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Innovation and International Competitiveness in Pharmaceuticals

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Introduction

The research-based pharmaceutical industry dates back to the 1930s with the discovery and development of the first anti-infectives. Schumpeterian competition has flourished in this industry since its inception. Recently, this competition has also become global in character. Competition in the pharmaceutical industry now focuses on the search for major new product advances capable of obtaining significant market shares on a worldwide basis. Furthermore, pharmaceutical firms have evolved into extensive multinational structures with research, production, and sales facilities in many countries.

Given the multinational character of the pharmaceutical industry, one can take two alternative perspectives with respect to international competitiveness. From one perspective, domestic firms and foreign subsidiaries are grouped together, reflecting their common ownership structure. From this perspective, for example, the discovery and development of a new drug in England by a subsidiary of a U.S. firm would be considered a U.S. innovation. The rationale for this approach would be that the U.S. parent firm owns the patent rights to that discovery and the residual returns from it will accrue to the parent firm.

An alternate perspective on international competitiveness focuses on the country of origin for new product discoveries, regardless of the ownership of the discovery. From this perspective, the discovery and development in a British laboratory of a new product by a U.S. subsidiary would be considered a British innovation. The rationale for this approach would be that regardless of who owns the patent rights, many of the benefits from an international competitiveness standpoint will accrue to the country of discovery (i.e., in terms of scientific prominence and R&D employment). Moreover, one can increasingly see countries competing for the location of high technology R&D activity undertaken by geographically diversified multinational entities. The

research-based pharmaceutical industry is relatively far along in terms of this kind of multinational development, especially when compared to many other industries.

Both the industry ownership and country perspectives on international competitiveness are of interest, depending on the particular issue under investigation. In this current essay, both perspectives are considered in an analysis of international competitiveness in pharmaceuticals. Historically, the United States has been the worldwide leader from both of these perspectives. That is, the U.S. pharmaceutical industry, comprised of its domestic and foreign operations, has been the world leader in new product innovations and global sales. Similarly, the United States has been the leading country in terms of new drug discoveries and product development (but not typically the country of first new product introduction).[1]

Over the recent years, however, the continued leadership of the U.S. pharmaceutical industry and the United States as the leading source of new drug research and development have been called into question. A study by the National Academy of Engineering (1983) presents various adverse developments in this regard. It also points to the recent rapid growth of the Japanese pharmaceutical industry. The NAE report suggests that Japan may become the worldwide leader in pharmaceuticals in future decades, consistent with their ascendancy in various other high-tech industries.

In this essay, the issue of international competitiveness is analyzed utilizing additional data and more recent data than that used in the NAE study. This study significantly extends the analysis in my article on this topic (Grabowski 1989). The first part of the essay considers international competitiveness from an industry ownership perspective with firm ownership structure being the basis for categorizing innovation and other performance measures. The second part of the essay focuses on international competitiveness using the country of origin, rather than the nationality of firms, to categorize innovative performance. The last section presents a summary and conclusions.

International Competitiveness: An Industry Perspective

Worldwide Sales Rankings

Table 1 shows the corporate nationality of the top twenty-five and fifty firms ranked by worldwide pharmaceutical sales in 1985. Two points clearly emerge from table 1. First, the drug firms in five countries—the United States, Japan, Germany, the United Kingdom, and Switzerland—dominate the worldwide pharmaceutical industry. Collectively the firms from these countries account for all of the top twenty-five firms and forty-five of the top fifty firms. Given that the fifty top-ranked firms in pharmaceuticals account for over 80 percent of worldwide sales, the prominence of these five national industries in the worldwide pharmaceutical market is clearly evident.[2]

A second basic point emerging from table 1 is the strong leadership position of the U.S. industry in terms of worldwide sales. In particular, the U.S. industry has thirteen of the top twenty-five firms. No other country has more than four of the top twenty-five firms. If one focuses on the top fifty firms, the United States is still the leader (with nineteen firms), but Japan is a close second (thirteen firms). The emerging presence of the Japanese industry with its strong representation in the second tier of top fifty firms is an interest-

1. One of the usual measures for gauging international competitiveness in other industries, the balance of trade, has limited applicability in a multinational industry like pharmaceuticals. This is because imports and exports account for a relatively small share of total pharmaceutical production in many of the leading countries (National Academy of Engineering 1983, 47–50).

