IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Skolnick, *et al.*

Appl. No. 08/483,554

Filed: June 7, 1995

For: 17q-Linked Breast and Ovarian Cancer Susceptibility Gene

Art Unit: Unknown

Examiner: Unknown

Petition Under 37 C.F.R. § 1.14(e)(1) for Access to, And Copy of File Wrapper Contents of, Allowed Pending Application

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Petitioner, OncorMed, Inc. ("OncorMed"), hereby requests under 37 C.F.R. §1.14(e)(1) access to, and a copy of the application file wrapper contents of, allowed pending application number 08/483,554, filed June 7, 1995. The U.S. Patent and Trademark Office (PTO) is hereby authorized to charge the petition fee set forth in 37 C.F.R. § 1.17(i), and the fee for the copy of the file wrapper contents set forth in 37 C.F.R. § 1.19(b)(2), to Deposit Account No. 08-3038. A duplicate copy of this petition is enclosed. In accordance with M.P.E.P. § 103, a copy of this petition has been served on the applicants of the above-captioned application as shown in the attached Certificate of Service.

Summary of Urgent Need for Copy of File Wrapper of 08/483,554

The above-captioned application ("the '554 application") is referred to by number and filing date in European Patent Application EP 0 699 754, published March 6, 1996 (copy enclosed). In accordance with 37 C.F.R. § 1.14, and M.P.E.P. § 102, Petitioner has ascertained that the '554 application is pending. Assignees of the '554 application and Petitioner are currently involved in litigation, and court papers indicate that the '554

application may be expected to issue soon.[1] OncorMed has a due date of **April 20, 1998** for reply to one of the motions in the Varmus lawsuit. The contents of the file wrapper of the '554 application, and the representations made therein, are critical to OncorMed's reply due April 20, 1998. As explained in detail below, the assignees of the '554 application are using the '554 application, and others, to interfere with OncorMed's business, a "special circumstance" warranting access by OncorMed to the '554 application. Due to the impending litigation deadline, the granting of this petition, and providing the requested copy, is a matter of extreme urgency.

Basis for Access

Under 37 C.F.R. § 1.14(a)(3)(i), access to the '554 application, and a copy of the file wrapper and contents, may be given to Petitioner when the application file is available and it has been determined by the Commissioner to be necessary for the proper conduct of business before the Office or warranted by other special circumstances. As will be explained in more detail below, Petitioner respectfully submits that such access is warranted by special circumstances and is necessary for the proper conduct before the Office.

Special Circumstances

As noted in M.P.E.P. § 103, "special circumstances" can be found where an applicant has relied upon his or her application as a means to interfere with a competitor's business or customers. *See In re Crossman, Kenrick and Le Mieux*, 187 U.S.P.Q. (BNA) 367 (PTO Solicitor 1975); *In re Application for Trimless Cabinets,* 128 U.S.P.Q. (BNA) 95 (Comm'r Pat. 1960). The '554 application is part of a group of applications and patents directed to the isolation, sequencing, and characterization of the human chromosome 17q-linked gene predisposing to breast and ovarian cancer (the "BRCA1 gene"), collectively referred to herein as the "BRCA1 intellectual property". Petitioner respectfully submits that the assignees of the '554 application are using the BRCA1 intellectual property as a means to interfere with a

1 One of the lawsuits is OncorMed, Inc. v. Harold Varmus, M.D., Director, National Institutes of Health and the University of Utah, Civil Action No. 1:96CV02623 (JR), United States District Court for the District of Columbia ("the Varmus lawsuit").

competitor's business, specifically, the business of OncorMed. Based on information available to the Petitioner, the assignees of the '554 application are believed to be Myriad Genetics, Inc. ("Myriad"), University of Utah ("Utah"), and the United States of America as represented by the Secretary of Health and Human Services, Technology Transfer Office, particularly, the National Institutes of Health ("NIH").

