involve competing innovators racing to the finish, which
would imply a very short patent term. Incremental innovations would similarly require
a short patent term, whereas non-incremental innovations would require longer patent
terms. If we could understand and explain innovation as well as is necessary to make
these determinations, we would probably not rely on a heavy handed, fixed patent
length for all inventions.

Here again, instrumental theory does not face this burden. The primary reason
for this is because it allows for clear and cogent reasons to explain the limitations placed
on intellectual property rights: IPRs ought to be crafted and limited to the extent that a
chosen IPR policy does or does not adequately achieve its end(s). Thus, instrumental
theory, though also relying on our incomplete understanding of innovation, does not
need to make specific predictions about innovation itself.

The final – and perhaps most critical – epistemic burden of natural rights theory
arises from how one explains the “as much and as good” Lockean proviso. Because
Locke himself is virtually silent on this issue, it is perhaps helpful to more fully elaborate
Robert Nozick’s (1974) interpretation. Nozick’s libertarianism in *Anarchy, State, and Utopia* derives explicitly from Locke. Discussing Nozick in some detail is useful, not only because he has clear Lockean leanings, but also because he discusses intellectual property rights specifically. The next several pages all deal with the difficulties inherent in defining “as much and as good” on a labor / natural rights view.

Nozick’s brief passages on patents in *Anarchy, State, and Utopia* draw on his Lockean view of the appropriation of property more generally. He develops Locke’s view that property rights are justified when one “mixes one’s labor” with something while keeping “enough and as good left in common for others” (the Lockean proviso). Critically, Nozick interprets the proviso to mean that Lockean property rights—acquired by mixing one’s labors with something—are justified *so long as no one is left worse off by another’s appropriation of property*.

To be true, this interpretive leap requires filling out several distinct epistemic claims. These include

(i) broad epistemic access for individuals to the thing appropriated, such that they “could have” done the appropriating;

(ii) a clear definition of the baseline against which individuals are or are not left “worse off”; and related to (ii),
(iii) clear advance knowledge on the part of the appropriator that no one will be left worse off by the appropriation.

Unfortunately, all are problematic. I address each in turn before turning to the practical uselessness of natural right theories, given present circumstances.

One might think that, because IPRs (such as patents) on medicines frequently result in higher prices, making some others worse off, they therefore could not be justified for Nozick. In fact, the opposite is true. Nozick offers two different examples that apply this line of reasoning to specifically to pharmaceutical-related cases.

In the first, Nozick describes the following scenario:

The fact that someone owns the total supply of something necessary for others to stay alive does not entail that his (or anyone’s) appropriation of anything left some people (immediately or later) in a situation worse than the baseline one. A medical researcher who synthesizes a new substance that effectively treats a certain disease and refuses to sell except on his terms does not worsen the situation of others by depriving them of whatever he has appropriated; the researcher’s appropriation or purchase of chemicals didn’t make those chemicals scarce in a way so as to violate the Lockean proviso (Nozick, 1974 181) (emphasis added).

In further justifying the appropriation, Nozick assumes that the researcher “uses easily available chemicals to synthesize the drug” (Nozick, 1974 p. 181). Here, then, is a clear expression of claim (i), the idea that for an appropriation to be justified other individuals must have had equal epistemic access to the ideas (or “substance”) in question. In other words, no one is worse off, in part because anyone else could have accessed the chemicals and synthesized the drug. As alluded to earlier (section 3.3.1), the harsh
reality is that this is not likely to be the case for modern pharmaceutical research and development. Pharmaceutical research is a complex, expensive, and risky enterprise to which most individuals lack this requisite direct access.

Similarly, it is unclear what sense of “scarcity” Nozick is after such that it does not violate the Lockean proviso. Does he mean the chemical is not physically scarce, in that it actually is available, somewhere? If so, he misses the point of intellectual property rights’ notion of exclusion: even if the substance were physically available, because of the property right, any buying, using, or selling requires the owner’s permission. Or, does Nozick acknowledge that the substance might be practically scarce, but in such a way that that the “as much and as good” proviso is not violated? If so, more clarification on this proviso is necessary. Either way, claim (i) about epistemic access appears to be unfounded, at least for the examples given.

Nozick’s other example begins clarifying his interpretation of “as much and as good.” I introduced this above as claim (ii), i.e., a clear definition of the baseline against which individuals are or are not left “worse off.” As I will suggest below, for a labor dessert or natural rights theory to be viable, the answer appears to require setting an unreasonably low baseline of comparison to determine whether others are harmed. Nozick writes:

For example, someone finds a new substance in an out-of-the-way place. He discovers that it effectively treats a certain disease and appropriates the total supply. He does not
worsen the situation of others; if he did not stumble upon the substance no one else would have, and the others would remain without it. (Nozick, 1974 181)

To be sure, Nozick acknowledges that defining the baseline for comparison is one of the critical issues at stake and that he does not intend to resolve it. However, he clearly has an idea of a baseline in mind – one that appears to necessary for his labor theory of property to work. This baseline is defined narrowly, i.e., only by an individual appropriation event and with little regard for either the consequences that might follow or the alternative property arrangements that could have resulted in a different or better outcome. In other words, labor theories of property necessarily address epistemic demand (ii), defining the baseline for harm, in an inescapably narrow way because anything else would permit alternative property arrangements.40

Nozick and other natural rights or labor theorists about property justify their position by considering only the direct consequences of a single appropriation. On this view, no one could be made worse off because without the appropriation in question, no one would have had the “substance” in the first place.

To further illustrate this, notice the similarity to the “But for the patent system” argument alluded to in Chapter 2, which I promised to discuss in more detail in this chapter. It appeals to the idea that we cannot criticize the patent system for creating

40 Unlike epistemic demand (i), this demand is slightly different because the key point is how natural rights or labor dessert theories solve the epistemic demand in question, rather than the demand itself, as in the preceding “epistemic access” discussion.
expensive medicines because, without the patent system, we would not have those medicines. This seems misguided, for several reasons.

The first problem is that, by appealing to the observation that the patent system fostered the discovery or creation of such medicines, it sounds less like a labor theory of property than it does a more instrumental theory. In this regard this appeal seems almost inconsistent.

The second problem is that the consequences in question deal only with the “direct” effects of a single appropriation. In other words, indirect effects – such as, for example, the time the researcher described above engaging in another activity or searching for a different substance – do not matter. Nor does the harm that might occur if an individual knows the substance in question now exists to treat his or her disease but is not affordable or available to him or her. Why does neither harm count in evaluating the intellectual property system under consideration? What justifies a baseline so narrowly construed? Beyond moral intuition, the answer is wanting.

Related to the concern over indirect harm is a third problem with the “But for the patent system” argument: Only rarely can we determine with any reasonable certainly that a particular invention would or would not have been without a patent system. This is analogous to the epistemic demand in deciding patent terms based upon how long it would have taken someone else to invent the same thing. We might not ever have the
relevant counterfactual, and as such, we cannot know whether other institutional arrangements might have facilitated discovery or invention sooner, more efficiently, or with greater access afterwards. Or, perhaps even a more benevolent labor theorist would decide not to prevent others from using the substance she discovered. The “But for the patent system” argument is unconvincing because it fails to consider such alternative arrangements.41

Finally, a fourth problem with this line of thinking about the “no worse off” baseline is the critical assumption it make between worsening others’ situations and failing to better them (Moore, 2003).42 Adam Moore, who offers a somewhat more detailed version of Nozick’s general claims, suggests that any other baseline but a narrowly defined one is obviously incorrect:

What if a perverse inventor creates a machine that will save lives but decides to not allow anyone to use the machine? Those individuals who had, before the creation, no chance (opportunity) to survive now have a chance and are worsened because of the perverse inventor’s refusal to let others use the machine. The baseline this case implies cannot be correct…we are all worsened in this respect by any value that is created and held exclusively. (Moore, 2003 211)

41 One piece of irony here is how the pharmaceutical industry and its representatives often appeal to the “But for the patent system” argument, neglecting alternative arrangements and focusing on single appropriations according to this narrow baseline. Yet, at the same time, they include opportunity costs in the figures for how much it costs to bring a new drug to market, thereby taking alternative scenarios into account when it suits their interest.
42 Like the “But for the patent system” argument, this statement echoes the normative stance in Chapter 2 about patents “hindering” access to medicines versus patents “aiding” access. Importantly, Moore acknowledges in a footnote that this distinction – which is necessary for his argument to work – is a “hotly contested moral issue” (Moore, 2003 210). Suffice it to say that he believes such a distinction hold, whereas I do not.
To an extent, Moore is correct in saying we can be worsened by any value that is created and held exclusively. From this, however, it does not follow that only a narrow baseline is correct. We can also be bettered in different ways, and so this statement reveals a gaping hole in natural rights theory: It fails to compare even different types and amounts of benefits, simply allowing any benefit (or even zero benefit) to justify an appropriation. Moreover, contra Moore, suggesting that we might be worsened – after all, we could be better off if the machine were not held exclusively – need not imply that no appropriation is justified. Instead, it forces us to compare how individuals are worsened versus how their situations are improved under different property arrangements. And even if no one were harmed (satisfying Moore’s baseline), we might be interested in whether or not individuals receive the same kind or as much benefit as compared to these other arrangements.43

Why are these “baseline” problems so challenging for defining the baseline of harm for the natural right or labor dessert theorist about property? The simple reason is that defining harm any other way requires consideration of alternative property arrangements. And that is what such theorists seek desperately to avoid. Yet again, it almost goes without saying that an instrumental approach to property suffers from none

43 Moore himself does not seek to justify all intellectual property rights, but “some” IPRs. He acknowledges that rights might be overridden if the consequences are “dire” (Moore, 2003 215). What counts as a “dire” consequence is thus an open question, and in the next chapter I explain why the current intellectual property rights system does result in “dire” consequences, undercutting his argument.
of these limitations. Rather than defining a narrow baseline of harm to make its theory plausible, an instrumental approach is inextricably concerned with different types and magnitudes of harms (including resultant inequalities or distributional problems) that might occur as a result of various approaches to property. Instead of neglecting them, it embraces them.

Lastly, we arrive at epistemic claim (iii), clear advance knowledge on the part of the appropriator that no one will be worse as a result of an appropriation. Much like the “would have invented” and “but for the patent system” claims previously discussed, this final claim requires substantial knowledge on the part of the inventor. It requires her to know, before acquiring exclusive rights to an invention (or, for Locke, before removing it from the commons), that no one will be worsened as a result of her appropriation. In certain cases – like the Lockean example of an individual appropriating a drink of water from an endless river – the answer appears obvious. However, such examples are almost certainly the exception rather than the rule, particularly in modern intellectual property and innovation systems.

Perhaps importantly, for the narrowly defined baselines to work as described by their proponents (Nozick, Moore, and others), this epistemic issue appears very demanding. It requires certainty that no one will be left worse off – not just a very few, or a very few in relation to the benefits of appropriation – but no one.
Like all of the above claims, however, the significance of this demand on natural or labor theories of intellectual property is best seen in contrast with instrumental theories. Quite simply, instrumental theories do not require this perfect knowledge because they do not require such a narrowly defined, fixed baseline that considers different types or amounts of benefits irrelevant. On the contrary, as I suggested in section 3.4, instrumental theories set out explicitly to elaborate the different ends that intellectual property rights might serve. By doing this, instrumental theories ought to also provide some guidance for how to measure whether or not such ends actually are being served, and at what cost.44

*Practically Useless.* I conclude this criticism of natural rights or labor theories of property with one final charge – that they are practically useless. In short, present circumstances and the historical events that produced them make it impractical to take seriously implementing a natural rights or labor theory of property. For these theories to work, they require a very specific procession of historical events that simply have not occurred, because of this, they also cannot offer any guidance on how to redress the inequities of this history. Here again, Nozick (1974) provides useful fodder.

44 This is not to suggest that instrumental theories are without epistemic demands, or that no instrumental theory could, in principle, be as demanding as the natural rights or labor views under discussion. The general idea is to place some epistemic limits on the theory, as well as point out that the natural rights or labor views meet their undue epistemic demands in unsavory ways.
Consistent with Nozick’s general philosophy, his theory of property is not concerned with the “end state” *per se* but with the process used to get to some “end state.” It is therefore not surprising when he concludes that the Lockean proviso holds as a justification for property, and that

were it not for the effects of previous *illegitimate* state action, people would not think the possibility of the proviso being violated as of more interest than any other logical possibility. (Nozick, 1974 182)

By “previous *illegitimate* state action” Nozick must mean something about how states have misgoverned property rights one way or another. Any student of history recognizes this as a true statement of how nation-states have historically behaved. Nozick acknowledges that much, where illegitimate state action is understood as violating the “as much and as good” proviso. But if true, one wonders what it means for how we ought to structure intellectual property rights *now*, given this. Can we reasonably return to a Nozick-like labor or natural right entitlement theory, if the present distribution of property rights and privileges might be a result of previous illegitimate action? Nozick appears to lack an answer. Even if the proviso did work to justify appropriation, more argument is needed to suggest that this is how we ought to structure property rights now.
In fact, the opposite is probably true. Given these previous illegitimate actions, what appears needed is a different way of looking at property rights. This would be one that begins with present circumstances and asks what end or ends property rights ought to serve, now and in the future, perhaps to redress prior illegitimate action. Not surprisingly, this would be an instrumental theory. In sum, Nozick’s view is too idealistic to offer much insight into how property rights ought to be structured, given that the historical process until today has routinely violated his proviso.45

3.5.3 The End of Natural Rights or Labor Dessert Theories of IPRs

This section (3.5) has discussed natural rights or labor dessert views of property rights in some detail, offering numerous reasons to reject them. Thus, some review and synthesis is in order before proceeding – a review and synthesis that recalls this argument in intellectual property rights terms, rather than the more general language of property rights.

Natural rights views of IPRs – i.e., the idea that “I invented it or labored on it, so it’s mine” – might be popular, but they are fundamentally flawed. Such views verge on inconsistency in explaining any limits on IPRs (such as time delimited patent rights);

45 To some extent, this criticizes Nozick’s theory (and others like it) as being too ideal, whereas what is needed is a non-ideal theory. Whether instrumental theories are more or less ideal, however, is not critical to my argument and is left for a different occasion.
suffer from an explanatory gap between “natural” rights and the social market rights entailed by intellectual property; require satisfaction of huge epistemic demands regarding how the “as much and as good” or “no one is left worse off” baseline is defined; and offer no guidance for how to practically structure IPRs now given prior illegitimate appropriations.

Not incidentally, at times during the above discussion I have implied that John Locke (often regarded as the founder of the natural rights view) himself might have recognized some of these flaws. For example, his “wastage” limitation on property rights would imply that an individual could not justifiably patent a medical substance that could save lives and then prevent anyone from actually using it. Thus Locke himself might have known that pure natural rights views were untenable, and that instrumental limitations based on welfare were needed.

Unfortunately, the failure to recognize this flaw is dangerous. It prevents us from scrutinizing IPRs and what ends the serve by placing emphasis on the “laborer’s” so-called natural right to her intellectual property. It doing so, it prevents people from considering instrumental views toward intellectual property that, critically, do not suffer from the same flaws as natural rights views. At most, natural rights or labor theories of intellectual property suggests that inventors deserve something for their intellectual labors, but it does not say what. Property rights are but one option. And fortunately,
instrumental theory can accommodate this concern for a laborer’s dessert without any of the theoretical baggage of natural rights views.

3.6 The Dominant Assumption: Maximize Innovation

For many readers, the rejection of “natural rights” views of intellectual property might be superfluous. And while they might agree that continued ascription to a natural rights view is dangerous, they need little convincing to recognize IPRs as instrumental – as a means to some end. If such readers are familiar with U.S. history, they might also cite Article 1, Section 8, of the U.S. Constitution, where Congress has the power “To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”\(^{46}\) They might also, following Shiffrin (Shiffrin, 2001), note that Thomas Jefferson seemed to reject natural rights when Jefferson wrote,

Inventions, then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement.

Yet this is not the end of the story, for it suggests an instrumental approach toward IPRs but does not fully answer the question, “Instrumental to what?” At this point, I return

to the Intellectual Property Rights & Innovation Thesis (IPIT) introduced at the
beginning of this chapter:

Intellectual Property Rights (IPRs) are normatively justified by their ability to
maximize innovation.

The IPIT represents one instrumental approach toward IPRs, but as should be clear from
my prior discussion, it is by no means the only one. Therefore, this final section
proceeds as follows, continuing on the increased focus on IPRs and medicines begun in
section 3.5. First, I show the IPIT to be the dominant assumption about IPRs, to some
extent in public discourse but to a greater extent in lofty policy discussions (3.6.1).
Rather than discussing theory *per se*, then, this section suggests that one narrowly
construed version of IP theory occupies much current thought and action about IPRs.

Second, I draw out several important implications of the IPIT (3.6.2). Recall my
erlier discussion that all theories of intellectual property rights are, in a sense, social
planning approaches by instantiating some vision of a just society. In this section, I
explain what the current vision seems to be. More specifically, I show how ascribing to
the IPIT—far from being agnostic about questions of distributive justice—actually creates
three distinct distributional problems:
Develop First, Distribute Later. First, adherence to the IPIT falsely assumes in maximizing innovation that this maximization operates independently of how those innovations are distributed. I call this the “Develop First, Distribute Later” paradigm.

Types of Innovation. Second, adherence to the IPIT forgets how maximizing innovation is blind to the types of innovation created. In other words, maximizing innovation might indeed maximize the number of innovations, but it might not maximize innovation in the kinds of things that society needs created.

Ownership of IPRs Themselves. Finally, adherence to the IPIT has another distributional consequence in so far as the goal of maximizing innovation is also blind to the question of who owns IPRs. For example, if a single intellectual property owner best maximizes innovation, the IPIT would prefer such a system of property rights. Even at this early stage, one can imagine how this might stand in contrast to personality or human fulfillment views of IPRs.

After elaborating these three problems, I discuss briefly how conversations about innovation and conversations about distributive justice in health care have been historically (but incorrectly) separated (3.6.3). I also suggest how this trend appears to be changing.

Finally, this chapter ends with a question: Do we have reason to change this dominant assumption for the sake of seeking other ends through IPRs? The next chapter
begins answering that question by suggesting that, at least for the case of access to
essential medicines, we do have good reason to consider such changes.

### 3.6.1 Intellectual Property Rights and Maximizing Innovation: The Dominant Paradigm

What role does the IPIT play in contemporary discussions about intellectual
property and access to essential medicines? Just as labor theory finds its way into
popular discourse, so does the intellectual property and innovation thesis. In addition,
and more importantly, the IPIT is evident in the business strategies of major
pharmaceutical and biotechnology companies, academic discussions, and high-level
policymaking.

Before elaborating the influence of the IPIT in each of these domains, a few
preliminary points are in order. Typically, the IPIT states not merely that IPRs maximize
innovation, but that strong IPRs maximize innovation (where “strong” refers to, e.g.,
lengthier patent periods, broader patent claims, broader subject matters, and so on). The
diversity of IPRs, from patents to copyrights to trademarks, and the different protections
inherent to each, makes the idea of broad claims somewhat problematic. But they do not
make it useless, and in what follows, I refer not just to IPRs but also the trend toward
strengthening them in this sense.
Moreover, “maximizing” innovation is obviously an extreme position to which not all adhere. Many proponents of so-called strong IPRs might not see the goal as maximizing innovation as much as simply encouraging it, or strongly encouraging it. Yet this too is not necessarily problematic, given the view I develop, for three reasons. First, like in the above, what I discuss encompasses a spectrum. I am interested in trends, and in so far as the trend appears to indicate a truncation of the ends of IPRs – by seeing IPRs narrowly as a way to spur more innovation – my general conclusions should hold. Related to this is a second reason: The present system results in these distributional problems because of a myopic focus on innovation and a failure to see the diverse ends of intellectual property. Yet even if it does not result in distributional problems, if these trends do indeed exist, we might still have good reason for considering changes to the global intellectual property right regime (a topic that occupies Chapter 4). Finally, any proponent who admits that IPRs ought not be designed to maximize innovation must then address why they ought not or what other values ought to come into play. This again opens the door for a discussion of distributional reasons for changing the now globalized IPR regime.

The last preliminary point relates to recent discussions about the present intellectual property rights regime (or more specifically, modern patent systems) implying that they fail at their goal of maximizing or even encouraging innovation (Jaffe
and Lerner, 2004). As parts of my second chapter implied, these critics might be correct. However, I am not as much interested in whether the current system best maximizes innovation as in whether other ends besides innovation might be recognized for the system. These other discussions, while important, are not my central focus.

Where does one see the emphasis on the connection between IPRs and innovation? Although this connection does not capture the popular imagination to the same extent as natural rights theories of property (a la the Little Red Hen), it is still present. Typically expressed as “tomorrow’s cures require today’s strong patents,” the basic idea is that strong IPRs are necessary for us to produce the treatments we all need and want. For example, Robert Goldberg (Goldberg, 2002) criticizes attempts to enable faster introduction of generic drugs because, “Shorter effective patent life [i.e., weaker IPRs] means less revenue for innovation.” More explicitly, in coverage of some recent U.S. Supreme Court cases involving patent infringement in the pharmaceutical industry, Patti Waldmeir writing for the Financial Times (London) (Waldmeir, 2005) describes a case as “one of two this term that ask the justices to revisit central tenets of intellectual property law, to maximise innovation in the 21st century.” Thus, even if the view about IPRs and innovation is not as popularized as the labor views of property, it is present (and in so far as it appeals to individuals’ fears about “no new cures,” it can certainly be convincing).
Scholarly discussions, on the other hand, typically discuss whether IPRs as currently structured best foster innovation without questioning whether this is the sole standard by which IPRs should be evaluated. The argument typically begins as follows: Innovation is critical now more than ever in the “knowledge-based economy.” Patents and other IPRs spur innovation and creativity by providing an incentive for inventors to create new ideas (Rosenberg, 2004). The argument then divides according to whether the particular author believes patents, as currently structured, do (or do not) best stimulate innovation. For example, some might argue for strong patent rights to spur more innovation in drug development by extending patent life (Office of Technology Assessment, 1981); others might argue for weaker patent rights over human genes to spur more innovation (Heller and Eisenberg, 1998). In either case, the dominant assumption seems to be that patents are meant to spur innovation and little else.47

At a somewhat more practical level, pharmaceutical and biotechnology companies appear interested in maximizing innovation, and they see IPRs as a tool to accomplish this. Innovation is the lifeblood of the industry and is critically important for product pipelines. For many of these companies, maximizing innovation means maximizing IP protection. Consider a statement from the tradegroup BIO (Biotechnology Industry Organization):

47 For another example, see (Cohen and Merrill, 2003).
As such, strong and predictable patent protection enables the flow of risk capital that is vital to achieving biotechnology’s promise. BIO supports strengthening the U.S. patent system and opposes efforts to undermine or limit protection and enforcement. America needs to protect and fully enforce intellectual property rights, without which the biotechnology industry would be irrevocably harmed.  

The trade group PhRMA (Pharmaceutical Research and Manufacturers of America) similarly suggests, “Experience shows that strong patent protection directly encourages pharmaceutical innovation.” Thus, industry advocates seemingly endorse the claim about innovation and intellectual property.

Perhaps most importantly, however, the emphasis on IPRs and innovation often takes center stage in high-level policy discussions among influential policymakers. Increasingly, the enforcement of intellectual property rights is seen as a major issue driving innovation-dependent economies.

48 See http://www.bio.org/ip/domestic/. Accessed 7 January 2007. Although some might argue that these statements are more about self-interest than actually maximizing innovation, taking them at face value is all that is necessary for my general argument.
50 The fact that it might be partially based in self-interest is further revealed by the ways in which generic drug manufacturers often see policy choices quite differently. For an example where the GPhA (Generic Pharmaceutical Association) directly opposes strengthening patents, see http://www.gphaonline.org/AM/Template.cfm?Section=Press_Releases&CONTENTID=1955&TEMPLATE=/CM/ContentDisplay.cfm. Accessed 7 January 2007.
Speeches delivered by U.S. officials underscore this point. For example, Chris Israel (International IPR Enforcement Coordinator for the U.S. Department of Commerce), said the following in oral remarks during a 2006 visit to India:

President Bush has made it clear to us that the protection of intellectual property rights (IPR) is a very high priority for his Administration...Intellectual property is the fuel that powers the engine of prosperity, fostering invention and innovation. Protecting it is an issue at the very heart of the global economy.51

In 2002, Bruce Mehlman (Assistant Secretary for Technology Policy, U.S. Department of Commerce) also appealed to the economic importance of innovation while discussing President George W. Bush’s high-tech agenda:

We’re seeking to strengthen intellectual property protection - both by devoting far more resources to the U.S. Patent & Trademark Office (21% more in 2003), and by enforcing IPR aggressively at home and abroad.52

Combined with well-publicized attempts to encourage “TRIPS-plus” provisions (i.e., IPR protection above that required through the WTO’s TRIPS Agreement) in bilateral trade agreements (Correa, 2006a), as well as the placement of nations on the Special 301 Watch List (for trading partners that fail to adequately protect IPRs from the U.S.

perspective), it seems clear that the trend is toward strengthening IPRs. Ostensibly, such actions claim to create incentives for innovation, even if U.S. national interests play a major role.

What is perhaps interesting in this regard is the apparent exception of the WTO TRIPS agreement in the (over)emphasis on innovation. According to the WTO, the TRIPS Agreement attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations. (World Trade Organization, 2006)

The fact that the WTO presents a more honest view of a critical issue is reassuring. The question, however, is whether the present balance is actually struck. With some arguing persuasively that this balance was subverted at the outset by the influence of the pharmaceutical industry (Sell, 2003), whose position tends to lean toward “innovation,” one has to wonder.

In sum, this section has offered evidence to support the assertion that the Intellectual Property & Innovation Thesis (IPIT) about “maximizing innovation” is an important and influential thesis. This appears true even if the IPIT is not about fully maximizing innovation, so long as a strong emphasis is placed on the singular role of IPRs in stimulating innovation.
3.6.2 Implication of the IPIT: Three Distributional Problems

Having described the practical relevance of an emphasis on IPRs and innovation, as described by the IPIT, explicitly reviewing and connecting the IPIT with other dominant themes of this chapter is now crucial.

I have argued that the dominant view of IPRs is that they are to maximize innovation, or at least, that their purpose is to encourage innovation. In other words, the dominant view of intellectual property is an instrumental one which sees the end of IPRs as producing new innovation. Superficially, this would fit within William Fisher’s (2001) “utilitarian” classification of IPR theories, and in doing so, this overlooks (or at least truncates) the other ends IP might serve. These other ends include personality approaches (including the view that IP represents an important part of human flourishing via human creative enterprises), social relations approaches (including the view that property rights ought to be structured with an eye toward how they impact relationships between people).

Moreover, this appeal to innovation is no more or less “expansive” in envisioning a just society than what Fisher (2001) had called “social planning” theories. This is because the emphasis on innovation and intellectual property inherent to the IPIT requires a complicated set of national and international institutions from patent offices (including judicial systems) to the World Trade Organization. Therefore, appealing to
the “simplicity” of the IPIT is misleading, in so far as its single goal might be simple while the requisite institutions needed to instantiate it are not.

More than that, the IPIT does instantiate at least a partial vision of a just society. In particular, a system of intellectual property rights focused on innovation instantiates a certain vision of distributive justice by creating three distributional problems: how the physical objects covered by the IPRs are distributed (i.e., access to medicines); what kinds of objects are created in the first place (i.e., the type of innovation); and who owns the IPRs in question. A closer look at each of these distributional effects is necessary.

*Develop First, Distribute Later.* By far the most commonly discussed distributional effect involves the impact of IPRs on the distribution of (or “access to”) the medicines covered by such rights. In Chapter 2, I argued that this is not merely an empirical question but also involves normative elements. Now some of the *distributional* normative elements will become clearer.

Taking the IPIT seriously – i.e., assuming that IPRs are meant wholly or mainly to stimulate innovation – seems to require one of two general theoretical orientations to this distributional question: either (i) the distribution of the medicines is unimportant; or (ii) the distribution of the medicines is left to other institutions to work out. Each requires some elaboration. Common to both, I argue, is an approach the medical innovation that is best characterized as “Develop First, Distribute Later.”
If one understands the goal of IPRs as maximizing innovation a classically utilitarian sense, it comes as no surprise that (i), distribution of the innovations, is in itself unimportant. Classical utilitarianism, as a result of its comparative aggregation of costs and benefits, is distributionally insensitive. So long as innovation is being maximized, distributional concerns are simply irrelevant. But surely this is too harsh. After all, even those pharmaceutical companies that ardently defend their IPRs suggest that they too want to ensure broad access to their medicines.

This brings up a more sophisticated reading of the IPIT, i.e., an expansion of the thesis to suggest that an IPR system that maximizes innovation at the same time maximizes social welfare. Such a view recognizes the “deadweight loss” (an ironic term, given the subject matter of medicines) associated with property right induced monopoly pricing. That is, the inflated prices permitted by monopoly pricing mean that certain consumers will not purchase the medicine at the higher price when they would have at the non-inflated price (in economic terms, at the marginal cost of production). The fact that these consumers could have benefited from the product but do not makes this a real welfare loss.

How is social welfare maximized, given this certain welfare loss? It must be offset by other gains in social welfare. As Owen Lippert suggests
The important points is that while a patent may incur a static welfare loss as a result of exclusivity, that loss may be offset in two ways. The product itself may provide overall benefits that would not have been possible before. Also dynamic market gains from the increased incentive to innovate and to invest may in the long term exceed the limited term loss. (Lippert, 2002:8)

Again, however, it should remain clear even in this defense of social welfare maximization that the appeal to “overall benefits” and future “incentives to innovate” are distributionally insensitive. It does not matter who receive the benefits or bears the costs of such arrangements so long as they on the whole maximize social welfare.

One can state this in a different way. William Fisher (2001) notes that the Kaldor-Hicks criterion might be employed to justify this welfare tradeoff. According to Kaldor-Hicks,

one state of affairs is preferred to a second state of affairs if, by moving from the second to the first, the ‘gainer’ from the move can, by a lump-sum transfer, compensate the ‘loser’ for his loss of utility [or welfare] and still be better off. (Fisher, 2001:177)

Thus, according to the Kaldor-Hicks criterion, we might surmise that the aggregate benefits of IPRs could be justified in relation to the aggregate welfare cost. We might again note, however, that the evaluation criterion is blind to the identity question of “who” for the “gainer” and “loser,” respectively.
Neglecting difficult issues of how to define “social welfare” (e.g., by wealth, willingness to pay, etc.), several problems emerge with these general “maximization” or “overall welfare” views.

At the first instance, the question of “who” experiences the burdens and the benefits of the IPR system just is an important question. This point becomes clearer in relation to the next two distributional issues (types of innovation and owners of IPRs), which I discuss below. If a system works to systematically advantage one group of individuals while disadvantaging (or perhaps not bettering) another group, we might have reason to question such a system.

A second problem with the IPIT is that certain welfare losses might not be compensable. This could be true in principle: take, for example, widely accepted prohibitions at directly killing one individual to save five, where the welfare gains of the latter cannot override the welfare loss of the former. This is because the former’s welfare loss is not of a kind that can be compensated by the latters’ gains. Placed in more familiar terms to this discussion, it seems unreasonable to suggest that curing erectile dysfunction even the world over could compensate for not curing a neglected and debilitating disease, such as leishmaniasis. It remains to be seen whether we actually

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53 Nancy Kokaz makes a similar point regarding the “who” issue in her discussion of international institutions and fairness, specifically in relation to mutually beneficial bargaining. See (Kokaz, 2005).
have good reasons for considering some welfare losses as not compensable. I take up this task with an eye toward human rights in the next chapter.