2. The data presented in *Script* (1986) indicates that the top fifty firms in sales account for 81.1 percent of total worldwide pharmaceutical sales in 1985. Of these fifty firms, the top twenty firms account for 61.7 percent of total worldwide sales.

TABLE 1. Corporate Nationality of Pharmaceutical Companies Ranked in Top Twenty-Five and Top Fifty Firms in Terms of Worldwide Sales, 1985

	Number of Companies Ranked in	
Nationality	Top 25	Top 50
United States	13	19
Japan	2	13
West Germany	3	5
United Kingdom	4	5
Switzerland	3	4
France	0	2
Italy	0	1
Sweden	0	1
Netherlands	0	1
	25	50

Source: Script, 1986.

Notes: Ranking is based on worldwide pharmaceutical sales in 1985 dollars. Currency conversion is based on the average annual dollar exchange rate for the year ending December 31, 1985.

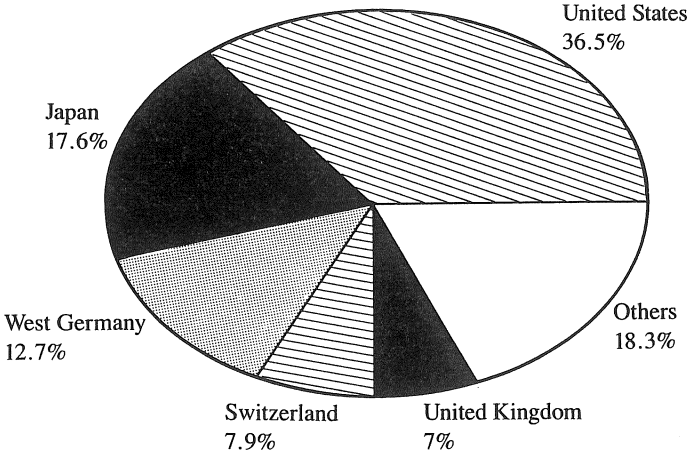

Fig. 1. Shares of worldwide sales in 1986 by corporate nationality. Total sales = $70.9 billion. (Data from IMS, Inc., audit surveys of thirty-three countries.)

ing finding. At this time, the Japanese pharmaceutical industry is much more fragmented than the other major research-intensive industries.

The picture of international competitive performance in table 1 is consistent with data on worldwide sales shares in pharmaceuticals. Figure 1 presents market shares of international sales in 1986 by corporate nationality. This is based on audit data surveys of drugstore and hospital sales in thirty-three countries, including all of the major developed countries. This is a different, but complementary, data source to the corporate income statements underlying the rankings in table 1.[3]

Figure 1 shows that the U.S. pharmaceutical industry is the worldwide leader with 36.5 percent of sales in 1986. This is more than twice the second-ranked Japanese industry's share of 17.6 percent. These two entities are followed by the pharmaceutical industries from West Germany (12.7 percent), Switzerland (7.9 percent), and the United Kingdom (7 percent). The industries from these five countries account for approximately 82 percent of the worldwide sales covered by the audit surveys.

The shares in table 1 and figure 1 reflect the past successes of U.S. firms in new product discovery and development. However, the principal concern of the NAE Report was future competitiveness. This is related to current and

3. The audit data is collected by International Medical Statistics using comparable survey methods for all major pharmaceutical market areas.

future new product introductions and to R&D activity now in process. These measures of competitive performance are considered in the next two sections.

New Product Introductions

Table 2 shows the historical shares of worldwide new product introductions accounted for by the drug industries of each country. These are taken from an analysis of this topic by Reis-Arndt (1983) and cover the period 1961 to 1980. As this table indicates, the United States drug industry was the source of more new drugs than any other country over these two decades. It accounted for approximately 24 percent of the total worldwide introductions over this period.[4]

Table 3 provides the results of a comparable analysis of new product introductions for the 1980s. The U.S. industry has maintained a share of worldwide introductions during the 1980s commensurate with its historical share shown in table 2. However, what is especially striking about the results presented in table 3 is the rapid growth in this decade of new product introductions emanating from the Japanese pharmaceutical industry. Their share during the 1980s is 27.9 percent, which exceeds that of the U.S. industry. This compares with a historical share during the 1961–80 period of only 10 percent. Correspondingly, most of the European industries exhibit declining shares in the 1980s, compared to their historical values in the prior two decades.