OncorMed is a Gaithersburg, Maryland-based company engaged in the scientific research necessary for the development and marketing of molecular diagnostic services, particularly directed to early detection of predisposition to cancer. After public announcements of the BRCA1 results, OncorMed requested in September 1994 that the NIH Office of Technology Transfer grant OncorMed a non-exclusive license to NIH's BRCA1 intellectual property. Before responding to this request, NIH entered into, *inter alia*, an "Interinstitutional Agreement" with Utah and a "Settlement Agreement" with Utah and Myriad (collectively "the Agreements"). Through the Freedom of Information Act, OncorMed has obtained a redacted copy of the Interinstitutional Agreement and the Settlement Agreement; a copy of each is enclosed. One of the major purposes of the Settlement Agreement was to settle a dispute between NIH, Utah, and Myriad regarding ***inventorship*** of the BRCA1 intellectual property. NIH, Utah, and Myriad themselves determined that Dr. Wiseman and Dr. Futreal (inventors from NIH) are joint inventors of certain BRCA1 subject matter. Petitioner believes that Drs. Wiseman and Futreal are inventors listed on the '554 application.

Through the Agreements, NIH extended to Utah an exclusive license under domestic and foreign patent applications in which NIH scientists were or were to be named inventors. The exclusive license to Utah includes a right to sublicense (paragraph 3.1 of the Interinstitutional Agreement). Petitioner believes that Utah has granted a sublicense to Myriad, OncorMed's direct economic competitor. Subsequent to the Agreements, NIH formally rejected OncorMed's request for an exclusive license. This denial was predicated solely on the basis that the exclusive license to Utah, consummated after OncorMed had filed its request for a nonexclusive license, had fully disposed of all of the government's rights. OncorMed alleges in the lawsuit referred to above that in extending an exclusive license to

Utah, the NIH violated the procedural and substantive mandates set forth in 35 U.S.C. § 209, "Restrictions on licensing of federally owned inventions".

The inventorship of the BRCA1 intellectual property agreed to by the parties in the Settlement Agreement determines the initial ownership rights of the respective applications and patents. The ownership rights of the NIH affect the availability of licenses to third-party companies such as OncorMed through, *inter alia*, the provisions of 35 U.S.C. §§ 200-212. Therefore, the Settlement Agreement, and the representations made therein in the '554 application, have a direct effect on the availability of a license to OncorMed, thus directly affecting OncorMed's business. Through the Agreements, the assignees of the '554 application have not only denied OncorMed a license, but have granted an exclusive license to Myriad, OncorMed's direct competitor.

As evidenced by the foregoing, the assignees of the '554 application are using the '554 application, and others, to interfere with OncorMed's business. Such interference is a "special circumstance" warranting access by OncorMed to the '554 application.

Proper Conduct of Business before the PTO

Through the Agreements, the assignees themselves have agreed to the inventorship of the BRCA1 intellectual property, including the inventorship of the '554 application. As admitted by the parties in the Settlement Agreement (fourth paragraph, page 1), the inventorship of this subject matter was disputed. The inventorship was purportedly determined by the assignees "pursuant to principles of U.S. patent law" (paragraph 2.1 of the Settlement Agreement). However, the assignees had a significant business interest in whatever inventorship determination was reached. More importantly, the inventorship determination that was reached would be a means for interfering with the business of a competitor, such as OncorMed, by affecting the availability of licenses.

Proper conduct of business before the PTO mandates that OncorMed be given the opportunity to determine the extent of interference with its business by providing OncorMed access to, and a copy of, the file wrapper contents of the '554 application. Proper conduct of business before the PTO also mandates that the PTO determine that the inventorship

determination made by the assignees for the '554 application is in accordance with U.S. patent law.[2]

Conclusion

Granting OncorMed access to, and a copy of the file wrapper contents of, the '554 application is warranted by special circumstances, and is necessary for the proper conduct of business before the PTO for at least the reasons detailed above. Petitioner respectfully requests immediate and favorable consideration of this Petition. If the PTO believes that communication with Petitioner will expedite handling of this petition, the PTO is requested to contact the undersigned at the number provided.