Third, what is more worrisome about these maximization/social welfare views regarding IPRs is the way they fail to address such welfare losses or take them as a given. Consider the Kaldor-Hicks criterion whereby a state of affairs is justified so long as the gainer “can” compensate the loser. What does this mean? Does it mean the gainer ought to compensate the welfare loser in some way? Or that the gainer must compensate the loser? Experience teaches that this does not mean the gainer will compensate the loser, but these other questions are left open by IPIT-like reasoning about IPRs. Practically speaking, in the area of pharmaceutical innovation, this might mean required pharmaceutical donations, monetary contributions toward funds aiding developing countries, or some other measure(s), the extent of which would be up for debate.54

Surely, none of these issues are “unimportant,” as the IPIT might lead us to believe. At best, the IPIT is agnostic regarding the distributional effects of a system meant to maximize innovation. It does, however, beg us to ask whether to prefer other systems of encouraging innovation where benefits and costs might be distributed

54 In the next chapter, I offer reasons for preferring one or another of these means. At this point it suffices to merely mention them.
differently for the same level of innovation, or whether the “maximization” of innovation assumption might be relaxed.

This agnosticism toward distribution wanes, however, once we take into account (ii), the idea that the IPIT works to maximize innovation but leaves it to other institutions to ensure the distribution of those innovations. On this view, the job of IPRs is to encourage innovation. Once innovations are created, it is the job of other institutions to ensure the distribution of these innovations. This appears more compelling than the “distribution is unimportant” view. However, it overlooks the fact that, far from being agnostic toward distributional issues, IPRs can actually constrain the distributional states that could otherwise be achieved.

Consider several difficulties with the appeal toward other institutions, all of which undermine the IPIT’s narrow focus on “innovation.”

First, at present, such distributive institutions seemingly do not exist, as the horrifying statistics regarding access to essential medicines show (i.e., 2 billion people lack them). The question then arises as to what we ought to do until such institutions are created. Do we continue to maximize innovation through IPRs as currently framed and wait, taking the present IPR system as a given? Or do we modify IPRs, relax the maximization assumption and tweak the system to enable better distributive outcomes?
Second, because IPRs give exclusive rights that lead to monopoly pricing, these rights will necessarily limit the effectiveness of whatever institutions could be created. In brief, monopolistic pricing places a severe constraint on the possibility of achieving better distributive outcomes by transfer of funds to enable the poor to purchase goods, such as medicines, that are subject to IPRs. So the distributional impact of these other institutions is limited by the IPRs in question. For an analogy, consider the discussion of HIV/AIDS treatment in Chapter 2. When exclusive rights and high prices made HIV treatments unaffordable in the developing country setting, institutions seeking to ameliorate HIV/AIDS focused their efforts on prevention (e.g., condoms, needle exchange, etc.) rather than treatment. Once prices began to fall through generic competition and civil society movements, however, treatment became an option. Until that point, the exclusive rights limited the options of institutions engaged in HIV/AIDS work. Because cost was an issue, and high cost was facilitated by monopoly pricing (itself facilitated by exclusive IPRs), the need to critically examine IPRs themselves should be clear.

Third, the appeal to a need for other institutions creates a type of blame shifting. Rather than focus on the distributive impact of their IPRs, those who hold such rights can continue to point to “other institutions” to figure out the distribution question. This acts to reinforce the IPIT, and the rights in question, rather than to submit it to
normative scrutiny from the standpoint of distribution. Moreover, the need to create these other institutions for solving the distribution issue should itself be a cost of the IPR system. If the true costs and benefits of the IPR system remain in question, as many believe, then further empirical investigation should include this particular cost rather than externalizing to other institutions.55

In short, neither (i) the idea that distributional concerns are unimportant in relation to IPRs, nor (ii) the idea that institutions other than the IPR regime must take up distributional concerns, can withstand scrutiny.

All this points to a very important idea: The system of intellectual property rights, taken in conjunction with reasonable background conditions or assumptions, operates in ways that at least partially determine the distributive outcomes of the innovations covered by such rights. Many of these background conditions or assumptions are necessarily complex because they involve the complicated process of medical innovation (or R&D). Yet in spite of this, we cannot forget the crucial idea that the awarding of exclusive, proprietary rights can act to constrain distributive outcomes.

55 Here is an example of where normative theorizing – about the distributional effects of the IPR system – can impact empirical studies, as Chapter 2 suggested.
Thus, the focus on innovation and intellectual property rights at the exclusion of other concerns results in a “Develop First, Distribute Later” approach to medical innovation.56

Because the present chapter emphasizes IP theory, it is worth pointing out that other views of IPRs, besides those that focus solely on innovation, are better positioned to recognize this crucial idea. Take, for example, the Kaldor-Hicks criterion that “gainers” in welfare *can* compensate “losers” and still come out with a net increase in welfare. Views of intellectual property that emphasize the power aspect of IPRs (such as social relations theory) might suggest that this compensation is not likely to be realized because of the power perverting aspect of IPRs. To this extent, a social relations theorist could imply that Kaldor-Hicks ignores important power dynamics; this “can” does not imply “ought” or even “will.” Similarly, a more diverse view of the instrumental end of IPRs that does not seek to “maximize” innovation as the IPIT does could include distributive “ends” in its theorizing, allowing some sacrifice of new innovation to better ensure a more just distribution. In other words, the “Develop First, Distribute Later” paradigm is somewhat unique to the IPIT’s exclusive focus on innovation, truncating discussion of other possible “ends” of IPRs.

56 The general idea that certain background conditions in the process of medical R&I constrain distributive outcomes is not necessarily unique to IPRs. For example, some argue that treating clinical trials as a global public good through equal cost apportionment and open access – i.e., not relying on the private sector to bear the expense and thereby under-supply trial data – would lower medicine prices and improve distribution/access. See (Reichman, 2006).
Type of Innovation. The second distributive effect of taking the IPIT seriously is similar to the first. Not only does an exclusive focus on innovation create problems in distributing the physical objects covered by IPRs, it also creates problems in the types of innovation created. In other words, a system focused on maximizing innovation is distributionally insensitive toward the types of innovation created.

This is far from a theoretical problem. In fact, observing the present results of the IPR system reveals that its focus on innovation (as noted in section 3.6.1) has disastrous consequences in this regard. What appears to be true is this: The present system, which depends upon exclusive rights alone to reward a long process of medical R&D, skews the types of innovations created toward those for which a large market exists rather than toward the creation of drugs for the world’s worst-off people. Or, even worse, it skews the types of innovations created toward those for which other treatments already exist (i.e., it encourages incremental innovation of uncertain value, or of value out of proportion to the cost of innovation itself).

What we know is that the current medical R&D process systematically under-represents certain kinds of diseases and conditions. Consider the following statistics:
• Only 10% of health R&D spending goes toward problems affecting 90% of the world’s population, creating the “90/10 gap.”

• From 1975-1999, only 16 of 1393 new molecular entities were for tropical diseases or tuberculosis (Trouiller, et al., 2002).

• In a recent U.S. Government Accounting Office report, analysts noted that, in spite of a 147% increase in R&D spending by the pharmaceutical industry from 1993-2004, only a 7% increase in new molecular entities occurred. Twelve percent of new drug applications (NDAs) represented “priority” new molecular entities, while 60% of NDAs were “standard” non-NME applications (United States Government Accounting Office, 2006).

• Arguably, the low number of patented medicines on the WHO’s Essential Medicine List (1.4% in 2004; see (Attaran, 2004b)) does not vindicate patents, but instead implies that few new essential medicines arise via patent.

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57 This common statistic traces originally to (Commission on Health Research for Development, 1990). The actual gap identified was closer to 95/5.
58 The FDA characterizes new drug applications (NDAs) according to whether the application involves a “new molecular entity” (i.e., whether a novel molecule is presented) and to whether the application deserves “priority” review (i.e., for NDAs representing the highest potential therapeutic impact) versus “standard” review. Of course, the FDA can be incorrect in these latter determinations, but the numbers remain telling. Standard, non-NME drug applications often represent what are commonly referred to as “me too” drugs.
59 I thank Anthony So for this point.
In sum, the present system of medical R&D preferentially creates certain kinds of innovations, and this preference is morally arbitrary (if not indefensible). From the perspective of reducing global health inequities, it would appear that these are the “wrong” kinds of innovations.

Two objections might arise to this characterization. The first is that I unfairly attribute the bias in the medical R&D system to patents or exclusive IPRs when, in reality, other parts of the system are at least equally to blame. For example, the high cost of clinical trials, lengthy regulatory approval processes, and short patent life following drug approval all create a system where the only way to recover R&D costs is to invent medicines with large market potential (understood as targeting relatively wealthy citizens and their conditions). Medicines for neglected diseases, or for diseases in populations who cannot possibly pay above the marginal cost of production (if that), do not fit this bill. Why focus on patents when these other issues are also at work?

First, by most accounts, patents are the lynchpin of the current medical R&D system. At the very least, the perceived importance of patents implies that they deserve serious consideration.

Related to this, one ought not forget that patents, as IPRs, help constitute an innovation system that depends on exclusivity. Practically, this exclusivity means that individual institutions (e.g., corporations) receive exclusive rights to an innovation as a
reward – but they also thereby bear all or most of the cost of developing that innovation. For an analogy, consider again Reichman’s argument (above, footnote 58) about clinical trials data as a global public good: *Not* treating such data as a public good might imply that the private sector will underproduce the data, bear all the costs, and thereby need to recoup those costs through high prices (Reichman, 2006). In short, exclusivity can be a blunt instrument for encouraging the production of certain goods, and its costs must be considered.

Third, just as the other issues surrounding medical R&D are important and deserve scrutiny (by drawing individual attention to decreasing needlessly lengthy drug approval times, reducing the cost of clinical trials, and so on), so too does the issues of IPR-mediated exclusivity. One barrier to serious scrutiny of IPRs, however, might be that individual attention to them means rethinking the patent system itself (rather than merely tweaking drug approval times or the efficiency of clinical trials). Thus, the importance of examining IPR-mediated exclusivity becomes clearer by contrast. One must consider whether rewarding innovation in ways that do not employ only exclusive rights could change the costs and benefits of the system as a whole, perhaps by addressing the distributive issues I am in the process of outlining.

The second objection is that I have given no reason to suggest that this bias is actually a problem that requires fixing. A full response to this objection occurs in the
next chapter, where I argue that recognition of basic human interests does give us such reasons.

In short, not only does an approach to medical R&D that emphasize the use of exclusive rights to “maximize innovation” ignore broad distributional issues surrounding those innovations (i.e., develop first, distribute later), but in practical terms it appears to skew the innovation system toward certain kinds of innovations. Not surprisingly, other IP theories, such as “social planning” theories more broadly construed, need not suffer from this flaw. These other theories could suggest structuring property rights or other means to foster the right kind of innovation; most importantly, as I noted above, this is not necessarily a “more expansive” vision of a just society – in principle or in practice – than the present system’s end of maximizing innovation. Again, the IPIT’s focus on innovation severely truncates the role IPRs might play in society.

Ownership of IPRs Themselves. The last distributive problem, in basic terms, is that an IPR system seeking to maximize innovation is also distributionally insensitive to the key issue of who owns the IPRs in question. Whether there is one IP owner or one billion is irrelevant, so long as innovation is maximized (or encouraged).
Certain facts reveal the heavily biased distribution of IPRs around the world:

- In 2005, the United States granted 143,806 patents, whereas Thailand granted 553. More importantly, whereas 89% of Thailand’s patents were granted to non-residents, 48% of U.S. patents were so granted (and of these, most were to inventors in other developed countries – nearly half to Japan alone).
- In Brazil, 34% (840) of patents granted in 2005 (2,439) were to U.S. inventors; by contrast, only 0.05% (77) of U.S patents in 2005 were to Brazilian inventors.
- According to Oxfam, in 2001, “less than 1% of U.S. patents were granted to applicants from developing countries, nearly 60% of which were from seven of the more technologically advanced developing countries.”

These statistics, and many others like them, point toward developing countries as net importers of IPRs and developed countries as net exporters of IPRs. Is this a problem? According to the IPIT, not necessarily, so long as net innovation is maximized.

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Even setting aside the question of whether such skewed ownership maximizes innovation, however, several worries emerge. First, according to other IP theories, such as those emphasizing the fundamental importance of fostering human creativity, this inequality in ownership could be problematic. In so far as a system relies wholly, or predominantly, on exclusive IPRs to reward such creativity, vast inequalities might suggest that certain individuals fall below some minimal creativity threshold. While this statement is admittedly vague – having neither suggested nor determined where such a threshold is – controversies over “biopiracy” perhaps reflect this concern. For example, a 2006 report cites numerous examples of potential medicines, cosmetics, and agricultural products representing part of “traditional knowledge” in Africa that are owned exclusively by foreign companies with little provision for benefit sharing (McGown, 2006). Whether or not such traditional knowledge can (or should) be properly appropriated by others, the concern over denying individuals in these countries that same opportunity remains.

The complexity and costs of modern scientific research compounds this problem by creating barriers to entry for new firms who might otherwise have a chance to play the IP game. As Peter Drahos (1996) words it

the ownership of some kinds of abstract objects [i.e., ideas] requires both high-level scientific capability and large capital investment. In certain exotic areas of science it may be that the ownership of the relevant abstract objects is open to only a handful of well-resourced players. And where those abstract objects are gateways to universally
important resources it follows that proprietors of those objects acquire vast threat power. (Drahos, 1996 161)

Following on this are the imbalances in power created by imbalances in the distribution of property rights. Drahos also notes another consequence which the creation of a property of abstract objects has for threat power within a social system is that this kind of extensive power is likely to be unevenly distributed within the social system as to become increasingly so. This is not an analytical consequence, but an empirically probable consequence of the nature of modern economic production...Scientific production, Marx correctly foresaw, would become more important and more costly. Under the pressure of competition, capitalists would be forced to meet this investment cost. (Drahos, 1996 160)

Restated, imbalances in the distribution of IPRs create imbalances in power, and moreover, these imbalances in power, among other things, tend to result in the powerful seeking ever-stronger property rights (e.g., through longer or broader patents) to recoup investment costs. And these ever-stronger property rights create or sustain imbalances in power. Finally, imbalances in power make it more difficult to address the maldistributions of the innovations produced.

This discussion thus also places us squarely in the hands of social relations theory and its emphasis on property’s power-mediated influence on social relations. What it points toward is a confluence of social relations and personality approaches to IPRs that can be seen as an indictment of any IPR system that pursues its ends at the expense of creating major imbalances of power or denying individuals’ creative
opportunities. Both would seem to condemn the present IPR system on these grounds.

To be sure, this is not at all a concrete policy proposal but simply a constraint to be considered, whether through the current IPR system or through alternatives to it (the topic of Chapter 5).

One objection to drawing this conclusion from the above patent data runs as follows: It is not the IPR system which creates this imbalance in IPRs, but poverty, the lack of economic development, or the absence of patent offices themselves in developing countries that prevents ownership by individuals around the world.

Such statements are to some extent true, but are also oversimplified. The interconnectedness of economic development and IPRs suggests that economic development is necessary for patenting to be available, but it also works in the opposite direction: it could be that some ownership of IPRs is also necessary for economic development (see the issue of biopiracy, above). Even if it were true that the lack of economic development and poverty were the real problems, rather than lack of IPRs, the head start of currently developed countries implies that developing countries could always be playing catch-up. Moreover, such statements fail to acknowledge the power dynamics just discussed, as playing catch-up in a game where the powerful set the rules is difficult (to some, it amounts to “kicking away the ladder”; see (Chang, 2002)).
Therefore, while it might be true that broader economic issues are also important, acknowledging so does not deny the potential importance of IPRs.

These, then, are the three major distributive problems created by an IPR system that sees IPRs as a means only to the end of innovation (as the IPIT suggests): Develop First, Distribute Later; types of innovation; and ownership of IPRs themselves. These problems go unnoticed because the IPIT incorrectly characterizes other theoretical approaches to IPRs that focus on different “ends” – such as helping ensure a more just distribution of innovations, fostering the “right” type of innovation, or enabling broader ownership of IPRs – as “too expansive.” The present discussion, by appealing to other theoretical approaches to IPRs and noting that all such approaches are, in a sense, “social planning” theories, implies that these distributive problems can, or perhaps should, be addressed in the context of IPRs. We are therefore left with a question: Why ought we to reconsider the structure of IPRs to mitigate these distributive problems? This is the subject of Chapter 4.

3.6.3 The Intersection of Medical Innovation and Distributive Justice

Before concluding this chapter, it might be helpful to explicitly connect the present discussion of the IPRs with the normative topic at hand, distributive justice. I have focused on the distributive problems created by a general theoretical orientation to IPRs. This focus, however, represents but a symptom of a larger problem: namely, the
wrongful separation of thinking about medical innovation or R&D and thinking about the distribution of health care resources generally. Thus, one reading of the present project is bring together two theoretical domains – medical innovation and distributive justice in health care – recognizing that the two are intimately related. This is because the types of medical innovations created by medical R&D determine, in large part, who will benefit from these new innovations (and what those benefits are).

A different way of stating this is as follows. The present discussion emphasizes the distributive impact of intellectual property rights, focusing on the mistaken view that IPRs ought only to encourage innovation, thereby neglecting how the present system of IPRs constrain distributional outcomes in three distinct ways. A mirror discussion exists, however, in that present treatments of distributive justice in health care often take for granted what health care exactly is to be distributed. Ignoring the fact that a “just” health care system can only distribute what the system of medical innovation makes available severely inhibits current thinking about distributive justice.

Fortunately, this paradigm is changing, and examples already exist that suggest this theoretical connection (even though they do not seem to be recognized as such). One of these is the U.S. Orphan Drug Act and its European counterpart. The 1983 U.S. Orphan Drug Act requires the U.S. FDA to assist companies in developing drugs for diseases afflicting fewer than 200,000 individuals (or drugs that have no reasonable
expectation of recouping expenditures via U.S. sales).\textsuperscript{62} This assistance includes tax breaks, small grants for clinical trials, and most importantly, what amounts to a minor modification of the existing IPR regime: if a company develops an “orphan drug,” then the FDA will approve no competing drugs for the same disease for seven years after marketing approval. The tacit assumption behind this Act is that, on certain occasions, the most effective way to redress an inequity in the distribution of health care is to modify the process by which health care benefits are produced. Closer to the task at hand, some prominent health care economists have explicitly proposed something like the Orphan Drug Act to provide essential medicines for neglected diseases (Grabowski, 2002).

A second example is more radical. It recognizes the connection between medical innovation and distributive justice but then, paradoxically, suggests dealing with this connection by separation of the market for innovation from the market for production. On one approach, the market for innovation would be fueled by a “prize fund” that could reward innovative efforts through monetary “prizes” through any number of socially determined criteria (such as whether the innovation treats a neglected disease or is a serious global health problem). The market for production would be left to generic

\footnote{\textsuperscript{62} For more information, see \url{http://www.fda.gov/orphan/oda.htm}. Accessed 10 January 2007.}
manufacturers who can sell drugs just above the marginal cost of production (rather than a monopolistic price) without the need to recoup R&D investments (Love, 2006).

At this juncture, I do not offer reasons for preferring either of these options, nor do I suggest these are the only two under consideration. They merely illustrate, in practical terms, the need to recognize the connection between theories of medical innovation and distributive justice.

3.7 Conclusion: Lessons from IP Theory for IP Policy

This chapter has built on the previous one. In Chapter 2, I argued that the debate over intellectual property rights is normative, as much as it is empirical. Chapter 3 has extended this line of reasoning, examining theories of IPRs and their normative bases (e.g., “natural rights,” “labor dessert,” “personality,” “utilitarian,” and so on) to conclude that the most viable IPR theories are instrumental: they see IPRs as a means to some end. Moreover, all IPR theories are, in a sense, social planning theories because they all instantiate some “vision” of a just society. That is, all IPR theories imply certain facts about what a society would look like if it adopted a particular theoretical orientation to IPRs.

I then argued that the presently dominant theoretical orientation to IPRs is one of “maximizing innovation,” or at least one of using IPRs predominantly to encourage
innovation. This assumption – articulated by the Intellectual Property & Innovation Thesis (IPIT) – proved problematic because it creates or supports three distributional problems, all of which appear empirically supported. The assumption of the IPIT does this at the expense of other theoretical approaches to IPRs, such as “personality” theories, which suggest that maximizing innovation need not be the only “end” of intellectual property. One of these ends, I have argued, might be the end of distributive justice, e.g., by mitigating the problems created by the IPIT. Given the globalization of IPRs, we might expect this end to be that of global distributive justice. Can we expect IPRs to serve such an end? Do we have good reason for considering changes to IPR rules in order to better facilitate global distributive justice? In the next chapter, I suggest that we do, based in part on well-justified theories of basic human rights. I also suggest that these same theories of basic human rights actually imply what kinds of changes to IPR rules ought to be considered.

Importantly, the present chapter has not proffered a systematic theory of IPRs, a task that is beyond the scope of this thesis. Rather, it has suggested that the pendulum has swung too far toward a narrow view of IPRs in society and has offered reasons for reconsidering this narrow view of IPRs. It sought to correct an imbalance, not offer a fully specified theory. Just as a purely “utilitarian” moral view encounters serious problems regarding the distribution of costs and benefits, or as a purely “deontological”
moral view encounters problems regarding the consequences of actions in the real world, a purely “maximizing innovation” view of IPRs cannot withstand scrutiny. Why we ought to retreat from such a strategy becomes the subject of Chapter 4.
CHAPTER 4. Global Distributive Justice, Human Rights, and IPRs

4.1 The Global Distributive Justice Disagreement Thesis Introduced

The prior chapter leads naturally into the present one: Theories of intellectual property rights (IPRs) have come to be seen as exclusively, or at least predominantly, as a means of maximizing innovation. This truncation of IPRs is unjustified; it occurs in spite of a diversity of normative, theoretical justifications for IPRs that imply how they might serve other “ends” besides innovation. Among these could be the end of distributive justice. Recognition of this comes from the increasing realization of how the means used to produce medical innovations determine, in large part, who receives the benefits of these innovations and what these benefits are.

The import of this statement is clear in two of the three distributive problems discussed in the prior chapter – “develop first, distribute later;” and “types of innovations” – with the additional distributive problem involving the ownership of IPRs themselves. The upshot of Chapter 3, then, is that modifications to current IPR rules might be required, for the sake of distributive justice, to solve or mitigate these distributive problems. And because my discussion has hinted at the global dimensions of this debate, these problems represent issues of global distributive justice.
All this sounds well and good until a skeptic presents the following, meant to stop the argument in its tracks:

Attempts to modify current IPR arrangements for the sake of global distributive justice are thwarted by irresolvable disagreements surrounding global distributive justice itself.

I call this the “Global Distributive Justice Disagreement Thesis” (or “Global Disagreement Thesis,” GDT, for short). The skeptic appeals to the difficulties of distributive justice, particularly at the global level, to argue that changes to the current IPR system could not be justified on the basis of “global distributive justice.” He might agree that the distributive problems of Chapter 3 are indeed problems, but scoffs at the idea that global distributive justice has anything to offer by way of a solution.

This chapter aims to refute the GDT. In doing so, it adds the final link to my general argument: Not only is the disagreement over IPRs and access to medicines a normative issue (Chapter 2), and not only do the normative, theoretical justifications for IPRs imply the potential to include concern for distributive justice, but also good reason exists from the standpoint of global distributive justice to consider changes to global IPR rules for its sake. More than this – and what I believe is a unique contribution of this chapter – it suggests not just that change is required, but that a certain type of change is required. This places normative constraints on the types of policy options available for effecting global distributive justice, a topic that I pursue more fully in Chapter 5.
The “standpoint of global distributive justice” to which I refer draws upon recent scholarship on human rights. Specifically, I argue in this chapter that a sound understanding of human rights in general, and of a delimited human right to essential medicines more specifically, gives us good reason to modify the current global IPR system. Human rights – framed as minimally sufficient conditions for a decent human life, or as the protection of basic human interests – thus intersect with global distributive justice by setting minimal thresholds for a decent human life and suggesting, in broad terms, how to ensure this minimum is met.

To this end, the present chapter proceeds as follows. First, in the rest of this section, I give examples of the Global Disagreement Thesis (4.1.1) and also give several reasons why one should worry about the GDT (4.1.2).

Then, in section 4.2, I begin questioning the GDT from the standpoint of what I call the “unified front of justice.” In short, I review how nearly every reasonable theory of justice condemns present global inequalities in health, even considering them “inequities” for one reason or another (4.2.1). Moreover, in further questioning the GDT, I suggest how nearly every reasonable theory of global justice either explicitly endorses basic human rights or is at least amenable to them (4.2.2). This leads to an enthusiastic rejection of the Global Disagreement Thesis. This enthusiasm is tempered, however, by
the recognition that in spite of this agreement, inequities remain (or are worsening). I explore this “curious failure” of justice in 4.2.3.

In section 4.3, I delve more deeply into human rights. I endorse the key concept of human rights as representing minimum thresholds for a minimally decent human life (4.3.1); more importantly, I argue that access to essential medicines is one part of this conception of human rights (4.3.2). Particular attention is paid to delimiting the right to access to essential medicines, including what counts as an “essential” medicine in the first place (4.3.3).

With the right to access to essential medicines in hand, the question becomes whether this right is currently being violated (or underfulfilled) and, if so, how to remedy this violation (or underfulfillment). This occupies section 4.4, and the discussion expands the concept of human rights in three main ways. First, in section 4.4.1, I argue that the traditional idea of “harm” (as used in describing human rights violations) is best understood as “systematic disadvantage.” My focus then turns to how human rights are themselves well positioned to remedy the “curious failure of justice” from section 4.2.3 by assigning and creating concrete duties regarding global distributive justice. Doing so requires exploration of the traditional duty-bearers of human rights (i.e., nation states) with an eye toward breaking with this tradition (4.4.2). It also requires exploration of
the types of remediation implied by human rights, in so far as human rights suggest how people ought to be treated (4.4.3).

This last claim – the idea of how people ought to be treated – turns out to be a critically important reminder to human rights scholarship. This scholarship all too often fails to appreciate how the conditions for a minimally decent human life are attained and whether simply meeting the threshold alone satisfies human rights. For example, supposing a human right to subsistence exists, does this right imply anything about how this subsistence right is fulfilled? In addition, does it imply anything about whether, in realizing this subsistence right, individuals ought to be enabled to move beyond this minimal threshold? Thus, section 4.4 contributes to the growing discourse of human rights by further specifying its implications for how, consistent with human rights themselves, human rights are realized.¹

Finally, in section 4.5, I conclude by reconnecting my discussion of human rights to access to essential medicines and IPRs. This is in preparation for chapter 5, where I apply these normative constraints to examples of proposed changes to the process of medical innovation – many of which modify existing IPR rules in different ways. There

¹ For example, would a human right to essential medicines imply that (i) donation programs from the major pharmaceutical companies and (ii) structural changes to enable greater access by modifying the way such medicines are produced are morally equivalent alternatives? On the view I develop, they are not.
I narrow this set of proposed changes to morally acceptable alternatives based on my prior discussions.

4.1.1 Examples of the Global Disagreement Thesis

Can it really be the case that disagreement about global distributive justice is so irresolvable as to thwart attempts at reforming IPRs? At least superficially, one would believe the answer is “yes.” This occurs at several different levels.

The first is at the level of perception. High visibility events, such as the protests during Seattle’s World Trade Organization meeting in 1999, not only suggest a radical, “anti-globalization” movement, but also widespread disagreement about global justice more generally. The different policy options pursued by WTO countries might engender a belief among those following the event that agreement on global justice – in this case, on the terms governing globalization – is elusive.² Similarly, many might believe that in spite of increasing global connectedness (e.g., through the Internet and otherwise), no real global “community” exists. And this sense of community could be necessary for global justice. Either of these perceptions might contribute to common, popular belief in widespread global disagreement.

² For different perspectives on the events in Seattle, see (Schott, 2000).
Other seemingly examples of disagreement are more worrisome because they arise at more fundamental levels, affecting the theory and practice of global distributive justice (Buchanan, 2004).

Regarding theory, Chandran Kukathas (2006) – drawing on work by David Miller (Miller, 1999a) – expresses disagreement at this level, suggesting that, “The primary reason for limiting the role of justice in international affairs is that understandings of justice are diverse and contentious” (Kukathas, 2006). What are these diverse and contentious views? Considering several prominent examples of what appear to be competing views of global justice (of which global distributive justice is just one part).3 For simplicity, I divide these examples into the general categories of communitarianism, cosmopolitanism, a somewhat “mixed” category, and libertarianism. The profound differences between these theories seem to suggest widespread global disagreement about global distributive justice.4

Consider first communitarianism, represented by Michael Walzer (Walzer, 1983) and Michael Sandel (Sandel, 1982). Walzer states that, “A given society is just if its

3 One view I do not consider in any detail is the “realism” or “neorealism” of E.H. Carr and Kenneth Waltz, respectively. Both see global politics as a Hobbesian anarchy, where national interest and power – rather than any explicitly normative concerns – drive global politics. Global distributive justice, on this view, is a non-starter. I take my first chapter, with its focus on the power of normative change, to justify only this brief mention of it. See (Carr, 1940) and (Waltz, 1979).

4 Any survey of this length is bound to leave out certain notable figures and obscure differences between those mentioned. For my purposes, however, any increase in the diversity of viewpoints only adds to the point I am trying to make. To examine a different categorization of recent thinking in global distributive justice, see (Beitz, 1999).
substantive life is lived in a certain way — that is, in a way faithful to the shared understandings of the members” (Walzer, 1983 313). On this view, the unit of central moral concern is a particular community, not its individual members. Clearly, such a view implies that conceptions of distributive justice will rely on the “shared understandings” of members of particular communities, and more specifically, on the value placed on social goods within these communities. The global diversity of communities would seem to imply the impossibility of truly global distributive justice.

A very different perspective is cosmopolitanism, with its emphasis on the individual as the unit of central moral concern (Jones, 1999). Under this general heading fall a great many diverse thinkers, including the utilitarianism of Peter Singer (Singer, 1972, Singer, 2002), Derek Parfit’s (Parfit, 1997) emphasis on giving priority to the worst off, and many others (Beitz, 1979, Buchanan, 2004, Moellendorf, 2002, Nussbaum, 1997, O’Neill, 2000, O’Neil, 2004, Pogge, 2002, Sen, 1999). Contra communitarianism, what these thinkers have in common is an emphasis on moral values (however limited) that transcend communities or moral obligations that hold independent of actual communal relationships.5 Surely the communitarian / cosmopolitan divide represents fundamental disagreement about global distributive justice, if anything does.

5 For a recent and insightful look at cosmopolitanism, see (Appiah, 2006).
In between these two lies a mixed category. I say “mixed” because this category recognizes the moral importance of individuals but at the same time holds that individuals outside particular communities – be they nations, states, or peoples – have only minimal moral obligations to “foreigners.” Examples in this vein, in spite of their obvious differences, are John Rawls (Rawls, 1999) and David Miller (Miller, 1995). Rawls, for example, suggests in *The Law of Peoples* that “reasonable disagreement” among different peoples about justice requires tolerance, rather than principles of global distributive justice. He also requires only minimal duties of assistance to other countries. Miller, for nationalist reasons that place him closer to a “communitarian” view, similarly suggests that individuals have much less stringent duties to foreigners abroad than to fellow citizens (Miller, 1995). In short, this mixed view recognizes the fundamental importance of individual persons but suggests that any obligations arising from this importance fall mainly on compatriots (i.e., fellow citizens, community members, etc.).

If this diversity of views were not enough, libertarianism adds one final theoretical approach. The libertarian view questions duties of global distributive justice, not because it is global *per se* (as the aforementioned views struggle with

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6 I say “certain forms of libertarian” because left libertarianism allow for duties requiring (individuals of) one country to compensate (individuals of) another country for unchosen differences in natural resource distribution or personal characteristics. See (Tideman and Vallentyne, 2001) and (Otsuka, 2003).
translating domestic or national or communitarian distributive norms to the globe).

Instead, it questions most duties to other individuals, particularly when state coercion is involved, placing primacy on property rights with only a minimal state (Nozick, 1974). Libertarianism, it would seem, thus presents a unique view of global distributive justice, though one that is generally dismissive of it.

Simply put, communitarianism, cosmopolitanism, libertarianism, and everything in between present radically different theoretical approaches to global distributive justice. This would support the widespread, deep-seated disagreement about global distributive justice that the GDT suggests.