The results given in table 3 appear to bear out the concerns of the NAE study that the Japanese drug industry will pose the greatest challenge to future leadership by the U.S. industry. Indeed, that future would seem to be materializing faster than anyone had anticipated at the beginning of the 1980s. However, one must be cautious in making inferences about likely changes in future international competitiveness using only the data underlying table 3. These shares are based on simple counts of new product introductions emanating from different national industries.

Consensus New Drugs

In my earlier paper (1989) I emphasized the importance of incorporating a measure of the *quality* of new product introductions in evaluating innovative importance. This is because the commercial and medical significance of new

4. By contrast, the United States was the country of first introduction only 7.9 percent of the time during the 1961–80 period. This is true despite the fact that U.S. firms were the leading originators of drugs over this period, as shown in table 2. This reflects the more stringent regulatory conditions in the United States, compared to other developed countries.

TABLE 2. New Drug Introductions by Nationality of Originating Firm, 1961–80

Country	Number of New Drug Introductions	Share (%)
United States	353	23.6
France	271	18.1
West Germany	201	13.4
Japan	155	10.3
Italy	119	7.9
Switzerland	109	7.3
United Kingdom	74	4.9
Others	216	14.4
Total	1,498	99.9

Source: Reis-Arndt (1983).

Note: Substances developed simultaneously in two countries are included in each country's totals.

TABLE 3. New Drug Introductions by Nationality of Originating Firm, 1981–87

Country	Number of New Drug Introductions	Share (%)
Japan	93	27.9
United States	77	23.1
West Germany	35	10.5
Italy	30	9.0
France	26	7.8
Switzerland	24	7.2
United Kingdom	15	4.5
Others	33	9.9
Total	333	99.9

Source: Scrip (various issues).

Note: Substances developed simultaneously in two countries are included in each country's totals.

product innovations varies widely.[5] In the earlier study I focused on the set of drugs that became "consensus" introductions in terms of international acceptance. In particular, consensus introductions are those that are marketed in a majority of the major markets worldwide. The shares of consensus New Chemical Entities (NCEs) were found to be very different from those presented in table 3. The analysis undertaken here extends my earlier work using this quality-adjusted measured of research output.

5. See, for example, the studies by Joglekar and Patterson (1986) and Grabowski and Vernon (1982) that show that the distribution of revenues emanating from new product introductions is highly skewed. In both studies the top few deciles of new product introductions account for a very large share of the total sales and profits from new drug introductions.

TABLE 4. Consensus New Drug Approvals by Nationality of Originating Firm, 1970–85

Country	Number of Consensus Drugs	Share (%)
United States	85	43.4
Switzerland	27	13.8
United Kingdom	19	9.7
West Germany	17	8.7
Sweden	10	5.1
Italy	9	4.6
Japan	8	4.1
France	5	2.5
Others	16	8.1
Total	196	100.0

Source: Data compiled by author from U.S. Food and Drug Administration (1985) and Paul de Haen International (1985).

Note: Consensus NCEs are defined as new drugs approved for marketing in at least six of eleven major markets over the period 1970–85.

In this paper, the sample of consensus new drug introductions has been extended in time to cover the period 1970 to 1985.[6] In addition, an analysis of the origins of each compound has been undertaken so that they could be classified both in terms of the country of discovery and the nationality of the discovering firm. In this section the analysis is concerned with industry groupings based on the ownership of new drugs, whereas I will consider new drugs classified by country of discovery in the next section of the essay.

Table 4 presents the distribution of consensus NCEs by the nationality of the originating firm for new drugs first approved for marketing between 1970 and 1985. A consensus NCE is formally defined as a new drug entity that was approved for marketing in at least six of the eleven major markets for which approval data were available. These eleven markets are the United States, Japan, West Germany, France, Italy, the United Kingdom, Switzerland, Norway, Sweden, Canada, and Australia.

Table 4 indicates that the U.S. industry had the largest share of the consensus NCEs (43.4 percent) for these eleven markets over the 1970–85

6. This sample extends in time the one assembled by Coppinger and Haas (1986) that was utilized in my earlier study (Grabowski 1989). While the sample covers all new drug approvals in the eleven countries between 1970 and 1985, the last year for which a consensus NCE occurs in this sample is 1983. This reflects the fact that it generally takes at least two years for a new drug to diffuse across six of the eleven markets considered in this analysis.

period. Furthermore, the share of consensus NCEs accounted for by the U.S. industry is approximately double its 24 percent share of worldwide NCE introductions over the same period. The pharmaceutical industries from the three leading European countries form a second group with Switzerland accounting for 13.8 percent, Great Britain 9.7 percent and West Germany 8.7 percent of the consensus NCEs. By contrast, the Japanese industry had only a 4.1 percent share of consensus NCEs over this period. France and Italy also have much lower shares of consensus NCEs than of total NCEs.