Respectfully submitted,

Andrea G. Reister (Reg. No. 36,253)
Attorney for Petitioner

Date: April 14, 1998

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2 See enclosed copy of the article in Science magazine jointly authored by forty-five scientists reporting that they had identified a "strong candidate" for the BRCA1 gene. *Miki et al.*, Science 266:66-71 (October 7, 1994).

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
Mark H. SKOLNICK et al.	)	
	)	
Serial No. 08/483,554	)	Attention: Special Program Law Office
	)	
Filed: 7 June 1995	)	
	)	
For: 17q-LINKED BREAST AND OVARIAN CANCER SUSCEPTIBILITY GENE	)	

#24

National Institutes of Health's Opposition to OncorMed's Petition Under 37 C.F.R. § 1.14(e)(1) for Access to, and Copy of, File Wrapper Contents of Allowed Pending Application

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The National Institutes of Health (NIH), as joint-owner with the University of Utah (Utah) of allowed, pending application number 08/483,554, filed June 7, 1995, objects to OncorMed's petition of April 14, 1998, filed pursuant to 37 C.F.R. § 1.14(e)(1), seeking access to, and a copy of, the file wrapper contents of allowed, pending application number 08/483,554.

Background

In 1996, OncorMed sued NIH in the United States District Court for the District of Columbia (District Court) under the Administrative Procedure Act (APA) when the agency allegedly violated the Bayh-Dole Act, 35 U.S.C. § 209, under the Due Process Clause of the Fifth Amendment, and the APA's prompt notice provisions. 5 U.S.C. § 555(e). OncorMed seeks to have the District Court invalidate NIH's existing exclusive license with Utah, and force the NIH to license the '554 patent application to OncorMed nonexclusively. The District Court

is currently considering the parties' cross motions for summary judgment under a briefing schedule set by the parties in early February.

There Is No Legal Basis For The Requested Disclosure

Title 35 U.S.C. § 122 states that "[a]pplications for patents shall be kept in confidence by the Patent and Trademark Office and no information concerning the same given without authority of the applicant or owner unless necessary to carry out the provisions of any Act of Congress or in such special circumstances as may be determined by the Commissioner." As a result, you should refuse to grant OncorMed's petition for several reasons. As a threshold matter, neither NIH or Utah have given authority for the requested disclosure. Therefore, 37 C.F.R. § 1.14(e)(2), which requires that any request for access to or copies of any pending application include "written authority granting access to the member of the public in that particular application from the applicant or that applicant's assignee or attorney or agent of record" has not been met by the petitioner here.

Additionally, absent such permission, the petitioner must show that the release is necessary to carry out the provisions of an Act of Congress. See 35 U.S.C. § 122. OncorMed has not alleged that such a situation exists here. Rather, it alleges that the Commissioner can release the application if he determines there are "special circumstances." Petitioner argues that such "special circumstances" are present with regard to the '554 application, but fails to explain, except in the vaguest way, what they are or to provide any support for its position. [1] OncorMed alleges that NIH and Utah "are using the BRCA1 intellectual property as a means to interfere

[1] Petitioner cites to two cases, April 14, 1998, petition at page 2, that are entirely inopposite. Both cases discuss the Commissioner's authority in "special circumstances" to disclose patent applications based on the use of a patent application to interfere with the business of others. However, both cases involve interaction between the patent owner and its competitor or its competitor's customers. Not only did the Commissioner of Patents determine in each of these cases that the correspondence in question did *not* constitute interference with the business of the other, but also Petitioner/OncorMed has not alleged that any such letters or contact between OncorMed and Utah/Myriad has taken place.

with competitor's business, specifically, the business of OncorMed," April 14, 1998, petition at pages 2-3, but provides no details about the nature of the alleged interference. OncorMed recites the fact that NIH and Utah privately resolved a dispute over inventorship, which was memorialized in a settlement agreement, and that NIH and Utah agreed to enter into an exclusive license arrangement. Those facts are not disputed. What OncorMed seems to assert is that, absent such agreements, it would obtain a nonexclusive license for use of the technology from NIH. Yet, that is entirely speculative. The mere fact that OncorMed applied for, but failed to obtain, a license is neither illegal nor evidence of interference with a competitor's business. Moreover, NIH's authority to license Utah, the co-inventor of the '554 patent application, is the subject of the District Court litigation, and should not be reargued before the PTO. Finally, OncorMed's failure to obtain a license is not within the jurisdiction of the PTO, nor is it a basis for claiming "special circumstances." If a company's failure to obtain every license that it seeks were special circumstances or constituted interference in a business relationship, every unsatisfied license applicant could petition the PTO for confidential information.