Lastly, rising above disagreement at the level of theory is disagreement in terms of practice (Buchanan, 2004 194). Part of this disagreement lies in the incapacity of current global institutions to effect global distributive justice (or, more specifically, redistributive justice) in any meaningful sense. It also lies in broader questions about whether this incapacity itself ought to be remedied (Miller, 2006). Lastly, this disagreement arises out of a belief that the number of possible reforms or policies that might be considered to effect global distributive justice is limitless, or indeterminate, or both. This is evident in the laundry list of reforms proposed regarding global distributive justice, including the Tobin Tax on currency trade (Tobin, 1978), Thomas Pogge’s (Pogge, 1994) global resource dividend, or more recently, Gopal Sreenivasan’s
(Sreenivasan, 2002) proposal for wealthy nations to transfer one percent of their GDP to less wealthy nations for the sake of global health. Many other reform proposals exist.

The above disagreements represent the content of the Global Disagreement Thesis: We cannot agree upon the correct theory of global distributive justice, and even if we could, we cannot agree upon the practical reforms necessary to effect. For my overall project to work, I must have convincing answers to both of these disagreements. The rest of this chapter seeks to present such answers, but a hint of what to come might be helpful.

First, regarding theory: While I do not wish to minimize the extent of disagreement presented in the unduly brief summary above, I will contend that this disagreement obscures what is actually remarkable agreement among reasonable theories of global distributive justice. This remarkable agreement revolves around the concept of basic human rights in general, and if one accepts these rights, the right to health more specifically (and access to essential medicines as one concrete part of this right).\(^7\)

Second, regarding practice: While at present, global institutions might be incapable of effecting global distributive justice directly, their indirect effects can be

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\(^7\) Throughout this chapter I use the term “right to health” to acknowledge that many determinants of health are not “health care” related (e.g., the environment, access to clean water, and so on). However, implicit the phrase right to health is likely to be some basic minimum of health care services, of which one part (I will argue) is access to an appropriately defined list of essential medicines.
powerful. The “incapacity” claim, after all, cannot be fully true if current institutions are incapable of effecting distributive justice when, at the same time, these institutions appear to have profound global distributive effects. For example, the prior chapter argued that IPRs have a profound effect on distributive outcomes. This suggests that changes to the IPR system could help effect distributive justice. We could do this, as Allen Buchanan suggests

...by creating a global intellectual property rights regime that will preserve incentives for innovation while at the same time contributing to a more equitable distribution of the benefits of biotechnology, especially so far as these benefits have a positive impact on the health of those in the poorest countries. (Buchanan, 2004 193)

Yet later I will argue for more than this; namely, that normative reasons exist for changing or amending this particular system (rather than creating other institutions to effect distributive justice, e.g., through donation programs or other redistributive means). While Buchanan is correct in general terms, he assumes at the outset the IPRs will be the means of effecting this change. In fact, there might be other, non-property right ways of achieving this same end, and some of these ways might be morally preferable. Thus, while a certain indeterminacy at the level of practice might be inevitable, I argue that normative, theoretical constraints remove some of this indeterminacy.

It is perhaps worth noting that philosophers typically gravitate toward the theoretical issue and leave the practical issues to political scientists, policymakers, and
others. Part of my project, therefore, attempts to engage with what James Nickel calls the “end game” of human rights theory, i.e., “defending the measures that will be necessary to protect and promote human rights internationally” (Nickel, 2007 3). I hope to show that philosophy has much to contribute to this end game, just as it does earlier stages of human rights theorizing.

4.1.2 Why Worry About the GDT?

One might ask a prior question about the current chapter: Why worry about global disagreement in the first place? Disagreement is real, as I have just noted; however, overstating the amount of disagreement can have potentially deleterious consequences.

First, disagreement over full-blown theories and principles of global distributive justice leads many to reject outright principles of global distributive justice. As Buchanan notes, prominent theorists like John Rawls, David Miller, and Michael Walzer all retreat from including global distributive principles in their writings (see (Buchanan, 2004 193)). As alluded to earlier, for Rawls this results in part from his deference to “tolerance” of what might be divergent conceptions of justice.

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Nickel’s own approach focuses on the “middle game,” which he describes as showing how specific norms follow from abstract considerations. His account plays a prominent role in my thinking about human rights. See (Nickel, 2007).
Second, this retreat from global distributive justice can lead to inaction, or even worse, the acceptance of realism or neorealism (the view that power and national self-interest predominantly determine the working of global politics; see (Waltz, 1979) and (Goldsmith and Posner, 2005)). Disagreement fosters inaction by encouraging a “wait and see” approach to whether current global inequalities represent real issues of global distributive “justice” and if so, who must do what to remediate them. This type of disagreement is evident in other areas of global importance, such as global warming. In that case, disagreement over the science of global climate change caused inaction regarding carbon emission caps (and therefore a decade of lost time in reducing those emissions). What’s worse, perceived disagreement might cause those interested in global distributive justice to throw up their hands and accept that realism is the only game in town. That is, they might concede that power and national self-interest alone determine global distributive justice issues, not any sort of systematic normative theorizing.

Third, even when action does occur, in the face of perceived widespread disagreement, it can occur without full consideration of the normative issues at stake. This appears evident in recent attempts to alter the intellectual property rights regime for the sake of improving its ability to foster innovation (Jaffe and Lerner, 2004). Such a limited view of reforming IPRs “from within” fails to consider the broader issues of
distributive justice that I considered in Chapter 3 (such as who owns the property rights and what counts as a socially desirable innovation).

Finally, not only does action occur without full consideration of the normative issues, but it also can occur from a normative background that is not well-articulated or well-justified. In other words, in the face of widespread disagreement, some seem to think it better to keep their normative commitments to themselves (or state them authoritatively, in spite of well-known disagreement). For example, groups like Médecins Sans Frontières and Human Rights Watch often call for changes to the global IPR regime for the sake of human rights and the human right to access to essential medicines. In doing so, they routinely appeal to human rights documents like the Universal Declaration of Human Rights, invoking the right to health and the right to share in the benefits of scientific advancement. Yet in doing so they neglect difficult normative questions regarding the scope to the human right to health, how to define an “essential” medicine, how much sharing in scientific advance is enough, or whether the Universal Declaration alone justifies this. Such normative questions are at the heart of the present work.

9 For one example of this, see the Human Rights Watch press release at http://www.hrw.org/press/2002/10/ftaa1029-bck.htm#VI.TRIPS-plus%20and%20Human%20Rights. Accessed 13 February 2007. For another example, see (Mukherjee, 2004). While I am sympathetic to these groups’ work, the normative underpinnings require more thought (and this project provides one part of doing so).
In sum, then, several distinct reasons suggest how important it is to address the Global Distributive Justice Disagreement Thesis.

4.2 The Unified Front of Justice (And Its Failure)

The purpose of this section is to argue, against the Global Disagreement Thesis, that lack of agreement about global distributive justice is *not* the barrier to reforming IPRs. To accomplish this, I make the following two claims.

First, in spite of the apparent disagreement among conceptions of justice noted earlier (section 4.1), all of them offer plausible reasons for condemning the status quo (i.e., current global health inequalities). This is the task of section 4.2.1, which emphasizes recent work by Gopal Sreenivasan, Thomas Pogge, as well as Ruth Faden and Madison Powers.

Second, and again in spite of this apparent disagreement, all of these theories seem equally willing and able to accept the concept of basic human rights. To make good on this claim, however, requires further argument. This is because certain theories appear to either truncate the list of basic human rights (by excluding the right on which I focus, the right to health) or to reject so-called “positive” rights (see section 4.2.2, below).

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10 This increasing acceptance could be seen as a sort of “moral progress.” Allen Buchanan argues exactly this point in an as yet unpublished paper, “Moral Progress and Human Rights.”
What emerges from these two claims is a picture where all but the most extreme views of global distributive justice take human rights seriously.

This leads me to discuss a curious failure of global distributive justice: in spite of this widespread agreement, global inequalities in health remain, or are worsening (see Chapter 1). I call this the “curious failure” of global distributive justice (section 4.2.3). What it implies is disagreement at another level of theorizing; namely, exactly what sorts of changes ought to be made to global institutions in the name of human rights. Allen Buchanan puts a similar point this way, stating

…there is an overlapping consensus (to use Rawls’s phrase) that among the human rights are positive or economic rights that are more generous than the right to subsistence; but there is much disagreement with little prospect for rational resolution for the foreseeable future, as to the content of these entitlements…It is quite possible a kind of least common denominator, a focus of overlapping consensus among rival conceptions of distributive justice, might eventually enjoy widespread support, and that implementing it would require major reforms in the global order. (Buchanan, 2004 224, emphasis added)

In other words, Buchanan acknowledges areas where widespread agreement can emerge even if disagreement occurs at higher-order levels of distributive justice. This is the kind of agreement I am pursuing: a right to health more generally, and a right to access to essential medicines more specifically, as a “least common denominator.”

Having rejected the GDT in section 4.2, I then move to the next section (4.3), where I describe the implications of this widespread agreement in more detail. There I emphasize that a full understanding of a human right to access to essential medicines
has implications for how this right ought to be fulfilled. Or, understood a different way, I make the case that the overlapping consensus about basic human rights\footnote{The use of Rawls’s “overlapping consensus” is also evident in (Nussbaum, 1999).} – and more importantly, recent well-articulated conceptions of human rights – make them well positioned to help remedy the “curious failure” I describe below.

4.2.1 Condemning the Status Quo

*We do not live in a just world. This may be the least controversial claim one could make in political theory.* (Nagel, 2005 113)

In this section, I elaborate the first claim against the GDT, i.e., in spite of the apparent disagreement among conceptions of justice, all offer plausible reasons for condemning the status quo (i.e., current global health inequalities). To elaborate this agreement is not necessarily new; on the contrary, as I note below, others have attempted this sort of consensus in different ways. As such, I examine three recent strategies at building consensus about the status quo.

Gopal Sreenivasan (Sreenivasan, 2002) articulates the first of these strategies, which might be referred to as “sidestepping” global disagreement. His argument proceeds as follows: At present, widespread disagreement about full-blown principles of global distributive justice exists. Often this manifests as controversy over “ideal”
theories of distributive justice, as opposed to “non-ideal” theory. According to this distinction, ideal theory represents just that – an “ideal” or “wholly just” arrangement. “Non-ideal” theory, by contrast, presupposes some ideal and asks practical questions about how to get closer to the ideal (Rawls, 1999). Whether one accepts this distinction (many do not), John Rawls and others regard elucidating ideal theory as critical to even starting to ask practical questions about non-ideal theory. Therefore, one way of reading the GDT suggests that, until agreement is reached on the correct ideal theory, no progress can be made in terms of non-ideal theory.

Sreenivasan (2002) argues against this view, claiming instead that real progress on global justice can be made without presupposing an “ideal.” In a sense, then, he accepts the Global Distributive Justice Disagreement Thesis (i.e., he presupposes radical disagreement) but thinks progress can occur in spite of it. For Sreenivasan, we can sidestep or at least “anticipate” certain requirements of ideal theory and make practical recommendations about the actions justice requires. Sreenivasan calls these the “minimum demands” of distributive justice (Sreenivasan, 2002 83). Thus, Sreenivasan assumes that widespread disagreement about global distributive justice exists and yet believes progress can be made (in his case, by well-off countries donating one percent of their GDP to worse-off countries).
While I am sympathetic to Sreenivasan’s proposal, I believe it is misguided on two counts. First, contra what I will suggest below, it overstates the level of disagreement about global distributive justice. In doing so, the practical recommendation it makes is unduly limited, emphasizing the redistribution of wealth from wealthy nations to poor ones without clear structural changes that could be necessary for long-term change. To be sure, I do not oppose Sreenivasan’s idea, nor do I assume such a proposal could play no role in alleviating global inequalities. Rather, I simply point to it as an example of how assuming too much global disagreement can limit the policy options available for remediation of injustice.

Second, far from sidestepping the disagreement about global distributive justice, Sreenivasan actually suggests an answer to it. After all, his proposal’s “minimal demand” gestures at a level of agreement about what the wealthy nations owe the poor, the normative foundation of which is what wealthy nations can give at minimal cost but with the prospect of great benefit.12 While this normative foundation is sure to be widely agreed upon, it gives up too much. In other words, Sreenivasan sets the threshold of agreement – the minimal demands of justice – too low. Later, I suggest that this threshold of agreement is best framed as a commitment to basic human rights,

12 Not only this, but the minimal demands might give way to real issues of distributive justice when it comes to implementing the 1% proposal: Which countries will receive the 1% - the worst-off? How will efficiency of resource use be balanced against equity? etc.
above which deep-seated disagreement might remain about the requirements of justice. Until I can offer more details, however, I simply note the drawbacks of attempts, like Sreenivasan’s, that either assume too much disagreement or adhere to overly minimalistic normative foundations.

Thomas Pogge (2002) articulates the second of these strategies in his book, *World Poverty and Human Rights*. This strategy, unlike Sreenivasan’s emphasis on non-ideal theory’s minimal demands of justice, argues that a single unifying principle exists that could ground many duties related to global distributive justice. This single normative principle is the negative duty not to harm.13

However, like Sreenivasan’s proposal, Pogge’s gives up too much by focusing on the negative duty not to harm. It would seem that negative duties are either limited in the end game – i.e., by eliminating any minimal (and widely accepted) positive duties of assistance – or generate duties of such an extent that they are more clearly characterized as positive duties.

Regarding the former, for example, Rowan Cruft (Cruft, 2005) points out how remedial duties of reparation for past injustice and duties of assistance to individuals with disabilities represent widely accepted positive duties left out by Pogge’s account. To be sure, Pogge himself need not exclude such duties altogether, but his account of a

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13 The real innovation from exploration of the “duty not to harm” principle is that it brings into the fold libertarians would otherwise be critical of redistribution. On my view, this grants too much to libertarians.
negative duty not to harm as a way to build moral consensus neglects what is uniquely characteristic of them, i.e., that they are positive duties.

The latter idea of mischaracterizing positive duties as negative ones is similarly problematic. One way of incorporating such duties would be for Pogge to characterize the duty to assist others as properly a duty not to harm someone by not making them as well-off as they might otherwise have been. Such a characterization is important to Pogge’s description of institutional reform to alleviate global poverty. He describes this with metaphors to “wealthy” and “poor” ships at see, where both move generally on course but only the latter faces a stiff headwind. It is this headwind that violates the negative duty not to harm, in spite of the fact that both wealthy and poor ships advance to their destination. This connection to a negative duty not to harm seems strained; it would be better incorporated by a commitment to positive duties. On my account, it is easier to simply accept the positive duties generated by human rights (an approach similar to Cruft (Cruft, 2005), citing Gewirth (Gewirth, 1996)).

Other difficulties remain with Pogge’s approach, and while a full discussion of it is beyond the scope of this work, two are worth noting. First, real questions remain about whether, from a broader historical perspective, meaningful “harm” is being inflicted on the global poor (Risse, 2005). This is important because, on Pogge’s libertarian-inspired view, the baseline against which harm is measured is critical.
According to Mathias Risse (2005), the only relevant historical benchmark is akin to a state of nature\(^\text{14}\) in the absence of any global institutional order; and according to this benchmark, it is clear that the global order has, all told, helped the poor as a group (not harmed them), even if massive inequalities have resulted.\(^\text{15}\) For Risse, the crucial premise in Pogge’s argument is that the global order actually harms to poor, and this premise is false.\(^\text{16}\)

A second difficulty arises from Pogge’s emphasis on our (as in “all individuals”) collective responsibility for the human rights violations he describes under our duty not to harm. For Pogge, we in wealth countries are all human rights violators by supporting an institutional order that harms the poor. The stringency of the duty not to harm is supposed to motivate us to act upon this order and reform it. However, the motivationally capacity of his view (which is also dependent on whether a convincing notion of “harm” exists) seems uncertain given the diffusion of responsibility among

\(^{14}\)It is not surprising that this “duty not to harm” requires the same narrowly defined baseline as the classical libertarian view of property rights discussed in Chapter 2.

\(^{15}\)For some relevant information about how difficult pre-Industrial Revolution life was, see (Landes, 1998).

\(^{16}\)Pogge has offered responses to this objection. On one, he suggests that, at least in recent years, inequality is worsening to the point that the worst off are being harmed, i.e., their income is decreasing in an absolute sense. This would still require demonstrating that their income has dropped below the “state of nature” level (Risse would argue that it has not). On another, he suggests that the historical difference now is that this poverty is now reasonably avoidable, whereas in the 1800s it was not. The addition of “avoidability” to the argument strikes me being unconvincing to the libertarian targets of Pogge’s argument. See (Pogge, 2005).
various individual actors in the global order. In addition, merely contributing to harm seems insufficient for the full attribution of responsibility (enough to be required to act, anyway), particularly when many different individuals each contribute small amounts to the harm (Buchanan and DeCamp, 2006).

To summarize: Sreenivasan’s and Pogge’s strategies to build consensus about condemning the status quo both fail. Both, in a sense, grant too much. Sreenivasan grants too much global disagreement about distributive justice and thus proposes an exceedingly (and misleadingly) minimalistic reform. Pogge grants too much to his libertarian objector and attempts to ground too much on a supposed negative duty not to harm.

This brings me to a final ecumenical strategy of condemning the status quo hinted at by Debra Satz (Satz, 2005) in her criticism of Pogge. She suggests

Whatever our views of causation, it should be self-evident that the fact that a billion people live in conditions of degrading poverty and die of easily preventable diseases while less than 20 percent consume most of the world’s resources and live in comparative luxury suffices to condemn the status quo. (Satz, 2005 53)

While I think Satz, in this passage, attempts to draw too much from the fact of dramatic inequality, she is on to something. Her remarks suggest that from within any reasonable theory of justice, different reasons could exist for condemning certain inequalities. This

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17 I thank Allen Buchanan for this point about the motivational capacity of Pogge’s view and leave it to him to further elaborate.
is the strategy I pursue, unlike Pogge, who wants to argue for a single reason why certain inequalities are unjust.

Interestingly enough, a second impetus for pursuing this strategy arises from an analogy with work on racial and ethnic disparities in health care within the United States. In their contribution to the 2002 Institute of Medicine report, *Unequal Treatment*, Madison Powers and Ruth Faden (Powers and Faden, 2002) provide an interesting account of why all reasonable theories of justice condemn racial and ethnic disparities in U.S. health care. Although the details of their work are not critical here, the framing of it is. In fact, in what follows, I construct a similar argument regarding global health inequalities as they do for racial and ethnic disparities. The key theme that emerges is how all reasonable theories of distributive justice offer internal reasons for being concerned with at least the worst global health inequalities.\footnote{As in the above description about global disagreement, what follows necessarily paints with broad strokes. Unlike the demonstration of disagreement, however, the demonstration of agreement is more difficult. Nonetheless, it does appear that nearly all theories of justice can, in principle, offer reasons for condemning the status quo, in spite of disagreement within and between conceptions (and about what to do about changing the status quo).}

For brevity’s sake, I will not consider in detail those conceptions of justice whose implications for the worst global health inequalities appear quite obvious. For example, egalitarian theories emphasizing strict equality would condemn the worst, and many other, global health inequalities. Similarly, broadly egalitarian views that retreat from
equality for its own sake often invoke “sufficiency” thresholds that serve as a type of limit on inequalities. Those emphasizing basic human capabilities and functionings, for instance, also give an important role to health with implications for global health (Nussbaum, 2000, Sen, 1992). While somewhat less egalitarian in that they might allow for inequalities in certain social goods (so long as they maximally benefit the worst off), Rawlsian theorists too would have reason to condemn the worst inequalities. Finally, welfare consequentialist views (and prioritarian versions emphasizing the welfare of the worst off) also offer good reason to condemn the status quo. All this seems readily apparent without argument. In what follows I focus on the libertarian and desert-based conceptions of distributive justice, as they might seem most unwilling to offer condemnation.

**Libertarianism.** Following Powers and Faden, I start with libertarianism because it, on the surface, presents the most formidable theoretical challenge to condemning radical inequalities in health. As they correctly note, citing Nozick (Nozick, 1974), the core of libertarianism is as follows:

The libertarian theorist rejects any pattern of distribution as the proper aim of justice, arguing instead that whatever pattern of distribution emerges from un-coerced contracts and agreements is morally justified. (Powers and Faden, 2002 775)

The problem with this view should be obvious in so far as it depends on a particular historical story (as discussed in Chapter 3). Or, as Lamont and Favor describe it:
The numbers of injustices perpetrated throughout history, both within nations and between them, are enormous and the necessary details of the vast majority of injustices are unavailable. Even if the details of the injustices were available, the counterfactual causal chains could not be reliably determined...As a consequence, Nozick’s entitlement theory will never provide any guidance as to what the current distribution of material holdings should be nor what distributions or redistributions are legitimate or illegitimate. (Lamont and Favor, 2007)

Lamont and Favor go on to note that even Nozick himself recognizes this, suggesting that something more egalitarian (like the Rawlsian difference principle justifying inequalities only if the work to benefit the worst off) might be the best real world solution. Therefore, libertarianism is at least able to condemn the status quo.19

Desert-based Principles. A second theoretical orientation – desert-based principles of distributive justice – might also appear problematic when it comes to condemning the status quo. The core idea behind such conceptions of distributive justice is that individuals deserve their distributive share of some good (e.g., income) as a result of their past actions. George Sher (Sher, 1987) is a notable example of this type of conception.

A close look, however, reveals certain elements of desert-based views that could condemn current global health inequalities. First, as Lamont and Favor (Lamont and Favor, 2007) point out, most contemporary desert theories are not complete theories;

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19 The question, of course, is what to do about it. In a later suggestion, I follow many others in arguing against the libertarian emphasis on negative rights and negative duties.
rather, those who emphasize desert also emphasize need-based or equality principles as further constraints on distributive outcomes. An example of this is David Miller (Miller, 1999b). If this is true, the magnitude of global health need is so great that it clearly requires consideration. Second, to be fully just, desert-based theories seem to presuppose that individuals have to some extent an equal chance at competing and contributing to the social product to receive their desert. This would seem to place at least a minimal cap on the type of (involuntary) restrictions on opportunity created by disabling disease and ill health. Third, if Lamont and Favor (Lamont and Favor, 2007) are correct that raising the social product or standard of living is the unifying goal of desert-based theory, then there should be huge incentives to raise the standard of living of the poor (one part of which would surely involve health). For any of these reasons, then, desert-based theories would seem to offer reasons for condemning the status quo.

The preceding reflections on a wide range of theories of distributive justice serves mainly to confirm what most already believe, that is, the status quo of global inequalities in health is morally indefensible. This condemnation occurs for different reasons within different conceptions of justice and is an important improvement over the alternative strategies of Sreenivasan and Pogge. Sreenivasan, recall, grants too much global disagreement while assuming universal agreement about “minimal demands” of
justice. Pogge, on the other hand, grants too much to the libertarian emphasis on negative duties.

### 4.2.2 Accepting Basic Human Rights

Having just argued that nearly every available conception of justice could, in principle, offer reasons to condemn current global health inequalities, I now proceed to argue more than this: Nearly every available conception of justice recognizes, in principle, basic human rights. Taken together, these two claims lead me to provisionally reject the Global Distributive Justice Disagreement Thesis with which I started. I say “provisionally” because the rest of this chapter will argue that taking this human rights claim seriously has implications for what could have been another area of widespread disagreement – the assignment of concrete responsibilities, or “who must do what,” for remediation of global health inequalities (see section 4.2.3 and the rest of this chapter).

As in the prior section, the demonstration of near universal agreement is a daunting task. Therefore, I similarly focus on three pressing areas where this agreement is most surprising, taking for granted theorists like Amartya Sen (Sen, 1999), Martha Nussbaum (Nussbaum, 2000), Thomas Pogge (Pogge, 2002), Allen Buchanan (Buchanan,
2004), James Nickel (Nickel, 2007), and others who explicitly accept human rights. The purpose of what follows is to demonstrate that what appear to be radically diverse conceptions of justice all seem to accept some notion of basic human rights.

*The Libertarian Challenge: Positive & Negative Rights.* Again, starting with libertarianism seems apropos given the libertarian emphasis on negative rights and negative duties “not to harm” already discussed in the context of Thomas Pogge’s work. Typically, the libertarian theorist places a strong emphasis on negative duties not to harm, not to torture, etc. (as well as on property rights, as discussed in chapter 3). From the libertarian standpoint, so-called “positive” rights – like the right to a basic minimum of health for which I will later argue – seem eliminated from the start.

This libertarian challenge is tired. It has been rejected several times since Henry Shue first dismantled the distinction between positive and negative rights (Shue, 1980). Rather than repeating these counterarguments here, the essence of them is perhaps best framed as the “Libertarian Dilemma.” Simply put, the Libertarian Dilemma suggests either that (i) the justifications used by the libertarian for the sake of negative rights also applies to positive rights or duties; or (ii) that, in the absence of any positive duties, the only justifiable condition would be anarchical.

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20 To this list I might also add Peter Singer, whose utilitarianism acknowledges human rights. See (Singer, 2002). In what follows, I also do not address seemingly unreasonable (and rare) views that suggest we have no obligations to others.

21 For more on this, see (Jones, 1999), (Buchanan, 2004), and (Buchanan, 2005).
To explain in greater detail, on the first horn of the dilemma (i), the libertarian might suggest that negative rights are the only “real” rights because they generate negative duties. For example, my right not to be tortured implies that all other individuals have a negative duty not to torture me. By contrast, so-called positive rights, like a right to a basic minimum of health, would require positive duties on the part of others to fulfill this right (and most importantly from the libertarian perspective, would require unjust takings of others’ property for its fulfillment). Yet this distinction breaks down once one realizes the extent of the positive duties necessary for the fulfillment of negative rights. As Buchanan states it clearly,

on any reasonable understanding of what it is to take ‘negative rights’ seriously, a multitude of ‘positive’ actions must be undertaken; so whatever difficulties afflict ‘positive rights’ attend ‘negative’ ones as well. For example, protecting property rights requires courts, police, legal services, the establishment of various authoritative social conventions concerning the marking of boundaries, the transfer of title, and so on. (Buchanan, 2005 83)

All told, then, horn (i) of the dilemma therefore appears doomed.

Some libertarians, by contrast, might bite the bullet and suggest that even negative rights, property construed, do not generate any positive duties. In other words, none of the seemingly positive duties just described by Buchanan regarding property are morally justified. “Positive duties” to maintain a police force for the prevention of theft could be similarly rejected. The problem with this second horn of the dilemma (ii) is that such a state seems intuitively like the kind of place reasonable individuals would
not like to live (i.e., a state of anarchy). Therefore, the libertarian truly is caught on the horns of dilemma: either accept some so-called positive rights and basic human rights or retreat to a state of anarchy.  

What this discussion shows is that even libertarians’ opposition to a great many basic human rights is unfounded. Taken in conjunction with the idea that libertarians’ emphasis on individual autonomy could be undermined by lack of access to some basic health services, the libertarian has good reason to accept a basic human right to health and other such rights.  

The Moral Relevance of National Borders. A second area of controversy in the area of global distributive justice generally relates to the moral relevance of national borders. As typically framed, the debate is between those who think our moral obligations to compatriots are more stringent or more extensive than those to foreigners.

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22 Attempts like those of Nozick (1974) to justify support of the police force and other such institutions on the grounds of “public goods” similarly leave open the question as to whether certain other so-called positive rights would count as “public goods.” On many accounts, public health is a public good, and so this would lend support to some basic human right to health.

23 This line of argument would seem to apply to others who make a distinction between basic civil and political rights, on the one hand, and social and economic rights on the other (“welfare rights”). Not incidentally, one such individual is John Rawls (1999) in The Law of Peoples, where he reduces the list of basic human rights by 2/3 for the sake of tolerance. See Allen Buchanan, “Taking the human out of human rights,” unpublished paper.
(“nationalists”) and those who think national borders who have no relevance to our moral obligations (“cosmopolitans”).

Although this debate might have relevance for the assignment of concrete duties as they relate to the fulfillment of human rights, it has no such relevance for the acceptance of basic human rights themselves. For example, staunch nationalist theorists like David Miller, who generally rejects any sort of egalitarian principles of distributive justice at the global level, can still accept the need to recognize basic human rights abroad and engage in resource transfers, when necessary, to enable nations’ political viability (Miller, 1995). More radical communitarians like Michael Walzer also accept, at the very least, that all individuals have rights to life and liberty (calling into mind the libertarian discussion above; see (Walzer, 2006)). He also suggest that certain communities might see health as a basic human need to be met for all, which could make plausible a view that recognizes health care as one of the basic rights of all individuals (Walzer, 1983).

24 Cosmopolitans need not, however, argue for the annihilation of nation-states or national borders. See (Beitz, 1999).
25 Miller’s account is, however, lacking when it comes to extent of such transfers or how they relate to a nation’s internal workings.
What this suggests is that the debate over the moral relevance national borders is, to a certain extent for now, tangential to the concept of basic human rights. While nationalist and communitarian views could have implications for the primary assignees of human rights (an assumption I question below, in section 4.4), no principled reason exists for them to exclude the recognition of the rights themselves.

*Equality.* Finally, it is worth pointing out another area of recent thought in global distributive justice where deep-seated disagreement is tangential to my project on basic human rights: recent philosophical literature on equality. This point is important in so far as a commitment to basic human rights (particularly on the conception I endorse, as described below) implies only a minimalist commitment to equality (Buchanan, 2005). I argue that this minimalist commitment to equality – often phrased as “sufficiency” – is common to nearly all reasonable theories of global distributive justice. More than that, this commitment to equality is best framed in the terms of basic human rights, as I will articulate further in section 4.3.

A different way of putting this point is as follows: no matter where one falls on the issue of whether inequality is more permissible between countries than it is within

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26 However, as Buchanan (2005) points out, if the pursuit of a more expansive egalitarian conception of distributive justice within national borders restricts the ability of nation to contribute to a minimally egalitarian *global* distribution, the “nationalist” view might have reason to reject this global view of justice. A way out of this conflict would seem to simply require prioritizing the worst off, who, after all, are suffering human rights violations or systematic disadvantage, as I describe below.
countries, a commitment to minimal levels of equality (or constraints on inequality) remains. One of the more recent examples of the commitment to greater equality within a country, for very specific reasons based on state coercion and autonomy, comes from Michael Blake (Blake, 2002). He states quite clearly his intent as, “The strategy I employ seeks to endorse the idea that we can defend principles of sufficiency abroad and principles of distributive equality at home” (Blake, 2002 258). Finding a serious philosophical view that does not take the idea of sufficiency quite seriously is therefore a tall task, even if it is not framed within the discourse of human rights.

To summarize, this section has attempted to make good on the second claim regarding the Global Distributive Justice Disagreement Thesis: Nearly all reasonable theories of global distributive justice seem to accept the idea of basic human rights in one form or another. This section and the prior have lent support to the idea that global disagreement about distributive justice is not as serious a problem as it appears to be, particularly at the most fundamental levels. To be sure, I have not addressed some of the more pressing challenges toward human rights (such as the charge of their cultural relativity, Western bias, or indeterminacy with regard to full-blown content), nor surveyed every possible philosophical view. What I have hopefully done, however, is given enough evidence to support the sort of overlapping consensus necessary to move

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27 To borrow Allen Buchanan’s phrasing, to endorse the permissibility of inequality between states as greater than within states is to endorse the “asymmetry thesis.”
forward with regard to remediation of global inequality. As Charles Beitz (2001) similarly notes

the doctrine of human rights is “common” in the sense that, considered in light of the political purposes it is expected to serve, reasonable persons could accept it despite differences in their reasonable conceptions of the good. (Beitz, 2001 278)

4.2.3 A Curious Failure

This near universal condemnation of the status quo (Nagel’s above quote) and acceptance of basic human rights (Beitz’s above quote) should be cause for celebration. After all, few issues exist in philosophy more generally, or in ethics more specifically, where this type of consensus is reached. Unlike other areas of justice – e.g., democratic deliberation, the death penalty, taxation, etc. – this one should be easy. Surely positive actions at eliminating the worst global health inequalities would flow naturally from this consensus.