The sharp divergence in the shares observed for Japan in tables 3 and 4 pose some interesting questions about Japanese innovative efforts in pharmaceuticals. These data would seem to indicate that the Japanese have been successful in turning out many new drug therapies, but few have been distinctive enough to receive widespread international acceptance. This, in turn, appears to be symptomatic of an industry concentrating on imitative, or "me-too," compounds rather than more fundamental advances.

The shares of consensus NCEs reported in table 4 may not, however, provide an accurate reading of the present situation for Japan. The Japanese industry has been evolving from a generic-oriented and imitative one in the 1960s and early 1970s to a more innovative industry in recent years (Yamamoto 1986). Moreover, the data on total worldwide introductions show a sharply rising trend in the Japanese industry share over the 1980s. If this were also associated with more innovative advances, this would become evident in consensus NCE shares only with some time lags.

In order to gain further insights into this issue, I have disaggregated the sample of consensus NCEs into three subperiods by the year of initial approval for marketing; 1970–73, 1974–78, and 1979–83. These results are reported in table 5. This table shows the U.S. industry had a dominant share in all three subperiods. The data, however, also show a rising share for Japan. For the most recent period, 1979 to 1983, the Japanese industry had a 12 percent share of consensus NCEs. This put it even with the Swiss industry for second place for this period. While the sample for this recent period is small,

TABLE 5. Consensus New Drug Approvals by Nationality of Originating Firm and Year of First Approval

Year of First Approval	New Entities	Share Distribution (%)						
		United States	Japan	Switzerland	United Kingdom	West Germany	Italy	France
1970–73	76	38	3	17	8	8	8	3
1974–78	79	47	1	11	11	11	1	3
1979–83	41	46	12	12	10	5	5	2

these results are consistent with the view that the Japanese industry is rapidly evolving as an innovator in pharmaceuticals. Nevertheless, the gap between the United States and Japan in this respect is still quite large.

One might argue that the measure of product quality being employed here, consensus NCEs, is biased toward national drug industries that are highly multinational in nature (e.g., United States and Switzerland) and against those which are not very multinational (e.g., Japan). While this may be the case, it should be kept in mind that there is a very active market in new product licenses in pharmaceuticals. Hence, if a new drug demonstrates therapeutic and commercial potential it can be readily licensed to other firms if the originator does not have the capabilities to market it in other countries. Indeed, the Japanese have become the major supplier of foreign licenses in pharmaceuticals in the United States in recent periods.[7] While licensing may cause a slower diffusion process compared to marketing through foreign subsidiaries, there should be no strong barrier to eventual diffusion if a new drug compound offers significant medical and therapeutic advantages.

It should also be noted that the calculation of shares based on other quality-adjusted measures are very consistent with calculations using consensus NCEs given above. In this regard, Barral (1985) has found a high correlation between new product ratings based on the ranking of medical experts, commercial significance, and the degree of internalization of a new drug compound. In addition, the Office of Health Economics (1985) presented an analysis of the origins of the leading products in 1980 and found that U.S. firms had developed 35 of the top 100 products ranked in terms of worldwide sales. This represented 39.4 percent of the total sales of these top 100 products. This is very close to the U.S. industry's share of consensus NCEs given in table 4. In addition, the shares of the top 100 products ranked by sales for the other national industries are also comparable to their shares of consensus NCEs.

Another related finding bearing on this issue involves the origins of the drug compounds introduced into the U.S. market that achieved major commercial prominence. This was defined as new drugs that obtained 100 million dollars of sales by their fifth year after market introduction. A list of these "blockbuster" drugs is presented in table 6. There were fourteen compounds in the 100 million dollar category among all the drugs introduced into the United States market between 1970 and 1982. Nine of these fourteen compounds were discovered and developed by U.S. firms. This is 62 percent, on a sales-weighted basis. The U.S. industry's large share of this group is con-

7. A recent analysis of this issue has been performed by Mattison, Trimble, and Lasagna (1988). Their study shows that since 1979, Japan has exceeded Western Europe as a source of new chemical entities acquired by U.S. firms.