The '554 Patent Is Not In Dispute In The District Court Litigation

OncorMed argues that it urgently needs access to the file wrapper in order to respond to one of NIH's briefs in the District Court litigation. Several facts show that this position is simply not well taken. First, Petitioner fails to mention that the inventorship of the '554 patent is not at issue in the litigation. Second, it brought its lawsuit under the APA. Hence, OncorMed's challenge to NIH's decision to license its interest in BRCA1 to Utah will be decided based only on the administrative record.[2] OncorMed did not challenge the Record. Even if Petitioner could obtain access to the '554 file wrapper, it could not introduce its contents before the District

[2] The Administrative Record in OncorMed v. Varmus, Civil Action No. 96-2623 (JR)(D.D.C.) was filed in December of 1997 and is partially under seal.

Court and the District Court could not rely on its contents in reaching its decision. Third, the April 20, 1998, deadline for OncorMed's reply to NIH's motion for summary judgment was established by agreement of the parties several months ago. As such, OncorMed's use of it as an absolute deadline can only be a pretext for its attempt to obtain information to which it is not entitled. We can only speculate about OncorMed's true intentions, which may be to obtain evidence to aid its cause in patent infringement with Utah and its exclusive licensee, Myriad. See OncorMed v. Myriad, (D.D.C.) Civ. Action No. 97-2722 filed November 17, 1997, and Myriad v. Utah, (C.Div. Utah) Civ. Action No. 97-922B filed Dec. 2, 1997.

Lastly, NIH notes that the issue fee for the '554 patent has already been paid and all outstanding formal matters have been complied with; issuance of the patent is imminent. It would be contrary to the public interest to stall issuance of the '554 patent in response to OncorMed's groundless, eleventh-hour request.

Conclusion

For all these reasons, NIH objects to OncorMed's petition and its petition should be rejected.

Respectfully submitted,

By _____
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Registration No. 28,957

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Dated: 17 April 1998

CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of April 1998, a copy of NIH's **National Institutes of Health's Opposition to OncorMed's Petition Under 37 C.F.R. § 1.14(e)(1) for Access to, and Copy of, File Wrapper Contents of Allowed Pending Application** was served by Federal Express upon the following:

Andrea G. Reister, Esq.
Howry & Simon
1299 Pennsylvania Ave., N.W.
Washington, D.C. 20004

Catherine R. Hoffman

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Skolnick, *et al.*

Appl. No. 08/483,554

Filed: June 7, 1995

For: 17q-Linked Breast and Ovarian Cancer Susceptibility Gene

ATTN: Special Program Law Office

Office of Petitions

#25

Reply to National Institutes of Health Opposition to OncorMed Petition Under 37 C.F.R. § 1.14(e)(1) for Access to, And Copy of File Wrapper Contents of, Allowed Pending Application

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

On April 14, 1998, Petitioner, OncorMed, Inc. ("OncorMed"), filed a request under 37 C.F.R. §1.14(e)(1) for access to, and a copy of the application file wrapper contents of, allowed pending application number 08/483,554, filed June 7, 1995 ("the Petition"). An Opposition to the Petition was filed on behalf of the National Institutes of Health ("NIH") on April 17, 1998 ("the Opposition"). Petitioner respectfully submits the following in reply to the NIH opposition. In accordance with M.P.E.P. § 103, a copy of this Reply has been served on the applicants of the above-captioned application as shown in the attached Certificate of Service.