Unfortunately, there is little reason to celebrate. As some of the numbers in Chapter 1 suggested, global inequalities in health are bad and are worsening, both in relative and absolute terms (recall the rollback in life expectancy in Sub-Saharan Africa as a result of HIV/AIDS). What is to explain this curious failure?

28 It is interesting to note that Powers and Faden (2002) face a similar problem: the near universal condemnation of racial and ethnic disparities in U.S. health care and the incredible inability to impact real change in eliminating them.
While a full examination of this failure would be beyond the scope of this project, several reasons might exist. Thomas Pogge (2002) notes and refutes several “easy” reasons to ignore these issues in the context of world poverty: (1) that annihilating poverty now will lead to more poverty deaths in the future as a result of overpopulation; (2) that the problem of global inequality and poverty are simply “too big” to be solved at reasonable cost; and (3) that global inequality is decreasing anyway, so we need not worry about it.\(^{29}\) Pogge’s explanation and refutation of each of these reasons, whether empirical or normative, are clear and convincing.

However, this is not the end of the story. To this I would add two more explanations for the curious failure of global distributive justice.

The first relates to the Global Distributive Justice Disagreement Thesis by (mistakenly) attributing our acquiescence of world poverty to irreconcilable differences in conceptions of global distributive justice. As I have argued above and will continue arguing below, while these differences might be stark in the “end game” of a fully just global society, with or without nations, they are not at all that stark at more fundamental levels. It could be, therefore, that individuals fail to recognize this fundamental agreement, either out of self-interest or perhaps other reasons. For Pogge (2002), this

\(^{29}\) On the view of human rights I endorse, whether inequalities are decreasing is not the critical issue – what is the critical issue is whether all individuals have some minimally sufficient amount.
fundamental agreement relates to duties not to harm others, whereas I will continue to argue for fundamental agreement about basic human rights.

The second reason relates to a higher-order disagreement: the assignment of concrete responsibilities to solve the real problems of the complex arena of global health. Thus, a version of the Global Disagreement Thesis that could be more plausible is this:

In spite of the widespread condemnation of the status quo and acceptance of basic human rights, radical disagreement exists about who should do what to solve the problem of the worst global health inequities.

To the extent that this thesis is true, it represents a real problem. I will argue, however, that the acceptance of basic human rights itself offers much more guidance regarding the “who” and “what” questions than is typically recognized. In fact, taking human rights seriously has implications for the types of institutional reforms necessary for fulfilling these rights. The example I will use to illustrate this is the basic human right to health, one part of which is the right to access to essential medicines.

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30 This is what Allen Buchanan and I have called in similar contexts the “Problem of Concrete Responsibilities” – see (Buchanan and DeCamp, 2006).
4.3 Human Rights

Several times in this chapter, I have hinted at – but delayed discussing in detail – what I see as the best current philosophical account of basic human rights. Instead, my focus was on how most reasonable theories of justice (or global distributive justice) appear to make room for basic human rights. At this point, it is time to describe in more detail my view of basic human rights. It draws heavily on the important work of James W. Nickel (Nickel, 2007) but with significant influence from Henry Shue (Shue, 1980), Allen Buchanan (Buchanan, 2005, Buchanan, 2004), Thomas Pogge (Pogge, 2002), Amartya Sen (Sen, 2004), and Madison Powers and Ruth Faden (Powers and Faden, 2006).

This section proceeds as follows. First, I elaborate the key features of what I believe to be the most well-justified human rights theory (4.3.1). This theory has the distinct advantages of being accepted by (or at least not inconsistent with) most reasonable view of global distributive justice, and of taking seriously the increasing practical import of human rights.\(^{31}\) In this section I do not mention the many objections to human rights in general (e.g., the “Asian values” challenge and other cultural

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\(^{31}\) Whether this theory might therefore be used to determine the reasonableness of certain theories of justice is perhaps a separate question that I do not consider.
relativity issues; I believe most, if not all, of these to have been successfully refuted). What emerges is a minimal egalitarian view (Buchanan, 2005) of global distributive justice, setting a limit on the absolute deprivation permissible but not necessarily excluding all relative inequalities.

Second, I suggest that the right to a basic minimum of health qualifies as such a right, and that however one fills out its content, it will surely involve a delimited right to access to essential medicines (4.3.2). Delimiting this right is a key challenge in this area. Therefore, I spend the rest of this section on that task (4.3.3). The final sections of this chapter (4.4 and 4.5) will then consider whether this right is currently being violated, and if so, what the understanding of human rights just elaborated might tell us about how to respect, protect, promote, and fulfill this right.

4.3.1 The Key Features of Human Rights

Before proceeding to discuss the key features of human rights – features that will figure large towards the end of this chapter and in the final one – a word or two is necessary about justifying human rights. Even though this is not the main goal of this chapter, and even though I have already suggested that the commonly held distinction

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32 For one among the many responses to the “Asian values” challenge that human rights reflect a Western bias, see (Sen, 1997).
33 This portion, then, has normative import for groups like Physicians for Human Rights and Médecins Sans Frontières who often invoke, but do not defend, something like a right to access to essential medicines.
between negative and positive rights is blurry at best, some readers might wonder about the justificatory issue.

Several noteworthy justifications of human rights have been offered that no longer rely on now rejected “natural rights” views. Henry Shue’s important book, *Basic Rights*, in its first 1980 edition and in the 1996 second edition, describes basic rights simply as providing “the rational basis for a justified demand” (Shue, 1996 13) or as placing “minimum reasonable demands upon the rest of humanity” (Shue, 1996 19). Much depends, of course, on what counts as a reasonable or rational demand, and others have followed Shue in elaborating this further.

One example involves James Griffin’s (Griffin, 2000) appeal to autonomy or personhood alone as justifying human rights. Unfortunately, as James Nickel (2007) points out, a focus on autonomy alone makes difficult the justification of anything other certain specific liberties, neglecting other well-recognized rights, such as equality before the law. A focus on autonomy, in other words, is too restrictive in terms of the eventual content of human rights.

As a second justificatory example, Amartya Sen’s recent work on human rights, can be read as suggesting that rational demands (in Shue’s sense) are the ones that can withstand open public scrutiny and debate. He writes,

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34 For a helpful discussion of this now rejected view see Thomas Pogge (2002), especially pp. 56-9.
35 See Nickel (2007), p. 54. He also cites (Tasioulas, 2002).
…the viability of human rights is linked with what John Rawls has called ‘public reasoning’ and its role in ‘ethical objectivity’ (Sen, 2004 349).

For Sen, human rights depend also on the ability of his “capability” approach to basic human freedom. This is an approach emphasizing capabilities as “the opportunity to achieve valuable combinations of human functionings: what a person is able to do or be” (Sen, 2004 332). Thus, one might consider human rights justified to the extent that they reflect human capabilities and functionings that withstand public reason.

Unfortunately, this pushes aside the question of which capabilities and functionings are most important, in spite of Sen’s helpful examples. Martha Nussbaum (2000) takes up this task and develops a specific list of thirteen capabilities (including life; bodily health; bodily integrity; senses, imagination and thought; emotions; practical reason; affiliation plus social bases of self-respect; relationships to other species; play; and control over one’s environment (both political and material)). Specifically regarding human rights, Nussbaum says that the language of capabilities gives important precision and supplementation to the language or rights…Regarding fundamental rights, I would argue that the best way of thinking about what it is to secure them to people is to think in terms of capabilities.(Nussbaum, 2003 37)

Like Sen, Nussbaum believes that her list of capabilities are revealed and legitimized by cross-cultural dialogue.
Do these approaches to human rights perform justificatory work, or do they merely demonstrate the universality of the content of human rights (i.e., “what is,” a fact of the matter)? Do basic human interests – functionings and capabilities – alone provide the grounding for human rights?36

Against this backdrop, James Nickel (Nickel, 2007, Nickel, 2005) reminds us that we need not expect (nor even prefer) any single, all-encompassing justification for human rights. He therefore provides a “pluralistic” justification for human rights based on several fundamental human interests and concerned with “avoiding misery and ruinous injustice” for a life that is “minimally good” (Nickel, 2005 392). This justification is based on (1) prudential reasons (i.e., people will individually recognize that they will be more likely to lead a good life when living under governments that respect basic rights); (2) utilitarian or pragmatic reasons (i.e., overall welfare is best served by systems that respect basic human rights); and (3) “deontological” reasons (i.e., by appealing to abstract moral claims that are universal, can support specific duties, and are “high priority” claims). It is the last of these three justifications that Nickel himself emphasizes, suggesting they “should be widely accepted as part of people’s moralities

36 Others tackle the justification question by avoiding issues of basic human interests. For example, Beitz (Beitz, 2001) and Rawls (Rawls, 1999) emphasize mainly the functional role that human rights play in international relations. While I think this view could be malleable enough to accommodate the view of human rights I endorse, it could also be unduly limiting. For example, the latter could be true if, as Rawls implies, the main function of human rights is to help determine the permissibility of forced or humanitarian intervention in the affairs of a foreign country.
so that one does not have to make a case for them before moving on to use them in defining human rights” (Nickel, 2007). For Nickel, these claims are as follows:

- A secure claim to have a life
- A secure claim to lead a life
- A secure claim against severely cruel or degrading treatment
- A secure claim against severely unfair treatment

It is from these basic human interests that Nickel is able to argue for specific, legally-recognized human rights (whether due process, basic rights to subsistence, and so on).

Nickel’s specific rights function, in Allen Buchanan’s terms, as

...normative relations (more specifically, claim rights) which, if realized in the case of all persons, would help to ensure that all persons have the opportunity for a decent or minimally good human life. The same point can be put in terms of basic human interests: the various human rights norms specify conditions that protect interests that are constitutive of a decent human life. (Buchanan, 2005 71)

Of course, the specific content of human rights derived from such claims is likely to be a difficult enterprise. Nevertheless, Nickel’s is a fruitful starting place for thinking about

\[37\] One place where I appear to disagree with Nickel, it appears, is regarding the uniquely legal status of human rights. Instead, I follow Pogge (2002), as I note below.
the minimal basic human interests, common to reasonable moralities, that provide sufficiency conditions for a minimally decent human life.

This sufficiency view of human rights is a popular one, and it is one that I endorse (for now). Moreover, if anything will serve to justify human rights it is a pluralistic account like Nickel’s or nothing at all. Therefore, at this point, I wish to assume human rights to be well-justified (or on their way to being well-justified). This will enable me to move forward with my argument, suggesting a right to a basic minimum of health (of which the right to access to essential medicines is one part).

Given this, what are the key features of a well-justified account of human rights? (By key features, I mean the key features for the present project, not all the possible key features of human rights.) All told, I focus on the following seven:

*Minimal Moral Claims of Special Import to Which All Can Agree.* First, as emphasized repeatedly in different contexts throughout this chapter, human rights represent minimal moral claims to which all can agree. This does not mean that everyone actually does agree. It also does not suggest that disagreement is a drawback of

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38 For example, Madison Powers and Ruth Faden (Powers and Faden, 2006) describe six essential components of human well being (health; personal security; reasoning; respect; attachment to others; and self-determination). Although they note that these dimensions might represent a useful starting point for the foundations of human rights, they do not articulate this clearly (and on occasion suggest that human rights are somehow orthogonal to their view). Their emphasis on “systematic disadvantage” is important, however, and plays a large role in the later sections of this chapter.

39 Later I will suggest that the emphasis on sufficiency has blinded us to how taking human rights seriously has implications not just for sufficiency itself, but for how it is reached.
the human rights enterprise. Nonetheless, what matters most is that reasonable individuals can agree to the minimal moral claims (Nickel’s or otherwise) inherent in human rights, and that these claims are of special importance (because of the second feature, immediately below). In addition, human rights are “minimal” moral claims in the sense that we ought not expect human rights to fully encompass social justice, or even distributive justice.

Conditions of Sufficiency or “Minimal Equality.” Related to this first claim is a second: Part of the agreement regarding human rights stems from their elaboration of the minimal conditions necessary for a minimally decent human life. The best expression of this is Allen Buchanan’s (2005) “Equality and human rights.” Properly understood, human rights appear to represent a sort of minimal egalitarianism (Buchanan, 2005). This egalitarianism is minimal because

...honoring the commitment to human rights does not require anything approaching equality of condition or outcome for all human beings, nor even that all human beings actually have decent lives; instead, it only requires that all have the opportunity for a decent life. In fact, the Modest Objectivist View does not even require equality of opportunity for a decent life strictly speaking. It requires neither that everyone is to have the same probability of achieving a decent life nor that the costs to each of realizing that opportunity must be the same. Instead, what is required is that no one is to face unduly burdensome obstacles to having a decent life, if he or she chooses to try to have such a life. (Buchanan, 2005 74-5)

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40 In fact, as Sen and Nussbaum suggest, disagreement could be necessary for refining human rights. Allen Buchanan more systematically discusses the importance of elaborating the specific content of human rights through institutions in “Towards an Institutional Theory of Human Rights” (unpublished paper).
41 As Powers and Faden (2006) point out, this does not necessarily mean that human lives which do not meet these minimal conditions are “not worth living.”
Moreover, when these minimal conditions are not met, concern is rightfully raised to consider whether the failure to meet such conditions represent a human rights violation (as opposed to, for example, a freely chosen life plan) (Powers and Faden, 2006).

Should this minimal egalitarianism at all constrain inequalities within or between nations? Broadly speaking, the answer is, “It depends.” Within countries, insofar as radical inequality systematically undermines attempts to meet the basic minimum (e.g., through political will, imbalance of power, etc.), such inequalities would seem to be objectionable.\(^\text{42}\) Between countries, the same might be true. But would this intrude unreasonably on individual nations’ right to self-determination (Buchanan, 2005), if that nation wishes to pursue more radical domestic egalitarianism (thereby taking resources away from helping fulfill human rights abroad) or simply happens to be well-off (as a result of luck or well-chosen policies)\(^\text{43}\)? The answer is probably that it would not \textit{unreasonably} impose on self-determination. If human rights claims are claims of special moral import, they would seem to take at least some precedence over domestically-pursued radical egalitarianism. And because the best contemporary

\(^{42}\) Norman Daniels makes this point in relation to “tiering” in the provision of health care services. See (Daniels, 1998).

\(^{43}\) What is somewhat odd about this issue is that one of the well-recognized functions of human rights is to impose at least minimalist restrictions on nations’ self-determination (e.g., about slavery, etc.). So the question becomes whether any particular restriction for the sake of human rights is \textit{unreasonable}. 
human rights theories take into account the cost and feasibility of fulfilling human rights, the notion of reasonable intrusion is already built into the theory. For the second scenario ("well-chosen policies resulting in great wealth"), much would depend on the empirical facts of the case, as well as whether the presence of great wealth implies that the burdens of helping abroad are less costly in relative terms. Unfortunately, this issue is not likely to be the most pressing one for the near future, as neither domestic egalitarianism nor a more just world appear imminent.

Subject-centered. A third key feature of human rights is that it is what Allen Buchanan calls “subject-centered” (Buchanan, 2005, Buchanan, 1990). As he describes the minimal standards of human rights,

> The point is that these are standards of a very special sort: they are subject-centered obligations, grounded in characteristics shared by all human beings. The fact that these ‘common standards’ take the form of rights, and, more specifically, human rights, is not insignificant. (Buchanan, 2005 72)

This feature of human rights, therefore, is critically important. It perhaps reflects the concept of “human dignity” expressed in international human rights documents, such as the Universal Declaration of Human Rights. Subject-centeredness also reinforces why human rights are as important morally as they seem to be, i.e., claims of great moral import that apply to all human beings by virtue of their being human. Moreover, as I will argue later, because subject-centeredness emphasizes, to some extent, the ways in which humans are situated to each other (i.e., their relationship as individuals of equal
moral worth), it has serious implications for how one is to go about protecting, respecting, and fulfilling human rights.

*Dynamic.* Fourth, human rights are *dynamic*; the possibility exists that the explicit content of human rights will change over time. This “human rights dynamism” is a departure from pre-institutional or “state of nature” views of human rights, which suggest that the content of human rights is somehow fixed according to the rights humans had in pre-institutional life. These views are now rejected. Again, Allen Buchanan provides a clear statement describing this “dynamism”:

As we learn more about the complex relations among various institutions that affect human well-being, it may be necessary to add new rights to the list of human rights. For example, if it becomes clear that liberal constitutional democracy is the only reliable form of government from the standpoint of securing certain especially important human rights, then it may become justifiable to include a right to this type of government among the human rights. There is a more fundamental way in which human rights could become less minimal over time. If biomedical technologies continue to develop and their widespread use becomes much less costly, our conception of what counts as a decent human life may well become more ambitious. For example, if an inexpensive vaccine became available that would significantly extend the human lifespan, we might come to think of a decent human life as being longer than we do now. Our conception of one standard threat to human well-being, premature death, might change and with it our conception of human rights. (Buchanan, 2005 76)

This dynamism might not apply, or is less likely to, at the theoretical level of, e.g., Nickel’s “minimal moral claims” described above. Nonetheless, recognizing human

44 In more informal communication, Buchanan discusses a fascinating quote found in Adam Smith that seems to express something like this point. Smith writes, “Custom, in the same manner, has rendered leather shoes a necessary of life in England. The poorest creditable person of either sex would be ashamed to appear in public without them.” See (Smith, 1994 (originally 1776)), Book Five, Chapter II, Article IV.
rights dynamism is crucial to my overall project. If access to essential medicines is to be seen as part of a basic human right to health, it is somewhat obvious that pre-institutional or “static” views of the content of human rights must be rejected (there being arguably no essential medicines in the modern sense even 100 years ago).

Institutional, Not Interactional. Dynamism as opposed to the “pre-institutional” view of human rights is more clear when considering the fifth key feature of human rights. Following Thomas Pogge’s (2002) helpful distinction, I consider human rights to be institutional, not “interactional.”45 In other words, for Pogge (and for me), human rights are primarily claims against coercive social institutions and only secondarily claims against the individuals who support these institutions. Importantly, on my view, the qualifier coercive ought to be read broadly – not just as institutions backed by the coercive threat power of law, but as institutions with the potential to radically shape the global basic structure of political, economic and social relations, often without the direct participation of those affected by the institutions’ actions.

This, too, is a critical point because it implies that institutions and individuals other than national governments and without the traditional coercive threat power of national law can violate basic human rights. Or, directly put, it implies that the global

45 The term “interactional” is somewhat confusing. A straightforward way of reading it would be to suggest that human rights are “interactional” if valid human rights claims can only be made against others with whom one interacts directly (as opposed to those with whom one interacts through social institutions, like the World Trade Organization, courts, etc.). This is my interpretation of Pogge’s terminology, however.
IPR regime or the absence of feasible alternatives could be violating or underfulfilling the basic human right to access to essential medicines, depending on how the content of this right is filled out.

*Moral, Not Necessarily Legal.* Sixth, on my understanding, human rights are fundamentally moral rights and not necessarily legal ones. This is again in broad agreement with Thomas Pogge (2002), though less so with James Nickel (2007). By considering human rights as moral, not necessarily legal, it implies that the fulfillment of basic human rights could occur independently of legal recognition of that right, either nationally or internationally. Pogge phrases this nicely as follows

A human right requires its own juridification only when it is empirically true – as it may be for some civil and political rights – that secure access to the object presupposes the inclusion of a corresponding legal right in the law or constitution. (Pogge, 2002 45)

Charles Beitz (Beitz, 2001) and Sen (Sen, 2004) share this view of rights as fundamentally moral, not to be confused with actually legislated rights. Sen notes that approaches to rights might involve recognition (as with the *Universal Declaration*); agitation or advocacy (as with non-governmental organizations, such as Human Rights Watch, who can urge rights fulfillment through “naming and shaming”); and lastly, legislation (as with the European Court of Human Rights, established in 1950 to consider alleged human rights violations) (Sen, 2004 344).
This recognition is important, not only for theory but also for practice. Anthropologists note how certain cultures (or even individuals) do not speak nor think of themselves in rights-based terms or as rights-bearing subjects, particularly in a “legal” sense. Clearly, these individuals have and recognize that they have fundamental human interests – interests that they would like to have fulfilled. The question, however, is not whether this interest is a “legal right,” nor perhaps whether it is recognized as a “moral right” in the traditional sense. Instead, the question, empirically, is whether individuals have reasonably secure access to whatever is claimed by the right. For example, some might consider that a basic human right to adequate shelter presupposes private property rights. Whether or not it does (and I do not think so), the empirical question on the human rights account I endorse is whether individuals have secure access to adequate shelter, not whether they call it a “right.”

Feasible Concrete Duties. Last but certainly not least comes the capacity of human rights to assign feasible concrete duties to help ensure their fulfillment. This feature of human rights is important, albeit controversial. For example, Onora O’Neill suggests in several contexts that the central problem with theories of human rights (as opposed to

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46 While the literature here is vast, the work of Sally Engle Merry on the experience of women and domestic violence laws represents one example. See (Merry, 2006).

47 Understanding this distinction, could go a long way toward resolving certain conflicts about the universality of human rights. But it is not likely to go all the way, because on the global stage, cultures who otherwise do not speak in “rights” terms might be required to in order to have their voices heard in a stage dominated by “rights” talk.
her own focus on obligations or duties) is the inability to generate unambiguous duties or to choose among duties (O’Neill, 2002a, O’Neill, 2000, O’Neill, 2002b). This, in other words, represents a “new” version of the global disagreement thesis arising once we realize the widespread agreement among different conceptions of justice regarding condemnation of the status quo and acceptance of basic human rights.

This criticism is important, but not fatal, to theories of human rights. What it urges is a real effort to translate the seemingly indeterminate content and obligations generated by human rights into concrete duties. In fact, the present project is an effort at doing just that. To the extent that this project succeeds or fails will to some extent serve as a response to this criticism.

In summary, these seven features of human rights are critical to understanding both what human rights are and the functions they will serve in global distributive justice. With this in hand, I now move to arguing for a basic human right to health and access to essential medicines as one part of this right.

4.3.2 The Right to a Basic Minimum of Health

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48 Why starting with obligations, as O’Neill does, avoids the ambiguity is to me questionable.
My argument for a human right to a basic minimum of health is a simple one that rests on either (or both) of the following two claims:

(i) If anything is a basic human right, there is a basic human right to a minimal level of health.

(ii) Even if health were not itself a basic human right, some minimal level of health is necessary for the enjoyment of other basic human rights (Shue, 1980).

I think both of these claims are well justified, assuming as they do the presence of some basic human rights and having rejected earlier the positive-negative rights distinction. However, it is worth pointing out that a human right to a basic minimum of health also appears to meet the most important five of James Nickel’s (2007) six tests for justifying individual rights:50

(1) Do people today experience substantial and recurrent threats to what is claimed by the right?
(2) Does the particular norm in question represent a “high priority”?
(3) Can the norm be formulated as a right of all people?
(4) Are the burdens of fulfilling the norm neither nor excessive nor unfair (e.g., by requiring the infringement on other rights)?

50 I say “five of six” because Nickel’s sixth test – that of whether “weaker” measures like charity could be more effective than a “right” – appears to me wrongheaded. It assumes a certain legal status to human rights that I would like to avoid. As becomes clear later, part of this is because I reject charity for different reasons that Nickel.
(5) Is it feasible to implement the norm in a majority of countries today?\textsuperscript{51}

A basic minimum of health meets all of these tests. Still, substantial questions remain about the right to a basic minimum of health.

The first question is, “Why a right to a basic minimum of health and not health care?” To some extent, the choice between health and health care is a terminological one that does not affect my argument (though it certainly would affect other arguments about the content of a right to health). The reason for this is that my argument, as I articulate below, applies to a very specific subset of health care, i.e., essential medicines. On either concept of a right – health or health care – it is hard to argue that essential medicines will not play a role in fulfilling that right. From a terminological standpoint, however, the question is one of comparing the breadth of the concept of health versus the duty specificity arguably present in the concept of health care (i.e., a certain definable set of health care services). In my view, it is preferable to keep the breadth of a right to health – with its explicit acknowledgment that in many cases it is the environment or other non-health care factors that determine health – and focus attention on defining the concrete duties implied by such a right. In this sense, the right to health encompasses the right to health care and, properly understood, need not commit one to

\textsuperscript{51} See Nickel (2007), chapter 5. I remain uncertain as to the role feasibility plays in justifying particular human rights, not because the theoretical import, but because of worries that feasibility will be interpreted too strictly in practice.
implausible views of supplying absolute guarantees to a set level of “health.”52,53 For these reasons, I will use the phrase “right to health.”

The second question is, “Is the right to health too expansive? (Or, can we define a decent minimum of health?)” Underlying this question could be either continued skepticism of “positive” rights or worries about deep-seated disagreements about the nature of health. If it is the former, the answer again depends on the ability of human rights proponents to make a solid case for a delimited right to health, i.e., for creating institutions to help define and refine the basic minimum. If it is the latter disagreement about the nature of health, this would not appear to be a problem for the foreseeable future. “Naturalist” concepts of health (based on a range of biologically normal functions) and “normativist” concepts of health (based intrinsically on value judgments about what is “good” or “bad,” socially or biologically) appear to converge when focusing on the worst global health inequalities.54 The answer to this question, in other words, depends partly on the success of this project, as well as on our ability to ignore these difficult questions about “health.”

52 The idea of a guarantee is itself antithetical to the modern conception of human rights I endorse. See question four below.
53 On occasion, reluctance exists to accept a right to health because it sounds “too broad.” Unfortunately, this in some part reflects the penchant of major international organizations, like the WHO, to define health as a “state of complete physical, mental, and social well-being.” As noted earlier, such a definition does not agree with the conception of human rights as minimal, rather than ideal, standards. See http://www.who.int (accessed 17 February 2007).
54 For an anthology of views about the concept of health, see (Humber and Almeder, 1997).
The third question is this: “Is the right to a decent minimum of health really a universal right?” It is hard to imagine health not being among the basic human interests appealed to in justifying basic human rights. Henry Shue (Shue, 1980) included basic preventive services in his conception of subsistence rights, James Nickel includes a slightly more expansive version of the right to health (Nickel, 2005), and so on for any of the human rights theorists discussed in this chapter. From a more practical standpoint, it is simply difficult to conceive that all human beings do not have an interest in an opportunity to attain some basic threshold of health, either for itself or for the opportunities it affords in pursuing one’s life plans. This is particularly true for conditions which are debilitating and yet easily treated or prevented. An example of this might be onchocerciasis (the world’s leading cause of blindness, easily prevented by a single annual dose of the drug ivermectin).

The fourth question is, “Does the basic minimum really take into account feasibility and cost?” The answer to this question is, by necessity of “ought implies can,” a resounding yes. What this means, however, is a difficult matter.

To start with cost: Surely any reasonable version of the right to health will acknowledge that fully implementing such a right can be costly. As Nickel (2007) notes, these costs include those arising from implementation of the right and its associated resources; those attached to other norms or rights that must be given up in order to
fulfill the right (e.g., the cost of stronger property that taxation entails); those that occur when the burden of fulfilling the right is unevenly distributed; and those occurring when respecting a right has efficiency costs (e.g., not torturing someone who has the right not to be tortured could have the cost of restricting the amount of vital information obtained). Importantly, the costs associated with a particular right are not always higher in regard to “positively” respecting that right – as in providing goods and services necessary for it – compared with “negatively” respecting that right – as in refraining from acting in a certain way (Nickel, 2007 86).

As Nickel (2007) further notes, these costs are often exceedingly difficult to fully account through empirical studies. This complex accounting involves hypothetical alternatives and different kinds of costs (some of which might not be represented well through econometrics). Moreover, the difficulties are not just empirical; the lessons of Chapter 2 inform us, for example, that which costs count, how to value different costs, and whether certain benefits are worth the cost will be tied up with important normative judgments. This includes the difficult question of how much resources should, at the first instance, be used in fulfilling rights. In short, judgments that fulfilling a right is “too costly” on the basis of empirical studies ought to receive scrutiny, in so far as the
burden of empirical and normative “proof” properly resides with those who reject fulfilling certain rights.55

Specifically regarding the right to health, it is important to recall the import of the minimal egalitarianism implied by this right (Buchanan, 2005). A well-justified version of the human right to health would not guarantee health in spite of any cost. Focusing on what counts as a reasonable (though not necessarily equal) opportunity to attain a certain minimal threshold of health, the “bottomless pit” infinite cost objection to a right to health is avoided.

Just as issues of cost are normative, not just empirical, so are issues of feasibility. Nickel (2007), for example, defines feasibility in a mainly descriptive sense, stating, “The duties imposed by rights should be ones that a majority of the addressees are able to fulfill” (Nickel, 2007 81). (Exceptions are given for “failed states” or those for whom implementing a right would be obviously beyond their means.) Nickel’s view is plausible, endorsing as it does the “ought implies can” principle, yet one should not read it too descriptively. “How much of a majority counts?” and “Who determines feasibility?” are critical normative questions in determining feasibility. To understand feasibility as merely descriptive would appear overly conservative in terms of the changes necessary for fulfilling rights – it fails to recognize that institutional innovations

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55 This becomes especially tricky when the cost of a right is tied up with some of the means that make fulfilling that right even possible - as I note is the case with IPRs and essential medicines.
of one kind or another could rapidly make possible the fulfillment of an otherwise “infeasible” right. As with issues of cost, moreover, we ought not assume that “negative” entitlements (such as eliminating discrimination) are more or less costly than “positive” entitlements (such as providing access to a set of basic health care services). Feasibility is, on my account, a dynamic normative concept that must somehow take into account the possibility of institutional innovation. The burden of proof for both cost and feasibility lies with the opponent of the right to health.

In conclusion, a basic human right to health appears justified, though its content remains uncertain. Some of these issues and their complexities become more clear once we consider a specific piece of the content of this right: access to essential medicines.

4.3.3 Essential Medicines as a Human Right

Is access to essential medicines part of the human right to health? To listen to groups like Médecins Sans Frontières (MSF) and Oxfam, one would be led to believe that a right to access to essential medicines already exists. Recently, for example, MSF echoed its 2001 work in South Africa (see Chapter 1) by criticizing the pharmaceutical company Novartis over an Indian court case. In a press release, Dr. Tido von Schoen-

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56 For example, the financial costs of moving from a health care system that excludes all care from a large minority population within a country could be substantial compared with, say, adding a minimal positive entitlement to prenatal care.
Angerer stated clearly, “Just like five years ago, Novartis with its legal actions is trying to stand in the way of people’s right to access the medicines they need.” This statement is interesting, implying as it does that (i) a right to access medicines exists; (ii) that this right involves medicines people “need”; and (iii) that part of this responsibility falls on a private, multinational corporation, Novartis. Do these claims make sense? In this section, I will argue around claims (i) and (ii), endorsing (i) but suggesting a narrower interpretation of (ii). Therefore, part of this section provides normative underpinnings for the types of human rights-based claims made by groups like MSF.

My argument for access to essential medicines as part of the basic human right to health is similarly simple: If anything is part of the basic human right to health, it is the right to access to essential medicines. This is reflected in – but not justified by – clarifications offered to interpret international human rights documents. For example, the Committee on Economic, Social and Cultural Rights, which gives comments on the International Covenant on Economic, Social and Cultural Rights, has suggested that essential medicines (as defined by the World Health Organization, discussed below) be included in the international implementation of the right to health.59,60 This

59 For more discussion of this descriptive point, see (Hogerzeil, 2006) and (Seuba, 2006).
interpretation is reassuring, but like all such international treaties, agreements, and laws, it does not necessarily justify essential medicines as part of this right.

A right to essential medicines seems plausible enough, but several objections immediately arise that require addressing.

First, one might object to the focus on essential medicines as part of the right to health, suggesting that other aspects of health are more important, such as poverty, basic sanitation, or the absence of health care personnel in developing countries. The last of these issues – the absence of personnel – was even the focus of the 2006 World Health Report (World Health Organization, 2006).