TABLE 6. New Drug Products Achieving 100 Million Dollars Sales[a] in the U.S. Market by Fifth Year of Market Life, 1970–82

Product	Year of Introduction	Originating Firm	U.S. Marketer
Keflex	1971	Lilly	Lilly
Motrin	1974	Boots (U.K.)	Upjohn[b]
Naprosyn	1976	Syntex	Syntex
Tagamet	1977	SKF	SKF
Clinoril	1978	Merck	Merck
Lopressor	1978	Hassle (Sweden) and Geigy (Switzerland)	Ciba-Geigy
Mandol	1978	Lilly	Lilly
Mefoxin	1980	Merck	Merck
Capoten	1981	Squibb	Squibb
Tenormin	1981	ICI (U.K.)	ICI
Cardizem	1982	Tanabe (Japan)	Marion[b]
Feldene	1982	Pfizer	Pfizer
Procardia	1982	Bayer (Germany)	Pfizer[b]
Xanax	1982	Upjohn	Upjohn

Sources: Sales data from IMS Surveys; origin and marketer data from Paul de Haen International (1985).

[a]Sales measured in 1986 dollars using the GNP price deflator.

[b]Marketed in U.S. under license from originating firm shown in column 3.

sistent with its high level of consensus compounds over this period and its observed shares in terms of other quality-adjusted measures.

Products under Development

Future new product introductions and market sales will be generated from the candidate drugs currently in the R&D pipeline. An annual survey is conducted of the number of compounds in clinical development by pharmaceutical firms. While there will be a high variance in the market value realized by those development projects, aggregate counts of products under development still provide some indication of the future potential for innovation of different national drug industries.[8]

In figure 2, the distribution of drugs under development in 1987 classified by industry share is presented. The sample is based on the top hundred

8. Only about 10 to 20 percent of drug compounds entering clinical testing (depending on therapeutic categories and other factors) become successful market introductions in the United States (Mattison et al. 1988). Moreover as noted in n. 4, the distribution of sales on the new product introductions is also highly skewed (Joglekar and Patterson 1986).

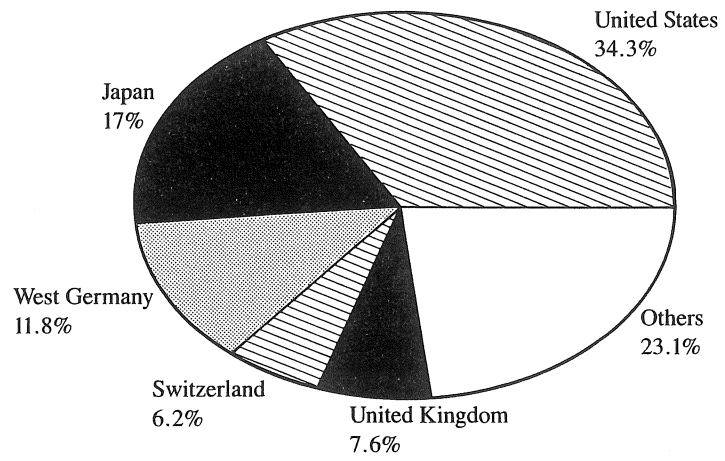

Fig. 2. Shares of compounds under development for top hundred R&D firms in 1987. Total compounds = 2,908. (From *Script* 1988.)

firms ranked in terms of drugs under development. While some bias may be introduced from examining only compounds under investigation by the top hundred firms, these firms historically account for the overwhelming share of new product innovations in pharmaceuticals.

The industry shares of products under development given in figure 2 are very similar to their shares based on worldwide sales given in figure 1. In particular, the U.S. industry has approximately the same share of drugs under development (34 percent) as it has of worldwide sales (36 percent). This is also the case for the other major R&D oriented industries. This relationship between sales and future drug candidates apparently reflects the fact that current sales provide the primary basis for funding R&D in pharmaceuticals.[9]

While the number of new drugs in the pipeline provides only a gross indicator of the likely future competitive success in pharmaceuticals, this measure shows that the U.S. industry is at least in a position to continue its world leadership based on the volume of the new drug candidates currently under investigation.

International Competitiveness: A Country Perspective

In this section, I consider how "R&D productivity" or innovative output per dollar of R&D expenditure varies across different countries. The focus here is

9. This issue has been investigated in the case of the U.S. industry by Grabowski and Vernon (1981) and Jensen (1988).

on the innovative performance of the research activities located in a particular country. This is in contrast to the preceding analysis, which focused on the performance of different industries grouped together in terms of parent companies and foreign subsidiaries.