This objection is important as a reminder to not overemphasize the role of essential medicines, whether pharmaceutical drug products or vaccines, as a determinant of health. It is also important as a reminder to continue making progress on these other important determinants of health. In spite of this, however, the importance of some medicinal products cannot be overlooked. Their importance is best framed as one whereby a minimally decent human life (the language of human rights) requires access to certain medicines. Onchocerciasis, an infectious disease caused by the parasitic worm *Onchocera volvulus*, is a good example of this: In endemic regions (mainly Africa

Of note, the 2001 Doha Declaration, meant to interpret the TRIPS Agreement, does not mention a right to essential medicines, but instead discusses “access” more generally. See [http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm). Accessed 10 March 2007.
and parts of Latin America), not only are the acute symptoms particularly debilitating, but permanent blindness eventually results. Surely this impedes the realization of a minimally decent life. Moreover, the fact that a single annual dose of ivermectin can prevent these sequelae seems to suggest that ivermectin is, in this context, an essential medicine.61 Similarly, in-depth studies of malaria reveal how infections with that parasite impact all aspects of social and economic life, including the fulfillment of other human rights (Sachs and Malaney, 2002). Many other examples undoubtedly exist (though I have not yet offered a broad definition of essential medicines).

The second major objection to a right to access to essential medicines calls upon just discussed concepts of cost and feasibility to suggest that access to essential medicines is too costly to be a right. This objection takes numerous forms, all of which misunderstand the general concept of human rights.

One form of the feasibility or cost objection suggests that a right to access to essential medicines is too demanding because it requires “giving away” medicines to the poor. Surely such an approach would be too expensive financially, but it is not the approach necessarily endorsed by a human rights view. In his application of a human rights approach to world hunger, for example, James Nickel elaborates seven different duties assigned to governments for fulfill the right to adequate nutrition. These include

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the duty to promote effective use of land and resources; the duty to keep population size under control in ways consistent with individuals’ human rights; and the duty to monitor the availability of food and water to vulnerable parts of the population. Only one of the seven duties actually entails direct food assistance programs, and it is immediately followed by the duty to combat corruption in such programs (Nickel, 1996). This example supports Nickel’s broader claim that one should not conceive of human rights as merely “giving everyone a free supply of the goods these rights protect (Nickel, 2005 398).” Recall also the repeated claim that human rights to not guarantee equal amounts of resources, but instead an equitable and reasonable likelihood of access (Buchanan, 2005).

A second form of the feasibility or cost objection is that a human right to access to essential medicines would be too expansive because every medicine could be considered an “essential” medicine. If the patient with onchocerciasis has a right to ivermectin to stay alive, what about the person with HIV who has failed first line antiretroviral therapy and requires expensive second line treatment? What about the person with multidrug or extreme drug resistant tuberculosis? What about the person with heart disease who needs a cholesterol-reducing drug to improve her survival? What about the patient with cancer who needs a new monoclonal antibody as a treatment of last resort?
These questions are difficult and likely to tug at one’s emotions because they involve real people. However, in this context, it is important to recall the concept of human rights as expressing a “decent minimum” or “morality of the depths.” In other words, lines will necessarily be drawn between “essential” and “non-essential” medicines for the purpose of human rights. This does not mean that good moral reasons do not exist for incorporating “non-essential medicines” into health care systems, nor does it mean than in some cases justice might require this inclusion (for example, if unjust discrimination results in a minority group lacking access to a particular non-essential medicine or service). Intuitively, though, we justifiably question whether cholesterol-reducing drugs, monoclonal antibodies, or second-line treatments form part of the minimum, particularly when compared to basic antibiotics or vaccines.62 Some minimum is necessary, and in line with human rights dynamism, this minimum might change over time. I take up the explicit task of defining “essential” medicines in section 4.3.4.

A third form of the feasibility or cost objection states simply that a human right to access to essential medicines is too expensive because of the high cost of medications. This objection is worth highlighting because of its importance to my overall project. Yet two responses are readily available.

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62 This is somewhat in contrast with individuals and groups who seem to imply that an obvious right exists to second-line antiretrovirals or treatments for multidrug resistant TB. MSF is one such group.
The first response directly questions the “cost” part of the objection in a fundamental way. Empirical cost figures depend (quite obviously) on pricing, and prices depend at least partly on the monopoly power of the current medical research and development enterprise and its dependence of IPRs (i.e., patents). Therefore, to the extent that the too expensive objection depends upon current cost figures and the current medical R&D system, it ignores other institutional arrangements that might have lower costs by not depending on monopoly pricing for pharmaceutical innovation and production. The oft-cited example of early antiretrovirals – considered by some to be an “essential medicine” – is again illustrative. The initial price of a year’s treatment with ARVs in the United States was over $10,000 per person in some cases. This might lead one to conclude that ARVs are “too costly” for inclusion as an essential medicine. However, advocacy philanthropy, and generic production eventually lowered the cost to under $1 per day per patient in developing countries, and some (like Brazil) even committed to supplying them to their citizens free of charge. Simply put, the too expensive objection is complicated because the cost of medicines often depends upon an institutional arrangement that is itself capable of reform.63

The second response to the too expensive objection asks it to consider not only the costs of the medicines themselves, but the costs (as foregone benefits) of not providing

63 Importantly, small differences in cost can make large differences for the health budgets of many developing countries, where a good percentage of the health budget is spent on pharmaceuticals.
medicines. To continue the example of malaria noted previously, the cost of malaria in many of the African countries where it is endemic often results in double-digit income losses – an “economic growth penalty” of malaria (Sachs and Malaney, 2002). Might widespread availability of malaria treatments mitigate the effects of this growth penalty? If so, how does it change the cost-benefit calculus of malaria medicines? Those who are quick to point out the costs of providing access to essential medicines might be prone to neglecting these potential aggregate benefits.

Therefore, drawing on health as a human right, one part of the human right to health will necessarily involve a right to access essential medicines. But how can this right be delimited, as the responses to the above imply that it needs to be? Fortunately, the World Health Organization has been engaged in considering exactly this question. The WHO’s work thus provides a useful starting point for a more detailed examination of the question, “What counts as an essential medicine?”

4.3.4 How To Delimit the Right to Access to Essential Medicines64

Since 1977, the World Health Organization’s Expert Committee on the Use of Essential Medicines (or a similarly named committee) has met at least every two years to

create a Model List of Essential Medicines. Eight to twelve members drawn from WHO Expert Advisory Panels make up the Expert Committee. In this context, essential medicines are “those that satisfy the priority health care needs of the population” and selected “with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.”\(^65\) The 14\(^{th}\) edition of the list contained 312 individual medicines, including (for the first time) antiretrovirals for the treatment of HIV/AIDS (the first list contained just over two hundred) (World Health Organization, 2005a).\(^66\)

The Essential Medicines list is made up of a “core” list and a “complementary” list:

The **core list** presents a list of minimum medicine needs for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment.  
The **complementary list** presents essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed. In case of doubt medicines may also be listed as complementary on the basis of consistent higher costs or less attractive cost-effectiveness in a variety of settings. (World Health Organization, 2005a 1)

The medicines on the list are arranged alphabetically by therapeutic category, from anesthetics to vitamins and minerals.

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\(^66\) The list is now on its 15\(^{th}\) edition, as of March 2007. A new proposal suggests a more specific pediatric list of EMs.
Given this brief description, might the Essential Medicines Model List provide a firm foundation for delimiting the content of a right to access to essential medicines? On the one hand, it is an astounding achievement. First, that an expert committee can come to a consensus about essential medicines for minimum health care needs is no trivial matter. Second, the Model List is committed to an evidence-based approach regarding drug safety and efficacy, as well as cost effectiveness. Third, the Model List’s revisions – including revisions to the procedures used to update the List itself – reflect a sort of “dynamism.” For example, the 2001 revised procedure for updating the Model List explicitly states that absolute cost alone should not exclude a medicine from the list; the inclusion of antiretrovirals in 2005 is thus noteworthy. Some debate currently exists as to whether cholesterol lowering drugs (i.e., statins) might appear on the future Model Lists. Fourth, the selection procedures are reasonably transparent and allow for the input of observers and patient advocacy groups (though they are excluded from decision-making parts). These features all suggest an institution that has the potential to delimit a right to access to essential medicines.

On the other hand, certain features argue against the use of the Model List to delimit this right, at least as the List is currently produced. First, while it represents a comprehensive, model list that individual nations can implement individually (based on their individual needs), it was not ever meant to be a “global” standard. Yet this is
exactly what the human rights enterprise needs. The Model List does not reference human rights, though others have attempted to use it in the human rights context (Hogerzeil, 2006, Seuba, 2006). Second, even if it had not intended to be a global standard, the content reveals that it almost assuredly is not. Its content is overly expansive; for example, the inclusion of ranitidine for use as an antacid or of the radiocontrast agent barium sulfate for upper gastrointestinal imaging appear to stretch intuitive notions of “essential” medicines from a human rights perspective. Third, the role of cost remains a subject of much debate (particularly because cost relates to the means used to produce drugs in the first place, as I have already noted). Fourth, the procedures would need to be more transparent or inclusive, allowing more than an Expert Committee for decision-making and more input from others – i.e., a broader vision of the “public reason” about human rights emphasized by Amartya Sen at the beginning of this chapter.

A fifth reason the WHO Model List is insufficient for delimiting the content of the right of essential medicines is somewhat paradoxical. Although I have just noted that the list is overly expansive – including medicines that stretch the notion of essential – it is also overly narrow. This is because it is concerned only with categorizing drugs currently in existence. As should be clear from the above explanation of James Nickel’s

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67 It could be that the list is expansive because the WHO’s own definition of health is expansive, as a state of “complete physical, mental, and social well-being.” See http://www.who.int. Accessed 10 March 2007.
approach to a right to adequate nutrition, delimiting the content of the right to essential medicines involves much more than simply listing the medicines themselves. Just as a right to adequate nutrition might require duties related to the efficient use of land resources, part of the right to essential medicines might require duties related to the efficient production of essential medicines themselves. The WHO List alone does not do this.

In sum, the WHO Model List provides an example of institutional innovation or design as a way to delimit the right to essential medicines. But it is not a fully articulated or justified one, because it does not attempt to be and because it lacks certain institutional characteristics necessary to serve in this role. Without offering more details on these characteristics, this conclusion is nonetheless important: It prevents inferences from the Model List to the specific content of a right to essential medicines and also calls for institutional modification or creation to help fill out the content of this right.

4.4 The Right to Access to Essential Medicines is Currently Being Underfulfilled

For those readers who hoped for me to provide a clear definition of “essential” medicines, the last section might appear unsatisfactory. I hinted at a process by which such a definition might arise but did not give any clear definition. If pressed, I would
suggest that essential medicines are likely to be found on the WHO List, but that not all the medicines on the WHO Model List are, strictly speaking, essential medicines (EMs).

(Un)fortunately, as this section points out, the absence of a perfectly clear definition of EMs is not absolutely necessary. This is because, by almost any measure, global inequalities in health regarding access to EMs are so extreme that much progress can be made without fully delineating the concept of EMs. In this section, I argue broadly that the right to access to essential medicines is currently being violated and that remediation is necessary. To do so, I argue for stretching the notion of human rights in three ways. First, I endorse a line of argument that sees violations of human rights as “systematic disadvantage,” rather than direct typical notions of “harm.” Second, I argue in a qualified way against the well-accepted lexical ordering of the assignees of human rights. Third, I argue that taking the human rights notion of “subject-centered” (Buchanan, 1990) justice seriously should have important implications for how rights are fulfilled. This section therefore returns to the debate over IPRs and access to EMs, drawing on these key elements of human rights.

4.4.1 Harm as Systematic Disadvantage

Supposing a right to access to essential medicines exists, how would we know if it were being violated? One could be led, drawing on analogies with other traditional or widely accepted human rights, to believe that an answer to this question lies at least
partly in a determination of individual harm. For example, evidence of individual harm – as groups like Physicians for Human Rights have done for decades – seems adequate for demonstrating violations of the right against torture or genocide.\footnote{See, for example, the PHR recent report on genocide in Darfur (Physicians for Human Rights, 2006) or its landmark report on chemical weapons in Iraq during the 1980s (Physicians for Human Rights, 1989).} For rights like this, even a single case of individual harm would appear to justify a judgment of a human rights violation (even if multiple cases represent a more serious violation).

Applying a similar approach to essential medicines would imply we ought to similarly look for individual cases of “harm,” where harm relates to individuals lacking access to essential medicine. However, this is not the approach I shall endorse, because traditional understandings of harm are both too broad and too narrow for investigating the right to access to essential medicines.

“Harm” is too broad a notion for EMs because demonstrating that a single individual was “harmed” by lacking access to a particular EM (e.g., penicillin) and that therefore her right was violated seems overly demanding. Suppose, for example, that this individual decided that penicillin was too expensive, electing instead to spend her available funds fulfilling a different interest, such as in a recreational activity. We might agree that her health was “harmed” in some way if the bacterial infection necessitating the penicillin worsens. Yet this does not seem to amount to a violation of the right to
access to EMs, unlike the case of torture (where demonstration of harm are somewhat more definitive).

Paradoxically, “harm” is also too narrow for a right to EMs for two different reasons. The first reason relates to the historical notion of harm where individuals around the world might actually, on the whole, better off now than 200 years ago (Risse, 2005). If this is true, it seems strange to discuss directly harming individuals.\(^{69}\) The second reason relates to the idea that “harm” does not adequately capture all the ways a right can be violated even without clear individual “harm.” Or, stated somewhat differently, “harm” fails to capture how institutional reform could make individuals better off than they otherwise would have been by giving them more secure access to basic rights. It is this latter point on which I will dwell, replacing “harm” with the more appropriate concept, “systematic disadvantage” (Powers and Faden, 2006).\(^{70}\)

Therefore, to answer my original question about violating the human right to access to EMs, two key features of my sketch of human rights are critical: (i) an institutional understanding of human rights (Pogge, 2002) and (ii) a commitment to minimal equality (Buchanan, 2005).

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\(^{69}\) Pogge (2002) takes such a harm-based approach, against which I argued above.  
\(^{70}\) Truth be told, I consider that “systematic disadvantage” suffices to adequately capture most human rights, even if “harm” serves as a proxy for the violation of certain rights.
The institutional understanding of human right I endorse recognizes that not all instances of preventable harms in the domain of a particular right are appropriately considered human right violations. As Pogge (2002) notes, the observation that a death was preventable (for example, with a particular medical technology) does not necessarily mean that a human right was violated when that death occurs. Similarly, the observation that an individual lacks access to a particular essential medicine does not necessarily mean that her human right to access to EMs was violated. On an institutional understanding of human rights, the key concept is “how social institutions relate to basic-good shortfalls” (Pogge, 2002:47).

The commitment to a minimal equality further expands this point. Earlier, I quoted Allen Buchanan’s description of minimally egalitarian view of human rights:

...honoring the commitment to human rights does not require anything approaching equality of condition or outcome for all human beings, nor even that all human beings actually have decent lives; instead, it only requires that all have the opportunity for a decent life. In fact, the Modest Objectivist View does not even require equality of opportunity for a decent life strictly speaking. It requires neither that everyone is to have the same probability of achieving a decent life nor that the costs to each of realizing that opportunity must be the same. Instead, what is required is that no one is to face unduly burdensome obstacles to having a decent life, if he or she chooses to try to have such a life. (Buchanan, 2005:74-5, emphasis added)

If we apply this feature of human rights to EMs, we should recognize that on an institutional, minimally egalitarian view, we should not search for individual “harm” as much as we should examine whether the workings of social institutions create undue
burdens for accessing essential medicines. Individual cases will be important as evidence for how social institutions work, but are not themselves fully constitutive of rights violations.

Together, this concepts suggest that we are looking for what Powers and Faden call “systematic patterns of disadvantage” (Powers and Faden, 2006:79) regarding EMs as one of the minimally essential components of well-being. Thomas Pogge, along similar lines (though somewhat in contradiction with his focus on the “duty not to harm”) suggests thinking in terms of “non-fulfillment or underfulfillment, rather than violation of human rights” (Pogge, 2002:47). This idea is reflected by those engaged in human rights activities. As Paul Farmer writes

> Human rights violations are not accidents; they are not random in distribution or effect. Rights violations are, rather, symptoms of deeper pathologies of power and are linked intimately to the social conditions that so often determine who will suffer abuse and who will be shielded from harm (Farmer, 2005:7).

However, the advantage of employing a concept of “systematic disadvantage” is not only that it comports well with the views of human rights activists. More than that, it best makes sense of the distributive problems discussed at length in Chapter 3 to imply that the right to access to essential medicines is currently unfulfilled.

Seen through the lens of human rights, the following statistics support a charge of “systematic disadvantage” against the current global medical research and development enterprise:
• Though statistics are difficult to obtain, estimates commonly suggest that 2 billion people (one-third of the world’s population) lack secure access to essential medicines. Even if this number were too high, imagining it to be so far off as to motivate changing our practical judgments appears unlikely.

• Only 10% of health R&D spending goes toward health problems affecting 90% of the world’s population, creating the “90/10 gap.”

• From 1975-1999, 16 of 1393 new molecular entities were for tropical diseases or tuberculosis (Trouiller, et al., 2002).

• According to Oxfam, in 2001, “less than 1% of U.S. patents were granted to applicants from developing countries, nearly 60% of which were from seven of the more technologically advanced developing countries.”

On harm-based views of human rights violations, it might be problematic to use such statistics in support of a charge of a rights violation. On the more plausible “systematic disadvantage” view, however, asserting that global medical R&D systematically disadvantages the needs of the poor, particularly in developing countries.

71 This common statistic traces originally to (Commission on Health Research for Development, 1990). The actual gap identified was closer to 95/5.
This charge is reinforced by the increasing globalization of IPRs enforced through the World Trade Organization. In other words, WTO members now share a common institution that creates this systematic disadvantage. (I note this because, were IPRs not part of a global institution, the charge of systematic disadvantage could be more difficult to substantiate.)

In sum, the concept of “systematic disadvantage” in conjunction with the key institutional and minimally egalitarian views of human rights gives reason to consider the current medical innovation system as a hindrance to the fulfillment of the basic human right to essential medicines. This is the first important step toward reform, but others remain. Who must act to remediate this situation? What must be done?

4.4.2 States as Primary Assignees of Human Rights

On the traditional understanding of human rights, the “who” question is answered by examining the lexical ordering of duties generated by human rights. James Nickel (2005) describes this ordering as follows:

(1) governments are the primary addressees of the human rights of their residents, with duties both to respect and to uphold their human rights; (2) governments have negative duties to respect the rights of people from other countries; (3) individuals have negative responsibilities to respect the human rights of people at home and abroad; (4) individuals have responsibilities as voters and citizens to promote human rights in their own country; (5) governments, international organizations and individuals have back-up responsibilities for the fulfillment of human rights around the world. (Nickel, 2005 396)
This appears to be the traditional understanding of the lexical ordering of duties arising from human rights. A radically different view appears in Pogge (2002):

Human rights are not supposed to regulate what government officials must do or refrain from doing, but are to govern how all of us together ought to design the basic rules of our common life. (Pogge, 2002 47)

The view of human rights I endorse lies somewhere in between these two, drawing on one of the earlier key features of human right: the capacity to assign feasible concrete duties.

Understanding the caveats I apply to Nickel’s lexical ordering helps set the context for how my view stretches conventional views of how to assign duties based on human rights.73

First, in accord with his general conception of human rights, Nickel adheres to the legalistic pedigree of human rights. By “legalist pedigree” I mean the idea that human rights are, by necessity, human legal rights established by the treaties and laws of national governments. Because of this, making national governments the “primary assignee” of human rights seems reasonable. However, we should not take this too seriously, especially in the context of vast inequalities in global health and resource poor countries. For most developing countries, simply affirming that their national

73 Nickel might agree with some of these caveats, though he is not very clear on these points.
government is the primary addressee is not likely to go very far in making substantial progress on access to essential medicines.

Second, as stated, the lexical ordering ignores morally relevant considerations that work not only to assign duties, but also to ensure the burdens of the duties are shared in morally justifiable ways. Examples of the types of considerations that could help assign concrete duties include the role of particular institutions in causing or contributing to human rights (under)fulfillment, as well as the capacity of particular institutions to aid in fulfilling human rights (Barry and Raworth, 2002). If a non-governmental organization or individual is centrally involved in a particular rights violation, it seems odd to require a (potentially powerless or resource poor) national government to bear the burden of stopping the violation.

This second concern relates to the third: Globalization and features of the present global basic structure (or international order) makes assigning obligations primarily to individual countries increasingly problematic. For example, when it comes to the effect of global IPR rules on access to essential medicines, one might wonder why so many developing countries signed on to the TRIPS Agreement thought to be so detrimental. As Thomas Pogge (Pogge, 2007) points out, citing several other sources, developing countries were hindered by a lack of technical expertise, an already low bargaining position as a result of their low resource status, and national leaders in whose interest it
might have been to sign on (even if it were not in the general interest of their general population). The observation that the TRIPS Agreement was itself driven by a select few industrial leaders from developed countries might further support a retreat from nations as the primary assignees in all cases (Sell, 2003).

At the same time, the increasing power of non-governmental organizations and foundations could make assigning human rights obligations to them more plausible. For example, the Bill & Melinda Gates Foundation, with an 2006 endowment of nearly US$35 billion, must by law donate nearly US$1.5 billion per year (their global health budget is only part of this amount). By comparison, the 2005 total GDP of Haiti was US$4.2 billion. Indeed, recent scholarship has focused on the need to consider more systematically the human rights obligations of non-state actors (Clapham, 2006, Joseph, 2003).

Fourth, and lastly, Nickel’s view of the assignment of duties privileges negative duties in a way that I have already questioned.

Therefore, whether Nickel intends to or not, taking his lexical ordering at face value implies an unjustifiable hierarchy of duties that ignores other morally relevant characteristics, is unduly dependent on a legal notion of human rights, and privileges

the responsibility of national governments in the face of ever more powerful non-state actors.

What does this imply? Surely it does not mean removing entirely the role of national governments as the primary assignees for human rights in all cases. Instead, it implies a need to think beyond states to international organizations and other institutions as assignees for the duties arising from human rights. For example, to the extent that private interests can be shown to have disproportionate influence on the shaping of public laws, such as TRIPS, that fundamentally impact the global basic structure, these interests might also be held accountable to human rights standards – not necessarily as “violators” per se, but as explicit duty-bearers to help fulfill basic human rights affected by their actions.

4.4.3 Remediation for Human Rights Underfulfillment: Meeting the Minimum Threshold

The prior two sections addressed the “what” and the “who” questions about fulfilling the right to access to essential medicine. They suggested that the basic human right to access to EMs is currently not being fulfilled (the “what” question, answered in terms of “systematic disadvantage”) and that we ought not look only to states in assigning duties related to this right (the “who” question, answered in terms of the increasing power of non-state actors). This final section asks the “how” question in an
equally general way. The feature of human rights playing a prominent role here is the concept of “subject-centered” justice (Buchanan, 1990).

It is a distinct advantage of human rights that they are “subject-centered.”

Subject-centered justice, as defined by Buchanan, resonates with human rights:

According to subject-centered conceptions, basic rights to resources are grounded not in the individual’s strategic capacities but rather in other features of the individual herself—her needs or nonstrategic capacities. The term ‘subject-centered’ seems apt since it serves to emphasize that moral status depends on features of the individual herself other than her powers to affect others for good or for ill. (Buchanan, 1990 231)

But what is the upshot of a subject-centered view of justice, such as a human rights view? As I will now start to argue (but will necessarily continue into the next section, and the next chapter), a human rights, subject-centered view of justice should have profound implications for how to fulfill the human right to access to essential medicines.

Perhaps an analogy with the human right to an adequate level of nutrition would be helpful to set the context. Does the human right to adequate nutrition say anything about how that right is fulfilled, for example, whether through food donation or through encouragement of development of sustainable, locally-sensitive agricultural practices? On the traditional account of human rights, emphasizing only “sufficiency thresholds,” these appear to be morally equivalent alternatives. Nonetheless, intuitively the two scenarios seem different. What explains this difference? One difference is that the latter solution arguably does a better job at enhancing the freedoms of those who develop
These local practices, which could perhaps lead to vertical movement above the minimal threshold over the long run. But is this difference explained by human rights?

On my view, this difference is explained by human rights. Two issues are important in arguing this point. The first is that contemporary human rights theory’s focus on “sufficiency,” “minimal thresholds,” or “minimal egalitarianism” can, without further reflection, inhibit how we think about human rights. This emphasis can have the unfortunate side effect of paying little attention to how one attains the sufficiency threshold (and the implications of how one gets to sufficiency for eventually moving beyond sufficiency). In other words, the concepts important to the justification and significance of human rights might impede how we think about reaching a “basic minimum,” if it implies that reaching the minimum is all that matters.

Fortunately, elements of an emphasis on the “means” are not necessarily left out of human right theorizing as much as they are undeveloped. These elements are implicated, for example, when James Nickel (2007) asserts that his abstract moral claims provide a ground for “human dignity,” though he does not elaborate fully on its import. They also are suggested in Powers and Faden’s (2006) emphasis on self- and other-regarding respect as essential parts of human well-being – an emphasis that is quickly lost when they return to their sufficiency view. In other words, the task of justifying the basic minimum – important though it is – leaves out an important dimension of human
rights: the way people ought to be treated, or how individuals relate to each other even as their rights are “fulfilled,” as one aspect of the “human dignity” reflected in all major human rights documents.

This dimension is reflected more concretely in the second important issue: A subject-centered, human rights view could tell us that certain practical solutions for fulfilling human rights are not morally preferred because they take the wrong stance toward the “subjects” of justice, and not only because they are “ineffective.”

The issue of “charity” illustrates this point nicely. Often, discussions of global distributive justice issue proceed as if the choice of remediating global health inequalities is one of “justice” versus “charity” (or “assistance”). These discussions might draw lines between amelioration of deprivation through “charity” (such as through income redistribution or, in the present context, donation of medicines to better fulfill human rights) and remediation through “justice” (such as through changing the institutional structure to better enable the fulfillment of human rights). John Rawls (1999), for example, famously argued for duties of assistance to aid other nations to the point where they could more effectively govern themselves. Typically, those who argue against a “charity” approach make one of two claims.
The first claim is that charity would be ineffective because it is, empirically, unlikely to work. Nickel endorses this approach to a certain extent in a passage where he quotes John Stuart Mill:

…mutual assistance is certainly to be encouraged, but offers little prospect of providing adequately for all of the needy and incapacitates if it is viewed as a substitute for, rather than a supplement to, politically implemented economic and social rights…There are often too few donors for the needs present…This spottiness was noted by John Stuart Mill. He remarked that ‘Charity almost always does too much or too little: it lavishes bounty in one place and leaves people to starve in another’. (Nickel, 2005 397)

On this view, charity is insufficient as an approach to human rights fulfillment because it is unlikely to work or would be inefficient. This is not a uniquely “moral” argument against charity; were the facts of charity to change, we might be convinced to pursue charity.

A second claim is more overtly moral. It argues similarly that charity would be ineffective, but this time because duties of charity are necessarily “voluntary” or “less stringent” than duties of justice. Sometimes this distinction is expressed as a distinction between “perfect” duties of justice (which have a very specific content – such as the duty not to torture) and “imperfect” duties of justice (which have a relatively less specific content or might be fulfilled in multiple ways). The distinction, however, is one of content, not of stringency. Imperfect duties might be just as stringent that something must be done, though they might in certain circumstances be less specific regarding what must be done (Buchanan, 1987).
This view of charity as morally impotent to effect change of the sort that could be implied by a right to the conditions necessary for a minimally decent human life is now rejected. In a landmark article, Allen Buchanan argues convincingly that a system of coercively enforced beneficence could be both justified and effective at implementing a basic minimum of health care (Buchanan, 1984). Moreover, this system could be justified even if the basic minimum were not understood as a “universal right.”

Taken together, these two claims initially suggest that we have little reason to reject “charity” as a means of human rights fulfillment. However, on my account, understanding human rights as “subject-centered” principles of justice does give us reason to be skeptical of charity as the preferred means to fulfill human rights. On this subject-centered view, charity is insufficient – not because it is unlikely, ineffective, inefficient, or not sufficiently stringent – but because it is the wrong kind of solution. It takes the wrong stance relational stance toward the subjects of justice, i.e., individual human beings with their individual human rights. ⁷⁵

Why does charity take the “wrong stance” toward the subjects of justice? (In what follows, I use the phrase “charity alone” to emphasize that I do not object to charitable giving per se, but to an exclusive focus on charitable giving. Charity will, by all accounts, play some role in fulfilling basic human rights, though not the only role.)

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⁷⁵ This would seem to require being able to distinguish between charity and justice in practical terms.
One reason might be that the implementation of “charity alone” could foster, or be perceived as fostering, a relationship of dependency between its recipients and those who engage in charity. For example, Sreenivasan’s (2002) proposal about the redistribution of 1% of GDP from wealthy to impoverished countries could be seen broadly as a kind of “charity” (in spite of his statements to the contrary). Even though Sreenivasan would never consider this proposal as the only requirement of justice, what can be said is that insofar as this type of proposal fosters a “dependency” on outside resource transfers, human rights are not adequately fulfilled. The theory of human rights as a subject-centered, institutional view should, at the very least, look skeptically at such proposals (e.g., through the lens of human dignity or notions of self- and other-regarding respect).

A second reason is that “charity alone” often does little to facilitate vertical movement above the minimal thresholds of well-being defined by human rights (and if it does do so, only in an indirect way). What a tragedy it would be, for example, if our efforts to charitably provide essential medicines to resource-poor countries in a charitable way (i.e., through donations) did nothing to allow individuals to move beyond the minimal threshold of a basic human right to health (or, what’s worse, actually prevented the types of changes that would facilitate fulfillment of this right). A
proper understanding of human rights should prevent this narrow minded focus on meeting the threshold alone.

Finally, a third reason to be wary of “charity alone” is that it fails to recognize the uniquely structural nature and causes of human rights underfulfillment, which is understood as systematic disadvantage. Consider an analogy with another accepted human right, the right against domestic violence perpetrated by men against women. In this domain, “charity alone” solutions could be construed broadly as fulfilling this right through free legal services to putative victims of domestic violence; sufficient resources devoted to police for the cessation or investigation of domestic violence; and adequate punishment of convicted offenders. The use of the phrase “charity” in this context might appear awkward but is more clearly delineated by what it is not: an effort to address the underlying social determinants of male-female power relations that cause such violence in the first place. A subject-centered, human rights view on my account will not see the right against domestic violence fulfilled unless these other structural determinants are addressed. A subject-centered view sees it as important to deal with the underlying causes of the underfulfillment of human rights, not just its symptoms. I want to make a similar claim for the fulfillment of the basic human right to health (of which access to essential medicines is one part).
In sum, a subject-centered, human rights view that takes seriously the fundamental moral equality of persons understands that this means treating persons in certain ways and not others. Not only does this have implications from the perspective of moral theory – implying as it does that certain actions toward others are done for the right reasons – but it also has implications for the practical measures undertaken in its name. To be sure, I have not clearly elaborated what counts as charity, or whether one can clearly delineate “charity” from “justice.” Doing so requires attention to real, practical proposals for fulfilling the right to access to essential medicines. It is with this task that I close the present chapter and begin the next.

4.5 Human Rights and IPRs

This chapter has, like Chapter 3, traveled a long path, at times taking extended philosophical detours away from the specific issue of access to essential medicines and global distributive justice. It has argued first that disagreement about global distributive justice is often exaggerated, particularly in the face of widespread agreement about basic human rights. Importantly, however, this widespread agreement is not crucial for my overall argument, so long as conceptions of basic human rights are themselves well-justified. To this end, I argued second that well justified theoretical conceptions of human rights do exist, and philosophical work continually improves these conceptions. Following these conceptions, I argued third in favor of a basic human right to health,
and that access to essential medicines represents one part of this right. Moreover, I argued that the present state of access to these medicines, when seen through the lens of human rights, suggests that this right is currently being violated.

The last sections (4.4.2 and 4.4.3) started the difficult task of specifying the duties that might arise, given this situation. On the subject-centered view of justice endorsed by human rights, I suggested that certain solutions might be morally preferable (especially regarding “charity”); I also noted that making this type of determination requires more work. This is the specific task of Chapter 5.

Before proceeding, however, I reflect briefly on two important issues. The first is an explicit return to the distributive problems of Chapter 3. The second is a brief discussion of a recent policy proposal regarding essential medicines and human rights, which better sets the context for Chapter 5.

4.5.1 Returning to the Distributive Problems of Chapter 3

Recall that one goal of this chapter was to provide a normative justification for modifying the present global IPR regime. The three distributive problems of Chapter 3 - develop first, distribute later; types of innovations; and the distribution of IPR ownership – can now be seen in a new light: They represent symptoms of a global medical R&D system that systematically disadvantages certain groups when it comes to
the basic human right to health. In other words, the present medical R&D system can be seen a playing a large role (though not the only role) in the global underfulfillment of the right to health, of which access to essential medicines (both current and future medicines) is one part. With this in mind, attempts at modifying the global IPR regime ought to keep all three of these problems in mind.

One of the three, however, appears out of place: the distribution of IPR ownership. To the extent that we are concerned with access to EMs, why should it matter whether the owners of IPRs are within wealthy developed countries or more evenly distributed among wealthy and resource poor countries alike? What if it is more efficient to fulfill the right EMs via one hugely powerful IPR owner in a developed country? One reason could be prudential: IPR owners might be more likely to engage in research and development on diseases priorities of particular interest to their compatriots, helping ensure that the types of innovations produced are relevant to their needs. This could be an important part of fulfilling a right to EMs. A second reason is normative: Insofar as ownership of IPRs (or something like intellectual property, though not necessarily in its current form) is partly constitutive of a minimally decent human life, balancing this right with the most efficient means of ensuring secure access to essential medicines could be necessary. Related to this is a third normative reason: To the extent that IPR ownership (or something like it, remembering to privilege “rights”)

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exists within resource poor countries, it could be a signal that “charity” in the skeptical sense described above is not occurring. It could, in other words, be evidence of “capacity building” for sustainable development in these countries. These points receive further elaboration in Chapter 5, but it is perhaps important to hint at them now.

4.5.2 Thomas Pogge’s Proposal for IPR Reform

To what extent do current proposals for IPR reform for the sake of access to essential medicines exhibit the characteristics of subject-centered justice and human rights this chapter describes? In order to see how they do not, I examine a recent proposal from Thomas Pogge on patent reform (Pogge, 2005).

Recall that Thomas Pogge endorses an institutional human rights view of global justice. From this, Pogge (2005) proposes modifying the existing IPR regime to include a voluntary alternative patent category whose “reward” is not a monopolistic right to make and sell what the patent covers. Instead, the reward is based on the global health impact of the product. One distinct advantage of this proposal is that generic production of medicines can occur immediately (thereby benefiting from competitive pricing), with the incentive structure set up to encourage wide distribution (the wider the distribution, the greater the global health impact – and the greater the reward).

I am deeply sympathetic with this real world (and potentially feasible) proposal for improving access to essential medicines. And while I consider it and similar
proposals in the next chapter, several preliminary features of this proposal are worth noting in how it relates to a human rights focused normative view. First, his proposal assumes (but does not elaborate on) a right to access to essential medicines as its normative foundation. While the present chapter begins filling in the normative foundations of this right, more work clearly remains to successfully delineate it. Second, what is also absent from the proposal is a clear account of how and why its content, or even its motivation, depends upon human rights. As Pogge himself acknowledges, the proposal might also be justified on prudential grounds; or, as I would argue, on utilitarian, prioritarian, or any number of other normative theories. Does this matter? On the one hand, it could be advantageous, skirting deep-seated normative disagreement about justice. On the other hand, it could be dangerous. If the line of argument I am pursuing has any merit, a human rights, subject-centered view of global justice ought to have serious implications for how a human rights are fulfilled. For example, Pogge’s proposal, without additional clarification, ignores the issue of who owns the IPRs in question, and it focuses on access to the medicines of the future (rather than the effective medicines we already have). Therefore, while it is a start, it fails to take seriously what could be the real import of a human rights centered view of global distributive justice and access to EMs; namely, its ability to constrain the types of
solutions pursued for its sake. Why not pursue a more direct relationship between a subject-centered normative view and its practical implications?

With this in mind, the next chapter considers real world proposals, based on a human right to access to essential medicines, of modifying or amending the current IPR regime to better effect global distributive justice.
CHAPTER 5. How Normative Analysis Contribute to IPR Reform Strategies

The three prior chapters elaborated the normative issues associated with intellectual property rights, essential medicines, and global distributive justice. Chapter 2, for example, argued that the debate over intellectual property rights is normative, not just empirical, and suggested several normative aspects of the debate (e.g., costs and benefits, how to weigh them, how they are distributed, etc.). Chapter 3 argued that IPRs – a pillar of the contemporary medical innovation system – both require normative justification and create three distributive problems (“develop first, distribute later”; types of innovation; and ownership of IPRs). Finally, chapter 4 argued in favor a human right to a basic minimum of health (of which access to essential medicines is one part) and suggested that the present medical innovation system currently works to underfulfill this right. Chapter 4 therefore argued that we have good reason to consider modifying the present medical R&D system.

Chapter 5 re-engages with more directly practical concerns. The question is: What can the normative elements developed in the prior three chapters tell us about how to modify the current system? Do these normative concerns offer any “practical upshot” for what ought to be done? Not surprisingly, they do. In fact, taking the normative framework of basic human rights and global distributive justice seriously offers broad conclusions about the kinds of solutions that ought to be pursued. By way of a preview, here are the conclusions to which this chapter arrives – each of which
connects directly to the normative concerns about the distributive impact of IPRs and the present IPR regime.

First, as implied by the prior chapter, it is generally critical of IPR reforms that address the first distributive problem in the wrong way. For example, systematic pharmaceutical donation programs could solve the problem of access to medicines by freely donating otherwise expensive medicines (as result of monopoly pricing power). Although any worthwhile solution to the problem of access to EMs will undoubtedly involve donation at some level, to focus solely on charitable donation takes the wrong normative stance toward the subjects of justice. If access to essential medicines is a human rights issue, solutions to the problem of affordable medicines require innovative, thoughtful solutions that recognize this problem as one of justice, not charity. This is the first distributive problem at work: “develop first, distribute later.”

Second, this chapter is critical of IPR reforms that do not acknowledge the failure of current medical R&D to create medicines for neglected diseases. Donation programs provide a somewhat obvious example of this failure because these programs can donate only what the traditional medical R&D system produces. However, drug donation programs turn out not to be the only example of a reform option that fails in this way. This is the second distributive problem at work: a skewed distribution of the “types” of innovation produced.

Third, this chapter is critical of solutions that fail to include a large role for capacity building. The unequal distribution of IPR ownership, with entities in developed countries owning much of the world’s IP, indicates a need for capacity
building in developing ones. “Capacity building” could be important for at least two reasons. First, unlike purely charitable donation programs, capacity building takes a more appropriate normative stance toward the subjects of justice by reducing dependency. This is because it emphasizes the role individuals and communities play in solving their own health problems (rather than depending on others to donate medicines on their behalf). Capacity building thus enables a certain kind of freedom.

Second, “capacity building” is reemphasized by certain views of intellectual property (see chapter 3) that consider IP as itself a vital human interest, as many do.¹ This is the third distributive problem at work: unequal ownership of IPRs.

In what follows, I demonstrate the impact of these evaluative criteria and several others on some of the recent IPR reform proposals in the area of access to essential medicines. After some important caveats (section 5.1), I introduce the proposals themselves (5.2) and the evaluative criteria in more detail (5.3). In section 5.4, I explain briefly how the evaluation works. Following on this, section 5.5 examines the main advantages and disadvantages of several of the proposals. Some provisional conclusions about the prospect of moving forward finish the chapter in section 5.6.

¹ I do not endorse such a view, particularly if it is understood that humans have a right to IPRs as currently envisioned. One must be careful, lest we become trapped in pursuing the availability of IPRs at the expense of other rights, like the one to health, particularly when some minimum of health appears necessary enjoy anything like a right to property. In addition, it is unclear why the current IPR system would be the one that protects this vital human interest, as opposed to the other options considered in this chapter. Of course, balancing the “most efficient” means of producing essential medicines – which for a time might not occur via local capacity in developing countries – with the need to build capacity within developing countries could turn out to be a difficult tradeoff. This point becomes clearer as I consider specific examples of IPR reforms that lack this consideration.
5.1 Some Caveats

Several caveat are necessary before proceeding to consider in more detail specific IPR reforms.

First, in the case of almost every reform, one should recognize that I do not discuss them to recommend simply replacing the current IPR regime or abolishing it altogether. What is undoubtedly true is that some system of incentives for research and development is probably necessary; what is up for debate is whether this system should solely, or mainly, be comprised of exclusive intellectual property rights. It could be, for example, that a system specifically geared toward creating incentives for essential medicines is needed in addition to the present one. This caveat is necessary to avoid the unfair criticism that the reforms I discuss are “radical” or require throwing out the entire IPR system as it is presently known. However, one cannot take this too far: If the presence of the two systems together undermines the effectiveness of the “essential medicine” system – e.g., by reducing the political will or resources to enable the fulfillment of this human right – then we have good reason to worry about their justified coexistence.²

The second caveat is related to the first; it notes that one ought not assume from the start that one single proposal is likely to work. In other words, in what follows I do not discuss the different IPR reforms with an eye toward finding the single “best” normative and/or practical idea. For various reasons, some combination of the different

² I discuss this in more detail in the context of Pogge (2005).
proposals is likely to be preferable. First, the reforms operate at different levels of the innovation pipeline. Some are more “upstream” (e.g., directed grantmaking or advance market commitments) while others are more “downstream” (e.g., generic production at or near marginal cost). Second, achieving a fair distribution of the burdens of reform (i.e., the burdens of fulfilling this particular human right) might best be achieved through some combination of reforms. For example, suppose one ignored the other normative problems with a “charity alone,” drug donation-focused solution to the problem of access to EMs. Simply requiring pharmaceutical companies to create such donation programs appears prima facie to be an unfair distribution of the burdens necessary in fulfilling this human right.\(^3\)

Not only should one avoid assuming that one single reform is best, but also one should avoid leaping prematurely to the conclusion that any combination of reforms is “best.” This is the third major caveat. To assume that one unique, normatively preferred solution to the problem of EMs represents a kind of idealism that is to be avoided. The old adage not to let the best be the enemy of the good captures part of this point, but not the whole of it: The idea is not simply that real progress could occur by retreating from an idealistic or utopian vision. Instead, if we understand human rights as reasonable access to the minimal thresholds of well-being, we could find ourselves in the position of choosing among different reform “solution sets” – all of which pass some “minimal threshold” test. If this is the case, we might decide that the best solution to

\(^3\) Truth be told, the situation is more complicated: The burdens of drug donation programs are at least partially offset by the tax benefits that facilitate them and the public relations benefits accruing to the companies who participate.
pursue is that which both passes some minimalist test and is most feasible or likely to be implemented.

With these in hand, I now consider some current reform proposals for increasing access to essential medicines.

5.2 Current IPR Reform Proposals

What options are available to reform IPRs for the sake of increased access to essential medicines? In this section I introduce several different proposals in preparation for evaluating them further in section 5.3. To be sure, space does not permit the consideration of all possible reform proposals. However, in what follows I attempt to enumerate at least a representative sample. Doing so permits drawing general conclusions that might apply to similar reform proposals.

Table 1 lists the proposals framed around whether they represent “new” or “alternative” visions of intellectual property rights, or whether they represent “modifications” or “traditional” visions of intellectual property rights (i.e., patents). This general feature occurs along a spectrum, and as a mere heuristic, it should not be taken overly seriously. On the one hand, it could be that reforms closer in line with the “traditional” view are more feasible in the near terms. On the other hand, no clear reason exists to assume this from the start. It is also worth noting that certain proposals – such as targeted grantmaking, advance market commitments, and limiting patents in poor countries – do not fit cleanly into either of these. For targeted grantmaking and
advance market commitments, this is because contracts often arise between the grantor and the grantee (or as a condition of the market commitment) that help determine the IPR arrangements. For limiting patents in poor countries, this is because eschewing patents represents an “alternative” while at the same time it operates well within the current system (individual inventors can always choose not to patent in a particular country). In this section, I describe but try to refrain from fully analyzing the pros and cons of each proposals.

5.2.1 Proposals Within “Traditional” IPRs

The following reform proposals represent mechanisms meant to solve the access to EMs problem by working primarily within traditional IPRs.

*Drug Donation Programs.* As discussed in Chapter 4, an obvious means to increase access to essential medicines could be via donation programs or pharmaceutical assistance. For example, in 1987, Merck began its Mectizan (ivermectine) Donation Program for the treatment of onchocerciasis (river blindness). This program has become regarded as “one of the foremost examples of a public/private partnership in international health, treating more than 25 million people annually” (Collins, 2004:101). Importantly, the program’s success is partially enabled by highly profitable veterinary uses of the same drug, as well as the need for only once-yearly dosing. An example of a donation-type program not necessarily linked to a particular kind of medicine, such as
the RxAssist program sponsored by AstraZeneca. This program provides free or low-cost medicines to individuals who cannot afford them, and most pharmaceutical companies offer some kind of assistance program.

Drug donation or assistance programs have several key features worth noting. These include:

- The ability to provide free access to existing medicines, eliminating the price problem; and,
- The involvement of public and private entities to create programs and infrastructure necessary to implement the program.

_Differential Pricing (Danzon and Towse, 2003, Redwood, 2001) & Licensing_ (Kapczynski, et al., 2005). A second type of reform operating within traditional IPRs locates the access problem not in patents per se but in how those patents are used through drug pricing or the licensing of the product. To some, addressing these two options as a single one might appear awkward because their practical implementation would contain substantial differences; however, the underlying concept of dealing with the access problem post-patent is the same.

Regarding drug pricing, some have suggested that a good way of increasing access to essential medicines would be to institutionalize a differential pricing strategy

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The basic idea would be to segment markets between developed and developing countries, charging developed countries high prices and developing ones lower ones (perhaps even below the marginal cost of production). The key issue with differential pricing is whether the “below market” priced drugs can be insulated from the “normal market” prices (i.e., whether drugs could be bought in the developing country and sold at the higher prices in a developed one unscrupulously). Differential pricing already exists, of course, to some extent; else individuals in the U.S. would not be inclined to purchase their medicines from Canada where governmental price controls maintain lower prices (Davey, 16 September 2003). The question is whether this could be better institutionalized at the global level for access to essential medicines.

Regarding differential licensing arrangements, the basic idea would be to encourage or require patent holders to license their products differently depending on what the licensee will do with the product, and where. Two prominent examples of this kind of approach are the Equitable Access License (EAL) and the Neglected Disease License (Kapczynski, et al., 2005). Both licensing strategies focus on how universities could license their technologies to industry while including provisions that would allow for generic manufacturers in developing countries to sell (not just manufacture) the technology in those countries. These manufacturers would pay some small royalty (zero to six percent) to be divided between the university and the conventional industry licensee in developed countries (Kapczynski, et al., 2005). The Neglected Disease License takes a similar approach but allows worldwide use of the technology for
research (and eventually, development and sale) so long as the use relates to a “neglected disease.”

Differential pricing and licensing exhibit the following key characteristics:

• An ability to work with traditional exclusive IPRs while potentially enabling greater downstream access;
• Lower drug prices through either price setting (for differential pricing) or generic competition (for differential licensing); and,
• The differentiation between high-income and low-income countries for implementation purposes.

Implementing TRIPs Flexibilities (Correa, 2000). On some views, the current TRIPs Agreement contains enough “flexibilities” to substantially remove barriers to access to essential medicines. These TRIPs flexibilities, which must generally be incorporated into the national legislation of individual countries, include the use of parallel imports, compulsory licensing, early working exceptions (described below), experimental use, transition periods, and other important provisions. A full review of the intricacies and import of all these flexibilities is beyond the scope of this chapter, but focusing on one in particular helps clarify the importance of flexibilities.

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5 Another example of this sort of approach is the voluntary out-license. See (Friedman, et al., 2003).
Compulsory licensing (CL) has, in recent years, been the subject of much debate, though it is not at all new (Reichman and Hasenzahl, 2002). CL is “when a government allows someone else to produce the patented product or process without the consent of the patent owner,” with remuneration to the patent owner. At present, compulsory licensing is permitted in certain circumstances (to be determined by individual countries). Widely accepted uses include: “national emergencies,” “other circumstances of extreme urgency,” “public non-commercial use” (or “government use”), and as remedy for anti-competitive practices. For these cases, there is no need for a country to first attempt a voluntary license for generic production. Of critical import, the popular misconception that these uses represent the only permissible condition for compulsory license requires correction.

Importantly, in 2003, compulsory licensing became ever more feasible through what has become known as the WTO’s “Paragraph 6 decision.” Prior to 2003, it was unclear whether a CL could only be used for domestic manufacture, making CLs infeasible for countries without adequate manufacturing capacity. The 2003 decision allows for compulsory licenses to permit importation of drugs from other countries. Norway, Canada, and India have changed their national laws to allow exporting under such circumstances; before their laws permitted CL only for use in domestic markets.

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Again, without delving too deeply into a legal quagmire, suffice it to say that full implementation of TRIPs flexibilities could go a long way, though not all the way, to facilitating better access to medicines. Carlos Correa, for example, at one time proposed that essential medicines not be patentable subject matter (Correa, 2000). Adding weight to this are studies suggesting that developing countries truly do not make full use of these provisions. A recent study of 11 Latin American countries suggested just that (Oliveira, et al., 2004). Partially implemented flexibilities in different countries included the transition period for implementation; defining a patentable subject matter; full use of compulsory licensing; and the early working exception (i.e., the “Bolar provision,” which allows completion of procedures and tests necessary for registering a generic drug before a patent expires on that product).

Thus, substantial room apparently exists for better implementation of TRIPs flexibilities for public health and access to EMs. The key features of this strategy are

- Its consistency within current international law and WTO agreements;
- The ability to enable generic production of pharmaceuticals at lower cost;
- and,
- Substantial flexibility for different countries to create different national policies and laws.

*Industry Incentives (Vouchers, Patent Extensions).* Most of the reform strategies pursued here to some extent provide “industry incentives.” However, two proposals
worth noting appear to be industry incentives of a more direct type. These include a proposal to exchange neglected disease research for a U.S. FDA “Priority Review Voucher” (Ridley, et al., 2006) and the idea of Transferable Market Exclusivity (TME) (Bourgeois and Burns, 2001, International Federation of Pharmaceutical Manufacturers Associations, 2004, Kettler, 2000).

The proposal by Ridley et al. (2006) rewards a drug company who develops a treatment for a neglected disease that is approved by the U.S. FDA or the European Agency for the Evaluation of Medicinal Products. The treatment must be more effective than previous treatments, and at least one manufacturer must be found. If these conditions are met, the company agrees to forego patent rights on the treatment in exchange for a priority review voucher (i.e., faster review) at the U.S. FDA for one or more of its other drugs in development. They also allow for orphan drug tax credits. Because this would save, on average, one year of review time at the FDA, a voucher could enable more “on patent” time for a blockbuster drug in development (and faster access to such drugs in developed markets), thereby subsidizing the creation of the neglected disease treatment. (Importantly, the developing company could also sell the voucher to another company, subsidizing neglected disease development in a slightly different way.)

A more direct route to using extended exclusivity time to subsidize drugs for neglected diseases is “Transferable Market Exclusivity” (Bourgeois and Burns, 2001, International Federation of Pharmaceutical Manufacturers Associations, 2004, Kettler, 2000). Instead of using an FDA voucher, TME would allow a company who develops,
for example, a drug for leishmaniasis to extend market exclusivity on another of its
drugs or sell the exclusivity right to another company (International Federation of
Pharmaceutical Manufacturers Associations, 2004). This proposal is important in so far
as market exclusivity held in developing countries for such diseases would be
insufficient as an incentive to create them. If the numbers of Ridley et al. (2006) are
correct, extension of exclusivity by one year could be worth, on average, US$300 million.

These types of industry incentives have the following characteristics:

- The use of existing IPRs and market structures to stimulate the development
  of drugs for neglected diseases;
- The absence of direct public funding to subsidize the R&D on such diseases;
  and,
- The cost-sharing of such subsidies by consumers in developed countries who
  pay for other products.

*Patent Buy-Outs (Kremer, 1998, Outterson, 2006).* A different way of using
traditional IPRs to stimulate R&D without the untoward monopoly pricing effects is
Michael Kremer’s (1998) patent buy-out proposal. Based on the historical precedent of
the Daguerreotype patent, which was purchased and placed into the public domain by
the French government in 1839, Kremer proposes patent auctions where the government
buys patents at fair market value. At these auctions, the government does not
participate but instead buys the patent at the high bid (while occasionally allowing the
private high bidder to buy, in order to ensure the fidelity of the auction – in other words, some drugs would remain in the hands of private patent holders and subject to monopoly pricing).

The key features of the patent buy-out proposal as applied to medicines include (Baker, 2004):

- In most cases, the separation of medical R&D from the marketing and production of its products because patents become public;
- The need to determine “fair market value” in order to price a drug patent accordingly at the auction (i.e., how will fair market value change the incentives of what gets created?); and,
- A general absence of political interference, as auctions are “private” with the government acting as a bystander.

*Patent Pools (Merges, 1999).* A final reform that has begun circulating in the past several years is the idea of a patent pool geared toward essential medicines. A patent pool is

an arrangement among multiple patent holders to aggregate their patents. A typical pool makes all pooled patents available to each member of the pool. Pools also usually offer standard licensing terms to licensees who are not members of the pool. In addition, the typical patent pool allocates a portion of the licensing fees to each member according to a pre-set formula or procedure. (Merges, 1999 10-11)

Historically, one of the more well-known examples of a patent pool is the Manufacturer’s Aircraft Association of 1917, formed at the behest of Franklin D.
Roosevelt (Dykman, 1964). The two major patent holders at the time, the Wright-Martin Aircraft Corporation and the Curtiss-Burgess Airplane & Motor Corporation, Inc., could not agree upon reasonable royalties and licensing terms. This nearly blocked the manufacture of aircraft at a time when the U.S. government was quite interested in their production (for World War I). To this end, the federal government essentially stepped in and insisted upon the formation of a patent pool with fixed royalty rates to both corporations under threat of simply taking the patents. (Of course, patent pools can also be voluntary, not just imposed by the federal government.\textsuperscript{9})

How might a patent pool apply to essential medicines? Consider Essential Inventions, Inc., and its recent proposal for an Essential Patent Pool for AIDS. Under this proposal, a non-profit entity, the EPPA, would identify patent relevant to HIV/AIDS treatment and request voluntary licensing to the pool for use in low-income countries. If a voluntary license is not obtained, a compulsory license would be sought. Licensees also agree to “grantback” any rights obtained through use of EPPA patents. Although the EPPA, were it formed, would seek to pool all patents necessary for HIV/AIDS treatment and prevention, of particular interest might be the use of multiple patents to create fixed dose combinations (FDCs) and products that for one reason or another are currently unsuitable for low income settings (e.g., the HIV drug Fuzeon, which requires sterile water for mixing, refrigeration once mixed, and then subcutaneous injection).\textsuperscript{10}


\textsuperscript{10} For more information, see http://www.essentialinventions.org/docs/eppa/. Accessed 10 March 2007. The website includes information on a tentative list of patents to be sought. Of note, others incorporate the idea
Patent pools thus represent

- A novel approach to access to essential medicines that would lower
transaction costs between patent owners;
- A historically useful tool for certain situations, as shown in the airplane
industry; and,
- Depending on licensing terms, a way to separate the innovation process from
the manufacturing one, lowering costs of medicines.

5.2.2 Proposals that Represent Both “Traditional” and “Alternatives” to
IPRs

The next two reforms represent mechanisms that operate at the interface between
the admittedly blurry distinction between “traditional” and “alternatives” to IPRs.

Targeted Grantmaking and Advance Market Commitments. Targeted grantmaking
and advance market commitments – to those familiar with these mechanisms – might
appear as strange bedfellows as a “single” reform. On the one hand, targeted
grantmaking is typically considered a “push” mechanism to directly encourage the
pursuit of a particular research area or target. A historical example of this sort of
approach was the National Foundation’s (“March of Dimes”) directed grantmaking to

of a patent pool into their proposals. Anthony So, for example, conceives of a technology trust – a patent
pool with a social purpose – in several key areas, and his future work will be of particular interest.
create a polio vaccine. More recent examples include the International AIDS Vaccine Initiative and the Bill & Melinda Gates Foundation Global Health Program. On the other hand, an advance market commitment (AMC) is typically considered a “pull” mechanism to encourage the pursuit of a particular research target under an agreement whereby a third party will purchase all or part of the eventual product (assuming it is safe and reasonably priced). AMCs have less historical precedent. However, in February 2007, Canada, Italy, Norway, the United Kingdom, Russia, and the Bill & Melinda Gates Foundation created the first AMC, a $1.5 billion market commitment for a vaccine effective against pneumococcal pneumonia and meningitis (Advance Market Commitments for Vaccines, 2007). Vaccines appear to be a promising area for AMCs (Barder, et al., 2005).

What these two seemingly disparate mechanisms have in common is the wise use of funds to encourage research in particular areas, whether they are particularly pressing public health needs or simply neglected diseases (or both). They have the following characteristics:

- The targeting of specific research or neglected disease areas by “pushing” or “pulling” (Berndt, et al., 2006);
- A potential to work within existing IPR systems (or alternatives) while controlling prices through contractual arrangements; and,

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For targeted grantmaking, the capability to effect capacity building within developing countries if, for example, grants target individuals and institutions in those countries.

Limiting Patents in Poor Countries (Lanjouw, 2003). One seemingly simple way around the issue of IPRs of access to EMs that qualifies as an “alternative” to patents while still respecting traditional IPRs is to simply not have them in poor countries. This is the spirit of Jean Lanjouw’s “Foreign Filing License” solution. Lanjouw suggests that poor countries – those below $5,000 per year in per capita income – ought to have immediate access to generic medicines so long as they represent less than 2% of global sales. Based on several assumptions, she suggests that this would cost the industry only about the same as one less week of patent protection in the rest of the world (Lanjouw, 2003). Lanjouw notes that the proposal applies only to inventions in developed countries, while those in developing ones would have whatever patent protection applicable to their country. In short, Lanjouw’s proposal claims to

• Allow for lower drug prices in developing countries by simply foregoing patent protection in them;

• Permit developing countries to incrementally honor patents as their economies grow above the minimal threshold; and,

• Require no more than existing IPR institutions and enforcement mechanisms.
5.2.3 Proposals that Represent “Alternatives” to Traditional IPRs

The following reform proposals represent “alternatives” to traditional intellectual property rights, either by modifying them or replacing them in some way. I introduce briefly several different examples in the next several pages.

Clinical Trials as a Public Good (Lewis, et al., 2007, Reichman, 2006). A particularly novel reform considered in recent years suggests an alternative to the status quo of treating clinical trials (and the data arising from them) as in some sense “proprietary.” This calls to mind my earlier discussion of how treating the data necessary for regulatory approval of new medicines as subject to exclusive control (“data exclusivity,” i.e., IPR-like). While the some advocate for clinical trials registries that make clinical trials’ data more available than they currently are – alleviating some of the drawbacks of a clinical trials system based partly on proprietary rights (International Committee of Medical Journal Editors, 2004, Moher and Bernstein, 2004) – other call for much more. According to Jerome Reichman, not only should international law not give exclusive rights to clinical trials data (Reichman, 2006), but also he (with colleagues Tracy Lewis and Anthony So) thinks a complete overhaul of clinical trials is needed (Lewis, et al., 2007).

The proposal by Lewis, Reichman, and So suggests that treating clinical trials as a public good via public funding would solve several of the current problems in how clinical trials are conducted. First, it would reduce the undersupply of clinical trials data themselves (as public goods supplied by private interests, economics suggests they will be undersupplied). Second, it would make the content of clinical trials more rational
(e.g., by conducting head-to-head comparisons of competing medicines, which pharmaceutical companies tend to avoid). Third, it would make clinical trials data more widely available, alleviating concerns over “hidden” data undisclosed by pharmaceutical companies (Harris, 2004). Fourth, public funding of all trials would eventually remove concerns about conflict of interest when the trial’s sponsor and its study team are directly linked. Fifth, and most importantly for this context, public funding of clinical trials could reduce overall R&D costs, which could both reduce medicine prices and perhaps allow for more research into neglected diseases (because the sunk costs of R&D that need to be recovered are lower).

Thus, reforming clinical trials as a publicly-funded public good has at least the following key features:

- Public funding and oversight of clinical trials, leading to adequate supply, appropriate content, and full transparency;
- Decreased overall R&D costs, leading to lower drug prices because the costs of R&D to be recouped by the market are lower; and,
- A potential to address smaller market medicines or medicines for neglected diseases.
Prize Funds (Hollis, 2005, Love, 2006, Pogge, 2005, Stiglitz, 2006). The central idea behind a prize fund is to reward innovation not with a monopoly-enabling exclusive property right, but with a financial “pot of gold.” An innovator, in other words, receives this financial prize for the innovation but does not maintain the traditional right to exclude; in pharmaceutical terms, this enables immediate production of generic medicines. In recent years, prize funds have become exceedingly popular as alternatives to traditional IPRs. For example, in one proposal, Tim Hubbard and James Love discuss mandatory contributions by all U.S. individuals or employers into R&D “pension funds” that act as intermediaries to distribute prizes to innovative firms (Hubbard and Love, 2004). In another, Thomas Pogge discusses an international prize fund whose resources come via the contributions of wealthy nations. How well an innovation impacts global health disease burdens will determine the reward disbursement from the fund (Pogge, 2005). The key elements of prize funds include

- Creation of a sustainable R&D fund via public and/or private money;
- Determination of criteria by which a prize is awarded; and,
- Immediate availability of generic manufacture, lowering prices of medicines to at or near marginal cost.

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13 Interestingly, some date the history of prizes to Michael Polanyi – in 1944. See (Polanyi, 1944).
Compensatory liability is a “take and pay” approach whereby an individual could use intellectual property without permission so long as they compensate those from whom the “property” was taken. While compensatory liability itself sounds as if it could turn the present system of exclusive property rights upside down, Reichman generally discusses its potential successes in a more narrow sense (not as replacing patents). Real issues arise regarding the terms and amounts of the compensation necessary under such a regime; Reichman suggests a royalty rate somewhere between 3 and 9%. According to Reichman, compensatory liability is

- Uniquely beneficial for all countries’ “subpatentable” innovations (e.g., incremental innovations that are valuable but might not meet the “non-obvious” standard of a full patent) or incremental innovation (Reichman, 2000); and,

- Well positioned to encourage local innovation and traditional knowledge (TK) in developing countries without the social costs of traditional exclusive patent rights. This would place TK in a semi-commons that could not be freely appropriated without compensation (Reichman and Lewis, 2005 354).

Compensatory liability is therefore a useful option to consider, and as I note below, one of the most conducive to capacity building and changing the distribution of intellectual property “rights” worldwide.
Open Source (Maurer, et al., 2004). Motivated by the successes of LINUX and other open source successes in software, some have begun contemplating open source development of medicines for neglected diseases. Open source proposals are based on recent advances in computing power, new chemical and biological databases of compounds and molecular targets, and the software to search them. Such tools are promising; for example, Maurer et al. note the use of them to identify a target with known inhibitors in the SARS genome published the in prestigious journal *Cell* (Maurer, et al., 2004 184). Open source principles of new drug development

- Replace patents with open source licensing of discoveries, leading to immediate “generic” availability of drugs (i.e., lower prices through competition);
- Depend on non-financial incentives for participants, who donate their time, skills and perhaps computing power to aid in the discovery of new drug targets; and,
- Require the cooperation of non-profit pharmaceutical companies (e.g., the Institute for One World Health or the Drugs for Neglected Disease Initiative) who are skilled at moving products through a development pipeline.