New Drugs Grouped by Country of Origin and Firm Ownership

As a first step in this analysis, the sample of new drug products first approved in the eleven major markets over the ten year period, 1976–85, were classified both in terms of the country where the drug was discovered and the nationality of the firm making the discovery. The results of this analysis are presented in the matrix given in table 7. Each row shows the NCE originating from a particular country's drug industry (i.e., parent and foreign subsidiaries) while the columns show the country where the drug was discovered.

Table 7 shows that the vast majority of the drugs in each country originate from the domestic drug industry in that country. That is to say, the diagonal elements of the matrix contain most of the entities. In the case of the United States, for example, ninety-one of the ninety-nine drugs originating from the United States over this decade were from the domestic industry. The other eight drugs were from foreign subsidiaries of Swiss and British firms. In the case of Japan, all seventy-four drugs originating in that country were from Japanese owned firms. One major exception to the dominance of the domestic industry is Belgium. In that country, fifteen of the seventeen new drugs originating in that country were from U.S. owned subsidiaries. This reflects the fact that Johnson and Johnson's subsidiary in Belgium, Janssen, has been a prolific source of new drug approvals. This single firm accounted for fourteen drugs attributed to U.S. subsidiaries in Belgium.

If one reads across the rows in table 7 rather than down the columns, one also is able to get a sense of how multinational the research efforts of a particular country's drug industry have been over this period. One can see that the most multinational in this regard are the U.S., Swiss, and British industries. These industries have had 20–30 percent of their total NCEs discovered by their foreign subsidiaries. All of the other research intensive industries have less than 10 percent of their NCEs discovered by foreign subsidiaries. For Japan, all its NCEs were discovered by its domestic industry over this ten year period.

R&D Productivity across Countries

Turning now to the issue of research productivity across countries, we wish to relate the research output of each country to the inputs utilized to discover and

TABLE 7. New Drug Approvals in Eleven Country Sample Classified by Country of Discovery and Nationality of Originator, 1976–85

Nationality of Originator	Country of Discovery (research location)										
	United States	Japan	West Germany	France	Italy	United Kingdom	Switzerland	Belgium	Other	Total
United States	91				4	6		15		116
Japan		74								74
West Germany			55	2	1					58
France			2	32						34
Italy					23		1			24
United Kingdom	4		1		2	17				24
Switzerland	4		1				20	1		26
Belgium			1					1		2
Other					1				22	23
Total	99	74	60	34	31	23	21	17	22	381

Source: Data from Paul de Haen International (various issues) and U.S. Food and Drug Administration (1985).

develop this output. This analysis raises some difficult methodological issues. One is the issue of R&D timing. There is a lengthy investment period in pharmaceuticals that can vary across countries.[10] A second major issue is the problem of the quality of research outputs. A simple count of new product approvals does not provide a good measure of research output in pharmaceuticals, given the large variance in medical and commercial importance among drugs.

With regard to the first issue in this study, no effort is undertaken to do a refined analysis of the timing of R&D inputs across countries. New drugs emanating from a particular country over the 1976 to 1985 period are divided by a country's R&D expenditures in 1975. This procedure gives us some rough comparative values that can then be subject to some sensitivity analyses on R&D input values. With respect to the quality issue, a two-part analysis is undertaken. In the first step, innovative output is measured in terms of total new drugs originating in a country over the 1976 to 1985 period (i.e., the values in the last row of columns in table 7). In the second step, the measure of innovative output is taken to be the number of consensus new drugs discovered in each country over this same period.

Figure 3 shows a comparison of R&D productivity for the five major research intensive countries using a country's total new drug discoveries as the measure of innovative output. The denominator is the country's R&D expenditures measured in hundreds of millions of 1975 dollars.[11] The United States and the three European countries exhibit similar R&D productivity values for this ten-year period. By contrast, Japan has a research productivity value that is roughly twice that of the other countries. This reflects the fact that the Japanese have almost as many total discoveries as the United States over this period (table 7) but less than half the R&D expenditures in this period.

Figure 4 shows R&D productivities by country with consensus NCEs rather than total NCEs as the measure of innovative output. The results are very different from those presented in figure 3. In particular, the United Kingdom has the highest R&D productivity when consensus NCEs are the measure of innovative outputs. The United States ranks just below the United Kingdom with this quality-adjusted R&D productivity measure. By contrast, Japan has the lowest R&D productivity, with a value only about one-third that of the two leaders.

10. The gestation lags in pharmaceutical R&D have been investigated in the case of the United States by Mattison, Trimble, and Lasagna (1988) and for the United Kingdom by Prentis, Lis, and Walker (1988).

11. R&D expenditures in 1975 by country were obtained from a survey by the Office of Health Economics (1985). R&D expenditures by country (in U.S. dollars) are as follows: U.S., 994 mil; West Germany, 451 mil; Japan, 323.1 mil; Switzerland, 195.2 mil; and United Kingdom, 185.3 mil.

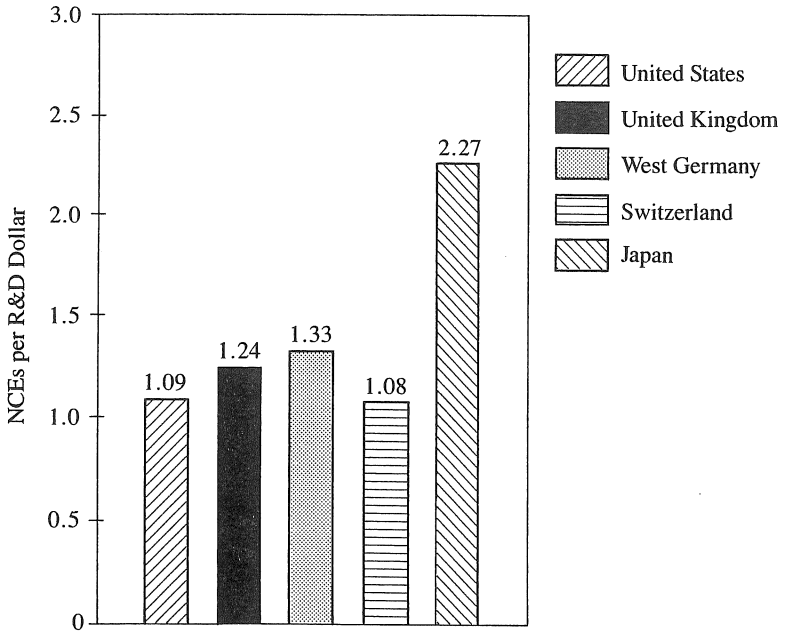

Fig. 3. R&D productivity using total new drug approvals as numerator

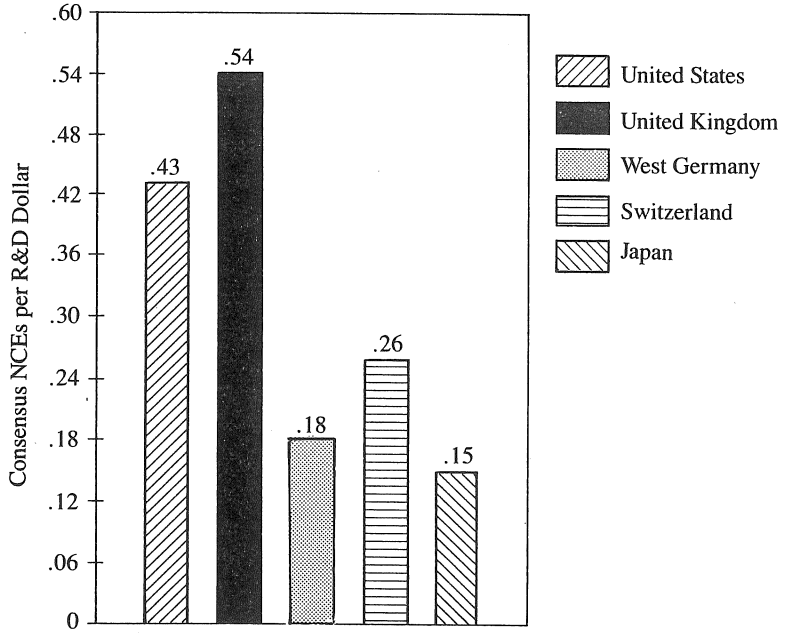

Fig. 4. R&D productivity using consensus new drug approvals as numerator

The complete reversal in Japan's ranking in R&D productivity when a quality-adjusted measure of innovative output is employed reflects the factors previously discussed, and the same caveats also apply. In particular, Japan appears to be in rapid transition to a more innovative approach to pharmaceutical R&D with greater emphasis now on discoveries of significant therapeutic values. Moreover, it takes longer for consensus drugs emanating from the Japanese industry to diffuse across other markets given the absence of a Japanese multinational structure in pharmaceuticals.