Thus, open source represent one potentially viable alternative for the development of essential medicine for neglected diseases.
These are the different proposals to consider, all of which aim to improve access to EMs through reforming IPRs in one way or another. Surely the above treatment has been overly short for those involved in any of these particular areas. However, for my purposes, they suffice to define a range of potentially feasible options to analyze within the normative framework I continue to develop. To this framework I now turn.

5.3 Defining the Evaluative Criteria

The evaluative criteria are delineated and described briefly in Table 2. Although my main interest is in the “three distributive problems” described in Chapters 3 and 4, in this section I include several other important normative criteria: the distribution of costs, the need for new institutions, and political feasibility.14

5.3.1 The Three Distributive Problems in Action

Perhaps the prior chapter on global distributive justice and human rights did not make the connection between the “three distributive problems” and human rights clear enough. If this is the case, this section remedies that problem.

14 Perhaps notably, I leave out “continued incentives for innovation” for two reasons. First, the emphasis on innovation is so pronounced in the current literature that the pendulum might rightly be swung back the other way by leaving it out. Second, and more importantly, I take it as a given that these proposals do allow for adequate incentives for continued innovation, or that they see the cost of a small decrease in innovation as offset by other benefits.
Recall that on the view of human rights I and many others endorse, human rights represent morally significant basic human interests – i.e., thresholds of minimalist equality. So understood, the key idea is protecting humans against the “standard threats” to these interests, but not in such a way as to imply absolute equality. Rather, the operative concept involves reasonably secure (and not necessarily equal) access to the thing covered by the right. More importantly, human rights represent a subject-centered view of justice. That is, they say something about how persons are supposed to be treated as persons and thus should say something about how persons are supposed to be treated.

The critical idea behind the three distributive problems is this: In so far as one accepts a basic human right to health, and a right to access to essential medicines as one part of this right, the three distributive problems represent a large part of the criteria for what determining “secure access” to essential medicines (now and in the future). I explain this is for each of the three problems below.

*Three Distributive Problems: Develop First, Distribute Later.* The first distributive problem relates most directly to the “Develop First, Distribute Later” paradigm of current medical R&D (as first discussed in Chapter 3). Simply put, this distributive problem acknowledges the monopoly pricing facilitated by the use of exclusive rights (i.e., patents) to encourage innovation. It accepts that high prices will prevent many individuals from accessing medications but suggests (at best) that having such new innovations increases overall welfare. As I argued in Chapter 3, this could be because the present innovation assumes that other institutions ought to be created to facilitate
this distribution. What should be obvious is that, with 2 billion people lacking access to essential medicines, no such institutions exist. Moreover, the present system also lacks incentives for creating such institutions.

The import of this distributive problem when considering a human right to access to EMs lies in the following question: Do individuals have reasonably secure access to already existing and future EMs? In other words, this distributive problem suggests that we need to evaluate reform proposals based on whether they will make medicines affordable, now and in the future.

*Three Distributive Problems: Type of Innovation.* The second distributive problem involves the types of innovations being produced. Recall that medical R&D currently produces a large number of medicines for the developed world, illustrated by the “90/10 Gap.” In addition, the present R&D system produces large numbers of “me too” or copycat medicines that might lower prices within certain classes of medicines but do not lower prices as substantially as generic competition (and often do not represent significant therapeutic benefit).

The import of this distributive problem when considering a human right to access to EMs lies in the following question: Do individuals not only have reasonably secure access to EMs, but also access to the right *kinds* of medicines (i.e., drugs suited to particular conditions, within particular settings, and so on)? Taking this distributive problem seriously thus fills in other important component of the content of the right to EMs. We should evaluate reform proposals along this distributive dimension to see whether they encourage the right kinds of EMs.
Three Distributive Problems: Ownership of IPRs (Capacity Building). The final distributive problem involves what I noted earlier as ownership over IPRs themselves. At this point, however, I must emphasize that this distributive problem (i.e., IPR ownership) is really only a symptom of a broader distributive concern. This concern is over the capacity of nations and communities to participate in producing their own medicines for their own conditions. The fact that it was revealed by gross inequalities in ownership of IPRs does not suggest that IPRs ought to be increased (e.g., by increasing IPR protection in developing countries); it simply reflects the bias of the current R&D system toward use of IPRs.

The import of this distributive problem when considering a human right to access to EMs lies in the following question: Does the reform proposal in question adequately address capacity building, broadly construed, by helping those in developing countries help themselves? Outcome measures for this could include whether the reform takes into account encouragement of local research capacity, industry, and so on.

These “distributive problems” fill out a large part of how a human right to EMs could have real impact in the evaluation of IPR reforms. They are not, however, the whole normative story.
5.3.2 Distribution of Costs

Another important normative concern that will differ between different proposals is how the costs of the reform are distributed. The evaluative criteria asks, “What are the burdens of a particular IPR reform, and how are they distributed?” For example, some proposals require large-scale government funding (and hence taxpayer funding) to be offset by the eventual savings through lower drug prices. Others leave out direct government funding and instead allow markets to work at distributing the costs. This evaluative criterion is important under the assumption that, at least for a time, the costs of neglected disease research will have to be borne by someone. Whatever policy is chosen ought not to replace one distributional inequity with another.

5.3.3 New Institutions

Related to the issue of how costs are distributed is the issue of whether, and what kinds, of institutions might be needed to implement a reform. This criterion to some extent reflects a belief that, all things considered, those proposals requiring the least amount of institutional change are more likely to be successful. In some cases, already existing institutions might be able to adequately implement the reform (e.g., national legislatures implementing WTO TRIPs flexibilities). In others, certain institutions might need to expand to take on new or slightly modified roles (e.g., if the WHO were to coordinate monitoring the impact of innovations on global health to administer a prize fund). And in still others, new institutions might need to be created (e.g., if a new
institution were created to systematically implement a coordinated drug donation program). However, one should not overestimate the potential costs of institution building, as opposed to using current institutions or modifying old ones, in determining a reform to pursue. The amount of relative cost is a question that requires deep empirical research.

5.3.4 Politically Feasible & Realistic

A more pragmatic concern with the proposals is whether they are politically feasible and realistic. In discussing his own proposal, Thomas Pogge describes these two related terms as follows:

To be feasible it must, once implemented, generate its own support from governments, pharmaceutical companies, and the general public (taking these three key constituencies as they would be under the reformed regime). To be realistic, the plan must possess moral and prudential appeal for governments, pharmaceutical companies, and the general public (taking these three constituencies as they are now, under the existing regime). (Pogge, 2005 185)

Surely these are important considerations. “Feasibility” is an ex post facto consideration decided by looking at how the reform would work once established. To be “realistic,” on the other hand, requires moral and prudential appeal for the three main actors Pogge identifies (governments, pharmaceutical companies, and the public).

However, they ought not be taken too far. First, how we understand what counts as “realistic” ends up being critical to the whole enterprise. Fortunately, however, the appeal to human rights ought to place boundaries on what any of these
actors might consider “realistic.” For example, were pharmaceutical companies to suggest that, to be realistic, any reform proposal could not adversely affect their bottom line appears to demanding. This is because we understand to be obligations that adhere, to some extent, to all of us, and we should expect that we all have some share of the burden in fulfilling them. Second, how we understand the main constituencies involved, and whether their views ought to carry equal weight in the reform process, is another crucial question. The juxtaposition of the general public with pharmaceutical companies in Pogge’s quote is here illustrative: Should pharmaceutical companies have equal say in what is “realistic” and “feasible” as the general public writ large? If not, how much less (or more)?

While these difficult questions require answers, the main point should be that feasibility is a real issue – and one that is likely to change over time. In the meantime, it is important to explore this issue while noting its potential limitations. Does the reform proposal have a chance at being actually implemented?

5.3.5 Subject-centered Justice

The final evaluative criterion asks simply whether the reform respects subject-centered principles of justice. Recall that subject-centered justice, understood on my view in human rights terms, suggests the following:

The point is that these are standards of a very special sort: they are subject-centered obligations, grounded in characteristics shared by all human beings. The fact that these ‘common standards’ take the form of rights, and, more specifically, human rights, is not insignificant. (Buchanan, 2005 72)
To a certain extent, the distributive concern relating to capacity building emphasizes subject-centered justice in that it expresses how people ought to be treated. That is, it emphasizes that people ought to be able to be free to perform research and development on their own country’s health priorities, not be in a relationship of dependency toward other, more wealthy nations. This is fundamentally to see people as the subject of justice, not just charity, and in doing so, it casts doubt on reforms that express an attitude of charity toward the subjects of justice.

The question, “Does a particular reform respect subject-centered justice?” is a difficult one to answer. A full answer requires a more clear understanding of what subject-centered justice means, and like human rights themselves, this meaning is likely to change over time. Provisionally, therefore, subject-centered justice is perhaps best employed as a way to cast doubt on reforms that overemphasize “charity.”

5.4 Explaining the Evaluation

Table 3 and Table 4 present the evaluation of the different proposals in summary format. In what follows, I highlight several of the critical areas of the evaluation.
5.4.1 The Three Distributive Problems and the Need for Multiple Reforms

Table 3 illustrates how the different proposals compare regarding the three distributive problems described previously. Allow me to be clear that this analysis – with its yes/no evaluative terms – is purposefully vague. First, without many other empirical assumptions, it would be difficult to “score” the proposals (e.g., from 1 to 5) in all but the most general ways. Second, in no way is it even intended to score proposals according to the number of “yes’s” or “no’s” received (an analysis that would give priority to targeted grants and advance market commitments). Nonetheless, the following themes emerge:

First, regarding access to medicines: Although all the proposals have the potential to increase access to EMs, not all of them do so in the same way. For example, many of the alternative IPR arrangements focus on access to future, innovative medicines, rather than access to currently existing (and already unpatented) ones. On the other hand, differential pricing and drug donation schemes focus on both current and existing medicines. Even without considering the other features of the proposals, this suggests a need to consider multiple reforms.

Second, regarding the types of innovations produced: Not all of the proposals can have an impact in this area. Of note, drug donations and differential pricing – just lauded for their ability to increase access to already existing medicines – are inept at creating the need for new, innovative treatments for neglected diseases. This is the
domain of vouchers, prize funds, open source methods, and targeted grants or advance market commitments. Again, the need to consider multiple reforms is clear.

Third, regarding capacity building: Comparatively few of the proposals address this adequately, and for some of those that do, this is a stretch. Targeted grants are perhaps most well-positioned for this, whereas differential licensing and compensatory liability schemes might be able to positively impact this as well. What this suggests is a need to consider other, more innovative ways of incorporating capacity building into IPR reform.

5.4.2 Other Normative Concerns

As in the above, Table 4 evaluates the proposals in very general terms according to cost distribution; need for new institutions; feasibility; and respect for subject-centered justice. It also lists the main advantage and main disadvantage of the particular proposals. For each of the areas, several themes again emerge:

First, regarding the distribution of costs: If we assume (reasonably) that developed countries will experience more of the financial burden, at least in the short term, to implement these proposals, three different lessons emerge from this table. One is the question of how to distribute the costs of implementing reforms between countries when international coordination is required. For example, under a differential pricing scheme, countries will need to find ways to prevent illicit transport of less expensive drugs to more expensive markets (which would otherwise undermine the system). How
should the cost of setting up such institutions, from monitoring to the manufacture of distinct pills and doses, be shared?

Another facet is the notion of distributing the costs of EM development not to the broader public per se but to particular disease groups in developed country. For example, the voucher and TME systems do not rely on an explicit commitment through taxpayer funding; instead, unlucky disease sufferers in developed countries will find themselves bearing this burden. Is this fair? Too often, we consider the voucher system in light of examples of what some consider “lifestyle drugs,” like sildenafil (Viagra). However, suppose instead the medicine to which a voucher were applied happened to be an important cardiovascular drug (e.g., a statin for the treatment of high cholesterol). Given the disparate impact of cardiovascular disease and the costs of its treatment among lower socioeconomic classes in developed countries, would it be fair for this group to bear the burden of an extra year of exclusivity?

Lastly, another aspect of the cost distribution issue is the inclusion of public (via governmental funding of a “prize”) versus private (via private foundations, like the Gates Foundation) involvement. Whereas the former seems to have implications for political feasibility, the latter has a great deal more flexibility.

All things considered, however, there might be reasons to favor involvement of public, explicit funding in IPR reforms. Part of this is pragmatic, in that reforms might be more likely to be effective under such circumstances. Another part is normative, however, in so far as understanding this as human rights issue implies that we all share the responsibility for fulfilling this right — even if our only “duty” is to pay our taxes or
otherwise support the reform. Understanding human rights in this ways seems to eliminate the “voucher”-type reforms.

Second, regarding the need for new institutions: In broad terms, no clear pattern emerges regarding the need for new institutions, although alternatives to IPRs tend to require more institutional innovation. Taking into account the institutional nature of human rights, however, one should not shy away from the need for new institutions. Instead, existing institutions might be underscored while these new institutions are created.

Third, regarding feasibility: The only reforms that, for now, warrant a judgment of “infeasible” include the voucher / TME reforms and a better implementation of TRIPs flexibilities. For the former (vouchers / TMEs), a judgment of infeasible is warranted, in my mind, by the type of unequal cost sharing employed. For the latter, recent experience suggests that full implementation of TRIPs is unduly hindered by lack of technical expertise in developing countries (Lewis-Lettington and Munyi, 2004) and by bilateral and multilateral free trade agreements that cause developing countries to “trade away” these flexibilities (Roffe and Spennemann, 2006). Given unequal power on the global stage, such power differences are likely to persist, making full implementation of TRIPs an important, though generally infeasible, solution to EMs (not to mention its inability to spur research into neglected diseases).

Fourth, regarding subject-centered justice: as previously alluded, the only category of reform that appears not to respect subject-centered justice in general terms is drug donation. This is because, as typically construed, donation is considered “charity,”
not “justice.” Again, this is not to condemn donation; surely drug donation programs are important. However, as noted on several occasions, understanding access to essential medicines as a human rights issue casts a skeptical eye toward the use of charity as only, or even the predominant means of fulfilling it.

5.5 The Main Advantages and Disadvantages of Different Reforms

Because the above elaboration of the information contained in Table 3 and Table 4 is altogether too brief, it is helpful to discuss in more detail the main advantages and disadvantages of several of the reform proposals with an eye toward real-world examples.

5.5.1 Reforms to Consider Regardless of Global IPR Reform

Certain of the reforms noted here are worthy of consideration in particular circumstances no matter what, if anything, were to occur with global IPR reform.

*Patent Pools.* One can imagine the utility of patent pools in at least two circumstances. First, when the existence of multiple IP owners requires coordination, particularly when the IP in question is under dispute, patent pools represent a possible solution. This has been discussed in relation to genomic and biotechnology patenting, for example, to reduce transaction costs and facilitate the bringing together of multiple gene sequence owners for DNA microarrays and diagnostic tests (Clark, et al., 2000).
The worry in this context is that the high transaction costs associated with negotiating between multiple IP owners could prevent inclusion of all the necessary gene sequences for a clinically effective diagnostic test. In global health, patent pools have most recently been discussed in relation to the production of a SARS vaccine (Simon, et al., 2005).15

According to Simon et al. (2005), the severe acute respiratory syndrome coronavirus (SARS-CoV) might provide the test case for patent pooling in the health sciences. This is because the research and sequencing that led to the identification of the virus following the 2002 outbreak occurred in a particular way:

- over a short period of time, making the patent applications at similar stages and with few third party agreements to complicate matters;
- within four parties that hold the key patent applications for SARS-CoV (CDC, Health Canada, Versitech, Ltd., and CoroNovative BV);
- without, as yet, a market for SARS related products, providing an incentive to contain costs; and,
- a close involvement with public health-related organizations who would like to drive the process forward. (Simon, et al., 2005 709)

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Thus, the SARS patent pool demonstrates the potential of pooling as a way to work within existing patent law to foster the development of an important product (i.e., the SARS vaccine). Another area where patent pooling could be effective is in facilitating fixed dose combinations (FDCs), as the treatment of many health conditions (such as TB and HIV) often requires the administration of multiple different drugs per day – a situation that could be helped (and has been helped in the case of HIV), by FDCs (Kaplan, 2003a, Kaplan, 2003b). Importantly, for these initiatives to go forward does not require global IPR reform.

Clinical Trials as a Global Public Good. Treating clinical trials as a global public good through public financing and oversight is a second example of a proposal that requires due consideration even in the absence of major IPR reform (Lewis, et al., 2007). In fact, the only revision to IPRs that appears necessary in this proposal is the abolishment of “data exclusivity” as a property-right like entity (Reichman, 2006). As noted earlier, a publicly clinical trial system would be more rational (by producing trials and trials data through asking questions that a private system underproduces – like head-to-head comparisons); more ethical (by removing concerns over duplicative clinical trials placing human subjects at risk for no benefit - (So, 2004)); and cost neutral (because the costs of public oversight could be offset by lower drug prices in the long run). This system is equally applicable to developed and developing countries alike (i.e., it need not be truly “global”). What remains to be seen, however, is whether such a system could adequately address the 90/10 research gap or be truly effective for essential
medicines. This suggests a need to consider this proposal with others that more directly address the second distributive problem ("types of innovation").

Open Source. A third example of a real-world proposal likely to move forward even without modifying the current IPR regime is open source science (Maurer, et al., 2004). The Tropical Disease Initiative (TDI) is illustrative here. TDI is using an open source model, using computational power to search and identify drug targets and potential drugs for malaria and schistosomiasis. Once a target is discovered, it can be offered to product partnerships, such as the Institute for One World Health or Drugs for Neglected Disease Initiative ("Virtual Pharma"), for further development. When promising drug candidates are identified, According to TDI, the advantages of its approach include the following.

First, it would give hundreds of scientists a practical way to donate urgently needed manpower. Second, open source discoveries would not be patented, permitting sponsors to award development contracts to the company that offered the lowest bid. Finally, competition from generic drug makers would keep manufacturing prices at or near the cost of production, significantly accelerating drug development for the 500 million people who currently suffer from tropical diseases.16

This open source initiative is intriguing. However, while it is likely to be useful for helping maintain the drug development pipeline for Virtual Pharma, it is also likely to be limited by the use of voluntary time commitments from scientists and others and the dependence on projects that can done in a virtual environment. These two limitations are not insignificant: If we understand access to essential medicines as a

human right, the idea that this right ought to be fulfilled through voluntary time commitment to a virtual enterprise seems inconsistent with human rights. Therefore, open source initiatives are important but cannot be the whole story.

*Differential Licensing.* Differential licensing terms represent a fourth obvious approach that does not require IPR reform. In recent years, a real-world example of this approach has been to examine the ways in which U.S. research universities license the technologies developed and patented (as consistent with the Bayh-Dole Act). A particularly high profile case illustrating the relevance of a differential licensing strategy was the controversy over stavudine (d4T). Originally discovered and invented at Yale University and then exclusively licensed to Bristol-Myers Squib, this antiretroviral HIV/AIDS drug was the subject of much controversy over high prices in the developing world – until Yale and BMS agreed in 2001 to allow generic production in developing countries (Lindsey, 2001b). Prices eventually fell, as a result of competition and public pressure from groups like Universities Allied for Essential Medicines, the Treatment Action Campaign, and others. Unfortunately, Yale again finds itself involved in a licensing controversy over Ed4T, a modified version of the original. Yale licensed to this drug to Oncolys BioPharma though appears not likely to enforce its patent in some countries, such as India (Check, 2006).

The emphasis on the unique role of universities in cases like the d4T case is not accidental. Universities in developed countries like the U.S. frequently discover new medicines, are freer to perform research on neglected diseases than industry, and often express explicit commitment to global social welfare. Moreover, overall licensing
income is low in comparison to the amount universities spend on research, and so including flexible licensing provisions for generic production and low and middle income countries would not cost universities a great deal (Sobolski, et al., 2005). In fact, several top U.S. research universities have expressly committed to recognizing the needs of those in developing countries in how they license their inventions:

Universities should strive to construct licensing arrangements in ways that ensure that these underprivileged populations have low- or no-cost access to adequate quantities of these medical innovations.17

A few recent examples demonstrate this strategy in action (Centre for Management of Intellectual Property in Health Research and Development, 2006). For example, in 2005, the University of California, Berkeley, issued a royalty-free license to Amyris Biotechnologies, Inc., and the Institute for One World Health for a yeast-based process to synthesize the anti-malarial artemisinin (Towie, 2006). The university retains royalty rights, however, on non-malaria based uses of the yeast process, such as for fragrances. This is an example of differential licensing by field of use. Along with differential licensing based the income of the country of target sales, this strategy demonstrates a potential for facilitating greater access to essential medicines – one that does not require reforming IPRs. Like the strategy of treating clinical trials as a global public good, however, the scope of this reform is limited. It is only able to differentially license what the current medical R&D system produces – meaning that unless a more

concerted effort is put forth toward neglected diseases and essential medicines, long-term sustainable impact is unlikely.

The same might be said for the strategy of differential pricing. Aside from the observation that difficult questions arise about how to administer and share the costs of a systematic differential pricing scheme, differential pricing can only differentially price whatever medicines R&D is likely to produce. If we understand part of the right to essential medicines as requiring secure access to certain types of innovations, this seems insufficient.

*Compensatory Liability.* The last example of a strategy that warrants some consideration whether or not global IPRs undergo substantial revision or modification is the compensatory liability scheme (Reichman, 1994). This scheme solves at least one problem of interest to the present discussion in a way that is perhaps unique, thus warranting further consideration.

The first is the concern over traditional knowledge. “Traditional knowledge” generally refers to long-standing traditions or practices of particular communities. For example, artemisinin, just described as an effective component of malaria treatment, comes from the Chinese wormwood plant that has been used for centuries by the Chinese for the treatment of fever. Understanding this long-standing use presents a quandary: On the one hand, this knowledge of Chinese wormwood could be part of the public domain, meaning that it cannot be appropriated and examined for its clinical effectiveness (one part of which is artemisinin for malaria). This could mean that no incentive would exist to develop artemisinin. On the other hand, this knowledge could
be fully appropriated by someone from a developing country, who uses this knowledge to discover artemisinin and develop it into a drug for malaria that those in China now must (re)purchase. Often, this situation is what people mean when they say “biopiracy.” This would suggest that the local community, whose knowledge was used in discovering the artemisin, does not receive any of the benefits from this discovery.

A compensatory liability regime, for Reichman, solves this problem in a unique way: Under compensatory liability’s “take now, pay later” approach, individuals can temporarily appropriate the public domain “traditional knowledge,” but they are bound to pay royalties back based on the commercial success of what is developed. Certain difficulties remain (such as how to distribute the royalty to a community), and this solution might not satisfy those who take biopiracy so seriously that they would reject any (even temporary) appropriation, it certainly seems more reasonable than the options of non-development or complete appropriation (Reichman and Lewis, 2005).³⁸

This potential solution to, or at least mitigation of, biopiracy is important in so far as it is one of the few reforms that appears to explicitly recognize the capacity building aspect of the third distributive problem (ownership of IPRs). It also recognizes that the way to deal with the unequal distribution of IPRs is not necessarily to increase ownership of IPRs themselves, because they are only a symptom of a broader problem. On my view, this makes compensatory liability – or other reforms like it – take on

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³⁸ Reichman makes a similar case for small scale, subpatentable innovation, but I will not discuss that here.
increasing import. Whether such a compensatory liability regime will prove feasible is a difficult, and open, question.\textsuperscript{19}

5.5.2 The Limits of TRIPs Flexibilities: Unsustainable Political Pressure

Having discussed at some length the relative strengths and weaknesses of a few proposals that are important to consider whether or not global IPR reform actually occurs, I now turn to the major proposals that are more closely linked to the idea of IPR reform (or explicit lack thereof). As before, I emphasize the real world application of the theoretical principles previously discussed briefly, but now in more detail.

The first of these is the better implementation of TRIPs flexibilities. Before I noted that TRIPs flexibilities often require incorporation into national law, and that frequently countries either fail to do so (Oliveira, et al., 2004) or are unable to do use them fully (Lewis-Lettington and Munyi, 2004). Two recent high profile cases illustrate this in more detail.

\textit{Thailand and Compulsory Licensing}. In January 2007, Thailand signed two compulsory licenses for the drugs lopinavir/ritonavir (Kaletra, an Abbott drug) and clopidogrel (Plavix, jointly marketed by Bristol-Meyers Squibb and Sanofi-Aventis). These followed a November 2006 compulsory license for efavirenz (Sustiva, a Bristol-Meyers Squibb drug marketed by Merck in Thailand). All three compulsory licenses

\textsuperscript{19} Compensatory liability is, to a certain extent, the most radical of the IPR reforms proposed in that it fundamentally changes the system from one of property to one of liability (“take first, pay later”). For a time, this would seem to limit its feasibility to particular applications for which it is best suited.
caused a vocal reaction from the pharmaceutical industry, HIV/AIDS activist groups, and many others. The compulsory licenses would allow importation or production of these medicines as generics. According to some estimates, the Kaletra compulsory license could save Thailand upwards of US$24 million per year. In response, Abbott elected in March 2007 to announce that it would withdraw pending drug registrations on seven drugs in Thailand (including a heat stable version of Kaletra itself), a decision to which many objected. Most recently (28 March 2007), talks between Thailand and Abbott again broke down, with the two sides unable to reach a price agreement.

Widely accepted, despite all of this controversy, is that the action by Thailand’s government does not violate the terms of the WTO TRIPs Agreement. In the end, Thailand might be able to successfully implement the compulsory license, utilize less expensive generic medicines, pay Abbott (and the other companies) remuneration, and still come out ahead. Or, Thailand might be able convince Abbott to lower prices, much as Brazil did through the threat of compulsory license in 2005 (Prada, 2005). In either case, however, one must wonder whether the need for the threat or use of compulsory licensing is the best way to help ensure affordable access to what I have argued is an issue of human rights. While it appears to be useful check or measure of last resort, it might also qualify as the kind of “extraordinary and unsustainable” measures that

occasionally lead to lowered prices but ought not be relied upon. In Chapter 2, I quoted several groups who assailed the suggestion that countries can make do with the US and European offers of concessionary prices does not deal realistically with the factors that lead to those price decreases (threats of compulsory licenses, extraordinary and unsustainable NGO and UN pressures, the existence of a competitive market for ARVs created by Brazil22), nor does it recognize the substantial price differences that still exist (Consumer Project on Technology, et al., 2001).

If taken seriously, this quote implies that even under the best of circumstances compulsory licensing ought to be a measure of last resort. It is unlikely to be as effective as other structural changes and requires a great deal of unsustainable effort to be achieved (particularly when developing countries find themselves up against more wealthy, powerful interests in the U.S. and other developed countries).

**Bilateral Free Trade Agreements and TRIPs-plus.** Not only are some of the TRIPs flexibilities (like compulsory licensing) best seen as measures of last resort (rather than proactive solutions), what flexibilities that do exist are sometimes given away in other trade negotiations (Médecins Sans Frontières, 2004). For example, in a review of many of the recent free trade agreements (FTAs) negotiated between the U.S. and different countries, Carlos Correa (Correa, 2006b) found that FTAs frequently require countries to give up certain flexibilities they have beyond the minimal provisions of TRIPs. For example, FTAs might call for mandatory patent extension based on “unreasonable” delays in drug regulatory approval; the granting of exclusive rights over data for at least five years (“data exclusivity” – TRIPs only requires protection against “unfair

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22 Part of the reason for Brazil’s competitive market was the fact that Brazil did not recognize pharmaceutical patents until 1996.
competition” in 39.3); the limitation of parallel imports; and, the attempt in some FTAs (such as between the U.S. and Australia and Singapore) to limit the conditions under which a compulsory license can be granted. Again, the pressure of a wealthy, developed country like the U.S. can be too much for some of these nations to overcome effectively, if the alternative is to be placed on the Special 301 Priority Watch List and its potential trade and economic consequences.23

A related example of the “ratcheting” up of intellectual property protection (though not through a bilateral FTA) is revealed by the recent case of Novartis against the Indian Government. This case – though focused on the anti-cancer drug imatinib (Glivec) – has much broader implications. Not only is Novartis challenging the Indian patent office’s decision to not award Novartis a patent on Glivec, it is challenging the underlying law that made the rejection possible: This provision allows the patent office to deny patents to drugs that represent only small changes to existing drugs. At issue, then, is a key flexibility that allows the Indian patent office (and others around the world) to determine when something is truly “novel” and deserving of a patent.

Moreover, the strong generic industry and its reputation as the generic pharmaceutical supplier of the developing world make this case particularly important. The outcome of the case will have a tremendous impact on what is patentable in India and therefore

23 The Special 301 Priority Watch List is when Office of the United States Trade Representatives “identifies trading partners that deny adequate and effective protection of intellectual property or deny fair and equitable market access to U.S. artists and industries that rely upon intellectual property protection.” See http://www.ustr.gov. Accessed 10 March 2007.
what will be able to manufactured as a generic drug (including the thousands of patent applications on AIDS drugs awaiting review by this office).

What these two examples – FTAs and the ratcheting up of IP protection – have in common is that both present evidence for how the current IPR system is ill-equipped for dealing with the access issue in any systematic way. More than this, of course, even if these measures did work, they would do nothing for the distributive problem that relates to the types of innovations being produced by the medical R&D system. In short, the extraordinary and unsustainable pressure needed to create change in this way appears insufficient if we take seriously the idea of access to essential medicines as a human right.

5.5.3 Donation Programs: Ineffective and Normatively Misguided

These two examples, however, are not the only ones that support a case for more systemic changes to the global IPR regime. Drug donation programs – one of the many reforms mentioned in this chapter – also argue for this. Before explaining why, I should point out that donation programs are themselves likely to be important, particularly in the short-term, as a way to increase access to essential medicines. So, what follows should not be read as unequivocal condemnation of donation programs. Instead, the conclusion from this section is that we ought not foster over-reliance on such programs or see them as fully able to realize the right to essential medicines.
The reason for this is twofold. First, drug donation programs as “charity,” take the wrong normative stance toward the subjects of justice. On my view, if we were discussing “non-essential” medicines, donation programs would be less of a problem. However, on a human rights, subject-centered view of justice, the attitudinal stance toward the subject of justice is of critical import. Recall the analogy with other human rights to help illustrate this point: Suppose we accept, like many do, the idea of a human right against domestic violence. If so, we might suggest that placing video cameras and extensive surveillance equipment in the homes domestic violence committers as a deterrent is an insufficient way to “fulfill” the right against domestic violence. I see the use of drug donation programs as the sole way to fulfill the right to essential medicines as fitting this general example.

Second, not only are drug donation programs normatively misguided in this way, they are also limited in effectiveness. For example, the long running and quite successful Mectizan Donation Program takes advantage of several unique features: One is that the treatment of onchocerciasis with ivermectin requires only a single annual dose. Another is that the drug itself was effectively subsidized by a profitable veterinary use of the same drug and in fact required a great deal of internal debate within Merck to even proceed to human use. Lastly, the tax benefits and public relations benefits of the program to Merck, at least for a time, might have outweighed the cost, making the program itself less a charitable donation (Collins, 2004).

The central question when it comes to looking at EMs through the lens of human rights is whether we ought to depend on these narrow circumstances in all cases to
enable access, or whether more fundamental and systematic changes are required. What should be obvious is that most diseases will not be treated by a single annual dose of a drug originally profitable in veterinary use. And again, like many of the reforms discussed here, drug donation programs themselves donate only what the current medical R&D system produces. If we understand part of the human right to health as involving access to certain types of medicines, then we surely would not depend on a donation-centered solution to the access problem (in spite of the generous donations of many pharmaceutical programs around the world, including Novartis’s own donation of Glivec in India).

### 5.5.4 Industry Incentives: Band-Aiding a Broken System

So what about the “industry incentive” options, like priority review voucher and transferable market exclusivity? Unlike the prior to options just considered, these options (drawing perhaps on the U.S. Orphan Drug Act), seek to create industry incentives for developing drugs for neglected diseases. Not only that, but they also require turning patents directly over to the public domain, or at least open licensing for competitive generic manufacture. While not solving today’s access problem to currently unpatented or recently patented drugs, it could be a solution for future access to EMs. Moreover, these solutions have the obvious advantage of being “industry friendly,” i.e., supported by a powerful industry lobby in the U.S. and other developed countries. (When I say “industry friendly,” I do so cautiously. Until now, I have not said anything that is industry “unfriendly,” except perhaps the idea of change to the current IPR
regime. If “change” alone is “unfriendly,” even if voluntary or as an additional IPR institution, then I am willing to accept that “change” is “unfriendly.”

Earlier, I expressed concern about the cost distribution associated with the voucher system. Restated, the problem was that the cost developing a neglected disease drug (which in my view is a human rights issue), rather than being borne by all of us in some way, was inequitably distributed among those unlucky enough to experience another year of exclusivity - e.g., on a new statin for high cholesterol. This seems to be an awkward way of “sharing the cost” for fulfilling a human right. After all, we typically conceive of human rights as having obligations that come to bear on all of us, even if we discharge those obligations in different and sometimes indirect ways.

The other aspect of these reforms that appears “odd” – and as yet I have no better descriptor that “odd” – is that it takes a broken system of medical R&D based on intellectual property rights and paradoxically solves it with more, stronger exclusive rights. From this standpoint, such industry-focused incentives appear more like an Band-Aid covering up the wounds of a broken system than they do a way of systematically solving this human rights issue. Perhaps this is “odd” from a political standpoint because implementing such a system might prevent the consideration of other, non-IPR focused reforms that could more effectively solve the access to essential medicine problem. Or perhaps it is odd because it takes a human rights issue and leaves it to the voluntary choice of industry as to whether the risk of addressing the neglected disease problem is worth the benefits of a year of exclusivity on another drug. It seems that recognizing the access to EM problem as a human rights issue as such ought not to
leave the solution to a matter of mere choice but instead call upon a focused, intentional solution.

Beyond the cost distribution issue, however, these ancillary questions about vouchers and TME remain relatively unexplored. I leave them now simply as questions, casting a skeptical eye and yet not rejecting them outright.

5.5.5 AMCs: An Opportunity for Immediate Action

Advance market commitments (AMCs) represent another potential reform that has garnered a great deal of attention in recent months. As noted previously, in February 2007, five nations and the Bill & Melinda Gates Foundation recently committed US$1.5 billion toward a pilot AMC for a new pneumococcal vaccine. Pneumococcal disease (pneumonia and meningitis) causes over a million deaths per year worldwide, and the sponsors claim a new vaccine could save the lives of as many as 5.4 million children by 2030. The World Bank and the GAVI Alliance (formerly the Global Alliance for Vaccines and Immunisation) will oversee the financial and programmatic portions of the AMC.

This AMC is important in that it represents an opportunity for nearly immediate impact in global health. According to the AMC, a new vaccine better targeted to the developing country setting will be available by 2010, 7-10 years sooner than would be

the case without the vaccine. In the meantime, the WHO recommends (through recent guidelines) use of the already available heptavalent (PCV-7) vaccine while awaiting the new product with broader coverage of perhaps 10 serotypes.25

Strangely, the white paper that serves as background for this pilot pneumococcal vaccine AMC barely mentions intellectual property. Where it does, it suggests only the following:

Concerns have also been raised about how AMCs will affect Intellectual Property Rights. The AMC is designed specifically to address a failure in market incentives – namely the lack of predictable and sufficient resources in developing countries to ensure a return on investments. For an AMC to be successful it should not—and does not—alter IP issues, as this would reduce predictability. In addition, the intellectual property issues around biologicals like vaccines are very different from pharmaceutical products.26

Not everyone agrees with this assessment, and in fact, many are considering the impact of a generic biologic industry (Coan and Ellis, 2001). Taking the above quote at face value, it would seem that this AMC falls prey to the traditional “Develop First, Distribute Later” approach to medical innovation. An AMC might be more effective – i.e., might get the most for its dollar – under an alternative IPR regime.

So just how does pricing work for the AMC? According to associated fact sheets, the AMC creates predictable pricing in two stages. Once a vaccine meets the performance standards to be eligible for AMC funding, each firm will be required to set their post-AMC price (prices can always be lowered). AMC funds are used to subsidise the

purchase of eligible vaccines demanded by governments. Once the AMC is depleted, the vaccine will be offered at the individually set post-AMC prices.\textsuperscript{27}

Much in this depends on how a fair price will be negotiated both before and after the AMC phases out. Unfortunately, past experience (in Brazil, Thailand, and elsewhere) suggests that the industry definition of a fair price and return on investment is different from that of national governments and others. Exclusive property rights and the power therein, however, give little room for negotiation. The extent to which an affordable price will be reached is an open question. It could be that in the future AMCs will, with good reason, pay more attention to IPRs (as well as to detailed plan for dealing with follow-on improvements to particular AMC-funded vaccines).

Another difficulty with AMCs has to do with the political commitment to fund the AMC in the first place. Notably absent from the list of funders for this AMC is the United States. When pressed, the Treasury Department suggested that

“\textquote{The United States welcomes the opportunity to work with others on the development of critically needed medical treatments,\textquotecut{\textquoteend} said Brookly McLaughlin, a Treasury Department spokeswoman. "However, given the budgetary restrictions on making a long-term binding commitment, we are not in a position to make a financial commitment at this time." (Ginsberg, 2007)\textsuperscript{27}"

This lack of political will is an important question. However, the language of human rights – if it is as powerful as it purports to be – ought to make the absence of such willpower less likely by holding those in power accountable for the lack of political will.

Right now, this AMC is dealing with an already late-stage clinical product that is nearly finished in the R&D pipeline. How would AMCs work with more early-stage projects? Could they adequately fund neglected disease research and help correct the biases in medical R&D? Might they better facilitate capacity building in developing countries? These questions remain, for now, unanswered until the pilot project materializes.

### 5.5.6 Prize Funds: Linking Innovation with Efficacy & Access

The final reform that I will consider in more detail truly represents IPR reform. It is a version of a “prize fund” as recently put forth by Thomas Pogge (2005). His proposal undoubtedly draws on an intellectual pedigree of prior versions of “prize funds” (Hollis, 2005, Hubbard and Love, 2004).²⁸

Pogge’s proposal is, in some ways, remarkably simple. Wealthy nations’ governments contribute some percentage of their GDP (approximately 0.2%, which would represent a portion of the commonly recommended 0.7% international aid benchmark) to an international prize fund, amassing US$70 billion. This fund will be used to reward innovation based upon the global health impact (e.g., reducing disease burden, effective treatment, safety, etc.). How is the reward administered? When an inventor has a global health related invention – a new pharmaceutical product for a

²⁸ The idea of using prizes to reward research is now at least more than 50 years old. For other relevant literature, see (Baker, 2004).
neglected disease, such as leishmaniasis – the inventor has a choice: Either pursue a traditional patent or decide on pursuing Pogge’s “patent 2.”29

Choosing patent 2 allows one to engage with the prize fund. Once chosen, the “patent 2” ends up not being a patent in the traditional sense, because the information becomes immediately open as part of the public domain. This means competitive, generic production on the new medicine can begin immediately, creating lower prices and encouraging access. What’s more, because the reward is based on global health impact, the inventor has the incentive to work more closely with generic manufacturers, set up distribution programs, and so on to ensure maximal global health impact. (The current system, recall, does not incentivize such actions directly.) According to Pogge, this reform proposal has the benefit of being in the interest of all the major stakeholders: governments, the general public, and the pharmaceutical industry, which will see it as opening a new market.

The truly unique part of this idea is how it conceives of the “reward” system for innovation (patents themselves being just one kind of reward): No other option yet considered determines the reward based on the impact of the innovation in alleviating the global health inequalities about which so many are concerned. Stated in another way, this proposal recognizes the “Develop First, Distribute Later” paradigm and turns it on its head. That is, even though it separates the market for innovation from the market for production, it explicitly takes into account how the way in which innovations

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29 Part of this comes from Pogge (2005) and part of this from personal communication and news interviews with Pogge. See, for example, http://www.abc.net.au/pm/content/2006/s1599392.htm. Accessed 20 March 2007.
are produced affects possible distributional outcomes. In addition, it effectively addresses both the price problem (the first distributive problem) and the type problem (the second distributive problem). This is to be lauded.

Nevertheless, substantial problems remain. One of these is the demand this system would place on a global health monitoring system. These include how to best measure the impact of a new innovation (e.g., will vulnerable or remote populations be given special weight, or will the impact be simply in aggregate?); how to deal with follow-on and competitive innovations once the prize has been rewarded (e.g., if another competitive anti-leishmaniasis drug comes out shortly after the first); and so on. However, it should be pointed out that these more empirical concerns and monitoring systems would likely be welcome in global health with or without the “patent 2” system. From this standpoint, to the extent that they could be solved, all the better.

A second problem is the same as one the AMC experiences: worries over the lack of political will to continue international contributions to the patent 2 fund. This lack of will is not an abstract problem. In fact, the Global Fund for AIDS, TB, and Malaria demonstrates the problem with long-term international funding of this sort. Created in 2002, this fund is not an R&D fund but instead seeks “to dramatically increase resources to fight three of the world’s most devastating diseases, and to direct those resources to areas of greatest need.”30 It is, therefore, mainly grant-making entity that in its first five year has, among other activities, enabled HIV antiretroviral treatment to nearly 800,000

individuals, provided 18 million insecticide-treated bed nets to protect against malaria, and trained 3.6 million people to deliver health-related services. Unfortunately, financing the Global Fund has proved to be problematic. Pledges and contributions are voluntary and *ad hoc*, typically leading to perennial shortfalls that prevent the expansion of its funded programs (Ahmad, 2005). Individuals and foundations have proven to be more reliable in following through on pledges than national governments.\(^{31}\)

However, one should not exaggerate the impact this present lack of political will as undermining the patent 2. After all, most, if not all, of the IPR reforms under serious consideration for neglected disease research and access to EMs require this level of political will. Or, stated another way, surveying *Table 3 and 4*, as well as my above discussion, might suggest that any of options which carry real normative weight all require this will. Presumably, the more one understands and gives content to the idea that this is a human rights issue, the more political will that could be generated. Whether this approach could eventually succeed is uncertain.

A third problem arises because the system, as currently framed, is a voluntary one. To be sure, making the patent 2 strategy voluntary is not a problem for truly neglected diseases; similar to other strategies (such as AMCs), patent 2 simply creates a market for these diseases. The problem arises for diseases that impact *both* developed and developing countries. Suppose a company develops a new antiretroviral HIV medicine. They now have a choice: release the knowledge into the public domain, for

\(^{31}\) A full list of pledges and contributions is available at the Global Fund’s website.
immediate generic production in India and other places (patent 2, rewarded by the prize fund), or maintain proprietary rights and exclusive control over the product (traditional patent, rewarded by high prices in developed countries). If the prize associated with “patent 2” is not big enough to exceed the market returns in developed countries, it is unclear whether it will be an attractive enough option (and, as the prior examples in Thailand and Brazil indicate, differential licensing of the “patent 1” has not proved to be an accepted strategy).

An obvious solution to this problem would be to make patent 2 mandatory for neglected diseases. Pogge, though, does not go this route – mainly because obtaining industry buy-in to the proposal is key to moving it forward, and industry buy-in is more likely under a voluntary system. “More likely,” but not assured: Looking into the future, industry might worry that certain high-profile diseases occurring in developed and developing countries – such as HIV/AIDS – will create public pressure to require them to take the patent 2 route, eschewing their traditional market models for certain diseases. To the extent that public pressure does arise in this manner, the patent 2 route might appear voluntary in name only.

At issue here is a pharmaceutical industry is extremely concerned about risk. Currently, the industry understands the rules and knows how to manage risk, even if many continue to worry about dry pipelines for product development. They are likely to oppose changes to the rules of the game both because they have business models geared toward the current rules and because, in some cases, they are able to exert a great deal of influence over those rules (Sell, 2003). Understanding the issue of access to EMs
as an issue of human rights, however, should cause us to think twice about worrying too much about the industry buy-in, as Pogge does. The industry behaves as it does because we, globally, allow it to behave this way. Cases like the Medicines Act in South Africa (see Chapter 1) suggest that, when push comes to shove, the general public can change the rules of the game.

In sum, the “patent 2” represents a novel “IPR reform” that, truth be told, does not involve IPRs at all. This arrangement provides incentives directly linked to the impact of an innovation on global disease burden and takes care of the pricing problem through immediate generic manufacture. It does not address the problem of access to currently existing, unpatented medicines (or perhaps medicines currently on patent), and it does not necessarily deal directly with capacity building (though immediate generic manufacture might favor industries in developing countries). In spite of these caveats, it is a reform option that is remains worthy of consideration.

### 5.6 Provisional Conclusions & Moving Forward

To a certain extent, the above discussion of a relatively broad range (though not comprehensive) list of reform options appears discouraging. After all, no single reform appears to address all of needs identified by the prior analysis of the right to access to essential medicines. Differential pricing and licensing, for example, do not change the research gap or systematic biases in the types of medical innovations produced by the current incentive structure. Prize funds, on the other hand, attempt to change this
incentive structure but do little for access to currently available medicines. And neither systematically addresses the need for capacity building – certainly not to the extent that targeted grantmaking might, for example.

This need not be discouraging, in that we ought not be surprised that some combination or another of these options could be preferable. One imagines, for example, a the systematic implementation of a prize fund or AMCs to created needed incentives for neglected diseases; the use of differential pricing and drug donation, where possible, to help foster access to medicines in the meantime; and the employment of targeted grants to developing countries in order to boost their own ability to solve their own health problems. Some of the other reforms discussed (e.g., patent pools, open source science) might play supportive roles, though the above suggests they have limitations as far as “fulfilling” the human right to essential medicine. Still others (e.g., the voucher / TME system) appear implausible for normative reasons having to do with the distribution of costs.

In all this, however, we need not lose sight of the forest for the trees. We ought to recall, that is, why we ought to favor IPR reform in the first place.

This project has suggested that a human rights approach to the problem of access to essential medicines indicates that something is very wrong with a world where 2 billion people lack access to essential medicines. Moreover, this wrong – because of the well-justified views of the basic human right to health, of which essential medicines are one part – is best conceived as a problem of “justice.” Many conceptions of global distributive justice seem to accept something like this (and for those that do not, we
probably have good reason to reject them). If true, this human rights approach suggests that we are all responsible for the underfulfillment of the human right to access to essential medicines, both as individuals and as collectives (i.e., from political entities like national governments down to corporations and private foundations).

What has caused this state of affairs? The present medical R&D system, with its emphasis on rewarding innovation through exclusive patent rights, has created a state of systematic disadvantage that underfulfills the human right to essential medicines. In this work, I have suggested that this systematic disadvantage is best expressed as “three distributive problems” all stemming from the present medical R&D system’s “Develop First, Distribute Later” approach: unequal access to affordable medicines (via monopoly pricing); unequal access to certain types of medicines (via a bias toward developed country health conditions); and an unequal distribution of IPRs themselves (suggesting the need for capacity building). These three components provide one part of the content to the “right to essential medicines,” in that each of these components ought to play a role in the fulfillment of this right (though, as I note below, much work remains regarding its full content).

In sum, we ought to favor IPR reform because the current IPR system, without modification, systematically disadvantages those in developing countries and results in the underfulfillment of their human rights. IPRs form part of the global basic structure and thus are subject to evaluations in terms of justice. This structural cause of human rights underfulfillment requires structural solutions – not simply donating back what has been taken away, an attitudinal stance that is wrong on a human rights, subject-centered
view of justice. The normative upshot of a human rights approach to access to EMs, then, is that it offers at least some guidance for how to understand this right and for how we might go about ensuring its fulfillment.

Much work remains, however. The first is a need for institutional reform, in at least two ways. One is the need to better define the content of a right to essential medicines. Earlier, I expressed concern that the WHO Model List might be insufficient in this regard because of its original intent, its content, and its procedures. Perhaps the WHO could create a different “core” list, focusing on how contemporary human rights theorizing conceives of these rights (i.e., as minimally sufficient conditions for a minimally decent life). Giving clearer content and scope to this human right might make its normative import more powerful. It would also be a start to a more systematic way of institutionalizing the general human right to health, given that this institutionally-based deliberation seems necessary for determining and continually modifying the content of this right. A start would be determining the procedures such an institution would follow.

The second needed reform lies in determining in greater detail an appropriate division of labor for fulfilling this right, once its content is better specified. For example, Thomas Pogge’s patent 2 explicitly strategizes the need for the pharmaceutical industry buy-in to modify IPRs for the sake of access to EMs. The power of human rights as discussed from Chapter 4 on, however, ought to be an ability to transcend such concerns even if this transcendence is difficult. The question is not whether a reform is acceptable to industry “so long as the profit margin remains untouched” any more than a political
reform is acceptable only “so long as taxes do not go up.” Instead, the question is how
to distribute the costs of human rights fulfillment in a fair manner, and determining this,
too, will likely require institutional innovation. Some of the IPR reforms discussed here
obviously take a general stance on this cost distribution (e.g., public versus private
financing), but beyond these general orientations lie many more specific questions.

Lastly, much work remains because, not only are the reforms mentioned here not
the only possible reforms, but also because much work remains in areas unrelated to
intellectual property. This project has focused on IPRs because they are important from
the standpoint of access to essential medicines, if recent controversies are any indication.
They are also interesting philosophically via engagement with theories of property,
global distributive justice, and the normative/empirical distinction. However, nothing in
this discussion ought to imply that a right to health is only linked to access to health care
services or pharmaceuticals, nor that general reduction in poverty, international debt
relief, or any of the other issues of “global justice” are not equally, if not more, important
in particular circumstances. Instead, this project has critically examined one specific
question – Do IPRs inhibit access to essential medicines? – and given us reason to think
that they do, that we have good normative reasons to change them, and that these
reasons suggest the kinds of changes to consider. This, I hope, adds intellectual force to
the power of normative change.
<table>
<thead>
<tr>
<th>Proposal</th>
<th>Brief description</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Within Traditional IPRs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Donation Programs</td>
<td>Provides free or low cost medicines to individuals</td>
<td>Mectizan Donation Program</td>
</tr>
<tr>
<td>Differential Pricing &amp; Licensing</td>
<td>Charges different prices, or allows for different licensing provisions, in low-income countries</td>
<td>Differential pricing Equitable licensing (Kapczynski, et al., 2005)</td>
</tr>
<tr>
<td>Implementation of TRIPS flexibilities</td>
<td>Takes advantage of existing WTO flexibilities often overlooked</td>
<td>Kenya (Lewis-Lettington and Munyi, 2004) Many others</td>
</tr>
<tr>
<td>Vouchers &amp; Transferable Market Exclusivity (TME)</td>
<td>Create incentives for targeted diseases by giving additional, tradable market exclusivity to other products</td>
<td>FDA Priority Vouchers Ridley TME (Bourgeois and Burns, 2001)</td>
</tr>
<tr>
<td>Patent Buy-outs</td>
<td>Government buys most patents at fair market value and releases them into the public domain</td>
<td>Kremer (Kremer, 1998) Outterson’s proposal for the cervical cancer vaccine (Outterson, 2006)</td>
</tr>
</tbody>
</table>
| Description | Patent Pools | Agreement between two or more patent holders to license patents to each other and to others | Essential Patent Pool for AIDS (http://www.essentialinventions.org/docs/eppa/)

**Both Traditional and Alternative**

| Description | Targeted Grants (push) & Advance Market Commitments (pull) | Grants “push” researchers to pursue particular problems; AMCs “pull” research toward particular problems, promising partial or complete purchases | Bill & Melinda Gates Foundation Global Health Program

Vaccine AMCs (Barder, et al., 2005, Kremer and Glennerster, 2004)

| Description | Limited patents in poor countries | Allows poor countries access to generics so long as they represent a small percentage of global demand | Foreign Filing License (Lanjouw, 2003)

**Alternatives to traditional IPRs**

<p>| Description | Clinical Trials as a Public Good (Public Funding) | Public funding reduces the undersupply of clinical trials and R&amp;D costs, leading to lower prices and better trials | Lewis et al. (Lewis, et al., 2007) |</p>
<table>
<thead>
<tr>
<th>Prize Funds</th>
<th>Reward innovation not with exclusive patent rights but with disbursements from a fund based upon safety, efficacy, health impact, etc.</th>
<th>Medical Innovation Prize Fund (Love, 2006) Medical R&amp;D Treaty(^1) Patent 2 (Pogge, 2005)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compensatory Liability</td>
<td>“Use first, pay later” approach; liability, not property</td>
<td>Jerome Reichman (Reichman, 1994, Reichman, 2000, Reichman and Lewis, 2005)</td>
</tr>
<tr>
<td>Open Source</td>
<td>Drug discovery via a collaborative enterprise at the interface of computing and chemistry; discoveries developed by others without patents</td>
<td>Tropical Disease Initiative (Maurer, et al., 2004)</td>
</tr>
</tbody>
</table>

Table 2: Normative Evaluative Criteria Explained

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop First, Distribute Later (access to currently existing medicines)</td>
<td>Does the reform allow for secure access to essential medicines, now and in the future?</td>
</tr>
<tr>
<td>Types of Innovations Produced</td>
<td>Does the reform create incentives for the right kinds of essential medicines, reducing the bias in medical R&amp;D toward developed country needs?</td>
</tr>
<tr>
<td>Ownership of IPRs (capacity building)</td>
<td>Does the reform facilitate capacity building in developing countries, so that they can research, develop, and produce medicines for their own identified needs?</td>
</tr>
<tr>
<td>Distribution of Costs</td>
<td>How are the costs of implementing the reform distributed, and if so, are they equitable?</td>
</tr>
<tr>
<td>Need for New Institutions</td>
<td>Are modified or existing institutions (for intellectual property or otherwise) needed to implement the reform?</td>
</tr>
<tr>
<td>Political Feasibility</td>
<td>Is the reform politically feasible, i.e., able to support itself with a reasonable chance of being implemented?</td>
</tr>
<tr>
<td>Subject-centered Justice</td>
<td>Does the reform display adequate respect for subject-centered justice, the hallmark of human rights?</td>
</tr>
<tr>
<td>Proposal</td>
<td>Access to Medicines</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Drug Donation Programs</td>
<td>YES – via free donation</td>
</tr>
<tr>
<td></td>
<td>Future and current medicines</td>
</tr>
<tr>
<td>Differential Pricing</td>
<td>YES – via affordable pricing</td>
</tr>
<tr>
<td></td>
<td>Future and current medicines</td>
</tr>
<tr>
<td>Differential Licensing</td>
<td>YES – via competition</td>
</tr>
<tr>
<td></td>
<td>Future medicines</td>
</tr>
<tr>
<td>Implementation of TRIPS flexibilities</td>
<td>YES – via compulsory licensing and other measures</td>
</tr>
<tr>
<td></td>
<td>Future and current medicines</td>
</tr>
<tr>
<td>Policy Area</td>
<td>Future Medicines</td>
</tr>
<tr>
<td>-------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Vouchers &amp; Transferable Market Exclusivity (TME)</td>
<td>YES – via competition enabled by release of patent into the public domain in exchange</td>
</tr>
<tr>
<td>Patent Buy-out</td>
<td>YES – via competition enabled by release of patent into public domain</td>
</tr>
<tr>
<td>Patent Pools</td>
<td>YES – depending on the licensing terms of the pool</td>
</tr>
<tr>
<td>Targeted Grants (push) &amp; Advance Market Commitments (pull)</td>
<td>YES – if the grant and/or AMC is able to set prices low</td>
</tr>
<tr>
<td>Limited patents in poor countries</td>
<td>YES – if countries have manufacturing, allow competition, or import medicines</td>
</tr>
<tr>
<td>Clinical Trials as a Public Good (Public Funding)</td>
<td>YES – if the decreased R&amp;D cost leads to decreased prices</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>Prize Funds</td>
<td>YES – via competition</td>
</tr>
<tr>
<td>Compensatory Liability</td>
<td>YES – depending on the royalty rate and lowered prices that result</td>
</tr>
<tr>
<td>Open Source</td>
<td>YES – via competition</td>
</tr>
</tbody>
</table>
Table 4: Reform Proposals and the Other Normative Concerns

<table>
<thead>
<tr>
<th>Proposal</th>
<th>Distribution of Costs</th>
<th>New Institutions</th>
<th>Feasibility</th>
<th>Subject-centered Justice</th>
<th>Main Advantages</th>
<th>Main Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Donation Programs</td>
<td>To pharmaceutical companies; recouped via tax credits, other sales</td>
<td>NO</td>
<td>YES – but scale is questionable</td>
<td>NO</td>
<td>Provides free access to drugs</td>
<td>Limited in scope (disease, treatment) Charity, not justice</td>
</tr>
<tr>
<td>Differential Pricing</td>
<td>Unclear who should bear the burden of preventing re-entry</td>
<td>YES – means to prevent re-entry</td>
<td>MAYBE</td>
<td>YES</td>
<td>Provides access to existing drugs at affordable prices</td>
<td>Limited to whatever R&amp;D system produces Requires market segmentation</td>
</tr>
<tr>
<td>Differential Licensing</td>
<td>Minimal amount of lost revenue to licensor</td>
<td>NO</td>
<td>YES – university precedent</td>
<td>YES</td>
<td>Does not require new institutions</td>
<td>Limited to whatever R&amp;D system produces</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Leverages public sector power</td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th><strong>Implementation of TRIPS flexibilities</strong></th>
<th><strong>Unclear whether developed countries ought to assist developing ones</strong></th>
<th><strong>NO</strong></th>
<th><strong>NO – undermined by FTA</strong></th>
<th><strong>YES</strong></th>
<th><strong>Does not require new international agreements, institutions</strong></th>
<th><strong>Unlikely to work, given realities of global politics (FTAs)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vouchers &amp; Transferable Market Exclusivity (TME)</strong></td>
<td><strong>Consumers of particular medicines in developed countries</strong></td>
<td><strong>YES – system to monitor and administer vouchers</strong></td>
<td><strong>NO – because of cost distribution</strong></td>
<td><strong>YES</strong></td>
<td><strong>Stimulates R&amp;D into neglected diseases</strong></td>
<td><strong>Cost borne by specific individuals in developed countries, rather than widely shared</strong></td>
</tr>
<tr>
<td><strong>Patent Buy-outs</strong></td>
<td><strong>Government (tax payers); recouped via cheaper prices</strong></td>
<td><strong>YES – auction system</strong></td>
<td><strong>MAYBE</strong></td>
<td><strong>YES</strong></td>
<td><strong>Lowers drugs prices on most drugs via competition</strong></td>
<td><strong>Limited to whatever R&amp;D system produces</strong></td>
</tr>
<tr>
<td><strong>Patent Pools</strong></td>
<td><strong>Depends upon how non-profit patent pool is funded</strong></td>
<td><strong>YES – but with historical precedent</strong></td>
<td><strong>YES – historical precedent</strong></td>
<td><strong>YES</strong></td>
<td><strong>Would help foster unique technologies: FDCs, multivalent vaccines</strong></td>
<td><strong>Does not create “new” incentives for neglected diseases Administration</strong></td>
</tr>
<tr>
<td>Approach</td>
<td>Beneficiary</td>
<td>Funding Source</td>
<td>Already Occurs</td>
<td>Enables Fast Targeting</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------</td>
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<td>----------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Targeted Grants (push) &amp; Advance Market Commitments (pull)</td>
<td>Private foundations; taxpayers</td>
<td>NO</td>
<td>YES - already occurs</td>
<td>YES</td>
<td>Enables fast targeting of projects by private foundations</td>
<td></td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Dependent in some cases on will of these foundations; less than ideal match with how R&amp;D works (stepwise, not all-in-one)</td>
<td></td>
</tr>
<tr>
<td>Limited patents in poor countries</td>
<td>Minimal revenue loss to patent holder in developing country</td>
<td>NO</td>
<td>YES - already occurs</td>
<td>YES</td>
<td>No new institutions needed</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Limited to whatever R&amp;D system produces</td>
<td></td>
</tr>
<tr>
<td>Clinical Trials as a Public Good (Public Funding)</td>
<td>Governments (tax payers); recouped via cheaper prices</td>
<td>YES - government oversight</td>
<td>MAYBE</td>
<td>YES</td>
<td>Better clinical trials for otherwise underproduced knowledge</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Uncertain whether it would lead to lower prices</td>
<td></td>
</tr>
<tr>
<td><strong>Prize Funds</strong></td>
<td>Governments, employers, private foundations; depends upon prize system</td>
<td>YES – prize administration</td>
<td>YES – historical precedent</td>
<td>YES</td>
<td>Allows targeting via the definition of the prize; rewards quality innovation</td>
<td>Requires continual political commitment by governments for most expansive version</td>
</tr>
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<td>-----------------------------------------------------------------</td>
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</tr>
<tr>
<td><strong>Compensatory Liability</strong></td>
<td>Governments who administer scheme</td>
<td>YES</td>
<td>MAYBE</td>
<td>YES</td>
<td>Databases, traditional knowledge, sub patentable invention</td>
<td>Radically different; replaces property with liability but could work with existing IPRs</td>
</tr>
<tr>
<td><strong>Open Source</strong></td>
<td>Relatively free (voluntary contribution)</td>
<td>YES – but growing</td>
<td>YES – success uncertain</td>
<td>YES</td>
<td>Low cost screening</td>
<td>Requires other organizations to take discoveries forward</td>
</tr>
</tbody>
</table>
Bibliography


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Harris, Gardiner. “Spitzer Sues a Drug Maker, Saying It Hid Negative Data.” *New York Times*, 3 June 2004, 1.


Merck & Co. Inc. (press release). “First Installment of Merck Gene Index Data Released to Public Databases: Cooperative Effort Promises to Speed Scientific
Understanding of the Human Genome.” no. Available at:

Merges, Robert P. “Institutions for Intellectual Property Transactions: The Case for
Patent Pools.” no. Available at:

Merry, Sally Engle. “Rights Talk and the Experience of Law: Implementing Women’s
Human Rights to Protection from Violence.” In Women’s Rights: A Human Rights
Quarterly Reader, edited by Bert B. Lockwood, 393-430. Baltimore, MD: The Johns

1848.

Miller, David. “Justice and Global Inequality.” In Inequality, Globalization and World
University Press, 1999a.


Miller, Richard. “Global Institutional Reform and Global Social Movements: From False


Moher, David, and Alan Bernstein. “Registering CIHR-Funded Randomized Control


Mukherjee, Joia. “Basing Treatment on Rights, Rather Than Ability to Pay: 3 by 5.”


Risse, Mathias. “Do We Owe the Global Poor Assistance or Rectification?” Ethics & International Affairs 19, no. 1 (2005): 9-18.


Biography

Born 29 June 1978 in Indianapolis, Indiana (USA), Matthew Wayne DeCamp is the son of Larry and Ann DeCamp. He has one brother, David. Matt graduated from Perry Meridian High School (Indianapolis) in 1996 and received his BS in molecular biology and biochemistry from Purdue University in 2000. The following fall, he entered Duke University’s Medical Scientist Training Program (MSTP) to pursue a combined MD-PhD. Following two years of medical school, and with the enthusiastic support of Jeremy Sugarman (founding director of Duke’s Center for the Study of Medical Ethics and Humanities; now at Johns Hopkins), Robert Cook-Deegan (director of Duke’s Center for Genome Ethics, Law, and Policy), and then MSTP-director Salvatore Pizzo. This thesis represents the outcome of five years of work in the philosophy department, encouraged by Allen Buchanan and Alex Rosenberg, culminating in a unique MD-PhD combination for Duke’s MSTP. Throughout the past several years, Matt enjoyed support from Duke’s Institute for Genome Sciences and Policy (2004-2005 graduate student fellowship), IGSP’s Center for Genome Ethics Law and Policy (2005-2006), Duke’s Kenan Institute for Ethics (2006-2007 Dissertation Fellowship), the Franklin Humanities Institute (2006-2007 Dissertation Working Group), and Duke’s Program on Global Health and Technology Access (Anthony So, director).

Matt thanks all his friends and family, but most notably, his wife Lisa Ross DeCamp, MD MSPH, for her love and support. A list of publications follows.