If one compares R&D productivity values using consensus NCE approvals for the most recent period for which data were available (drugs first approved between 1979–83), it shows that much of the gap between Japan and the United States observed in figure 4 is eliminated.[12] However, the total sample of consensus NCE introductions becomes quite small when one disaggregates in this fashion (41 drugs) so that these results are quite preliminary. Nevertheless, this finding points up the importance of this issue for future research. It will be interesting to track the performance of Japan in pharmaceuticals as it shifts to a more innovative focus in its research efforts.

Summary and Conclusions

In this essay, the issue of international competitiveness has been examined from two perspectives. The first perspective involves the innovative performance of multinational industry structures comprising domestic parent firms and their foreign subsidiaries. The second perspective involves the innovative performance of different countries, comprised of all the firms that undertake a particular activity within that country's geographical boundaries.

Historically, the United States has been the world leader from both perspectives. The U.S. owned firms have been the world leaders in drug discoveries since the end of World War II, and the United States has been the leading R&D location for these new drug discoveries. In recent years, however, concern has been raised by the National Academy of Engineering and others that Japan would soon surpass the United States in both dimensions.

The analysis undertaken shows that during the 1980s, the Japanese pharmaceutical industry has become the world leader in terms of worldwide new drug introductions. In addition, R&D productivity, as measured by total new drug introductions per R&D dollar expended, was found to be higher in Japan than in any of the other major countries undertaking pharmaceutical R&D. However, both these measures involve simple counts of drug introductions

12. The United States was the source of seventeen consensus NCEs over this period as compared to five for Japan. Since R&D expenditures in the United States were between two to three times greater (depending on the time lags employed), the R&D productivity for this later period is much closer in value than for the full 1976–85 period.

with no adjustment for commercial importance or therapeutic significance. It is important to make such adjustments in pharmaceuticals because the distribution of new drug introductions is highly skewed in terms of market value and therapeutic gain.

When a quality-adjusted measure of innovative output was employed, the findings were quite different. In particular, the analysis focused on consensus new drugs, or drugs approved for marketing in a majority of the world's major pharmaceutical markets, as a means of controlling for product quality. The U.S. pharmaceutical industry was found to be the leading source of consensus new drugs in all periods examined, whereas Japan ranked very low among the research-intensive industries until quite recently. Similarly, the United Kingdom and the United States have the highest R&D productivity in terms of consensus new drug approvals per dollar of R&D expenditure, while Japan has the lowest value of the major research-oriented countries.

The Japanese industry does appear to be evolving rapidly to a more innovative situation in the 1980s. This is shown by the upward trend in consensus new drugs emanating from Japan. In the most recent period examined, the Japanese along with the Swiss had the highest share of consensus new drugs after the U.S. drug industry. However, the gap between the United States and these countries still remains large.

Based on the analysis undertaken here, continued U.S. leadership in pharmaceuticals would appear likely at least for the immediate future. The U.S. industry has not only been the leading source of recent drug advances, but they also have the largest number of new drug compounds currently under clinical investigation. With the long gestation period in pharmaceuticals, the major drug introductions of the next decade are already somewhere in the R&D pipeline.

Over a longer-run perspective, however, competitive performance in a dynamic Schumpeterian industry like pharmaceuticals will be significantly affected by a number of factors, including the public policies of each country. It should be noted that the economic environment for pharmaceuticals in the United States, traditionally the most attractive and open of all developed countries, is now undergoing rapid change.[13] Generic drugs are obtaining an increasing share of the U.S. marketplace. A number of public and private sector cost-containment measures are also beginning to have an impact on pharmaceutical sales and innovation incentives. Moreover, outpatient drugs consumed by the elderly will be subject to cost containment beginning in 1990 as a result of the recently enacted Medicare Catastrophic Coverage Act of 1988. This will lead to a significant increase in mandated generic usage as

13. These changing trends in the U.S. economic environment are discussed in Grabowski (1986; 1988) and Grabowski and Vernon (1986).

well as possibly other cost-containment measures. In sum, the economic environment for new pharmaceuticals during the 1990s may be very different from what previously has been the case in the United States. This could have a significant bearing on R&D incentives and competitive performance in the next decade and beyond.

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