Legal Basis for the Requested Disclosure

NIH asserts in the Opposition that there is no legal basis for the requested disclosure because the Petition does not meet the requirements of 35 U.S.C. § 122. By the plain language of 35 U.S.C. § 122[1], the U.S. Patent and Trademark Office (PTO) can grant access to OncorMed if it is shown that "such special circumstances as may be determined by the

1 Applications for patents shall be kept in confidence by the Patent and Trademark Office and no information concerning the same given without authority of the applicant or owner ***unless*** necessary to carry out the provisions of any Act of Congress ***or*** in such special circumstances as may be determined by the Commissioner. 35 U.S.C. § 122 (emphasis added).

Commissioner" exist. OncorMed does not ***additionally*** have to provide authority of the applicant or owner, or show that access is necessary to carry out the provisions of any Act of Congress. The regulations reflect that OncorMed's burden is only to establish that a "special circumstance" exists. Under 37 C.F.R. § 1.14(a)(3)(i), access to the '554 application, and a copy of the file wrapper and contents, may be given to OncorMed when the application file is available and "[i]t has been determined by the Commissioner to be necessary for the proper conduct of business before the Office or warranted by other special circumstances." Accordingly, the legal basis for the requested disclosure was properly set forth by OncorMed in the Petition.

Existence of Special Circumstances

The Petition sets forth clear bases for the existence of special circumstances. The inventorship of BRCA1 intellectual property, including the inventorship of the above-captioned application ("the '554 application"), was agreed to by the parties to the Settlement Agreement (redacted copy enclosed with the Petition). As noted on pages 1 and 8 of the Settlement Agreement, the parties to the Settlement Agreement are: NIH; University of Utah ("Utah"); and Myriad Genetics, Inc. ("Myriad"). Page 3 of the Opposition is misleading and inaccurate when it states that "***NIH and Utah privately*** resolved a dispute over inventorship, which was memorialized in a settlement agreement" (emphasis added). Myriad is also a party to that Settlement Agreement of the disputed inventorship, and Myriad is a direct competitor of OncorMed. Contrary to the assertions in the Opposition, this situation is not one of a "company's failure to obtain every license that it seeks" (see page 3 of the Opposition), but one where parties to an agreement are determining inventorship in a manner that ensures that licenses are not available to third parties such as OncorMed. This interferes with the business of OncorMed, and is a "special circumstance". The PTO certainly has "jurisdiction" in a situation where the underlying issue is inventorship. Particularly, proper conduct before the PTO mandates that the PTO determine, prior to issuance of the '554 application, whether the

assignees[2] have disclosed to the PTO the facts relating to this "***private***" inventorship resolution.

The Varmus Litigation

The Opposition provides great detail about the Varmus litigation[3], noting that "the '554 ***patent***"[4] is not at issue in the litigation. It is axiomatic that the '554 ***application*** is not at issue because the application has not yet issued as a patent. The urgency of the Petition derives from litigation deadlines since representations made in the file wrapper of the '554 application are germane to the issues of the Varmus litigation. OncorMed has filed a motion with the court to extend the time to file its reply brief in the Varmus litigation; this motion has been granted by the court. Therefore, the request for access contained in the Petition has not been rendered moot by the passing of the April 20, 1998 due date in the Varmus litigation. However, irrespective of the litigation, proper conduct before the PTO mandates that OncorMed be given the opportunity to determine the extent of interference with its business by providing access to the '554 application, and that the PTO determine whether the inventorship agreed to in the Settlement Agreement is proper.

Conclusion

Granting OncorMed access to, and a copy of the file wrapper contents of, the '554 application is warranted by special circumstances, and is necessary for the proper conduct of business before the PTO for at least the reasons detailed above. It would be contrary to the public interest to continue to keep the inventorship issues from the public eye by denying the Petition. OncorMed respectfully requests immediate and favorable consideration of the Petition.

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2 The Opposition states that NIH is a joint-owner of the '554 application with the University of Utah. However, it is not clear why the Opposition does not list Myriad Genetics, Inc. as a joint owner as well.
3 OncorMed, Inc. v. Harold Varmus, M.D., Director, National Institutes of Health and the University of Utah, Civil Action No. 1:96CV02623(JR), United States District Court for the District of Columbia.
4 The Opposition filed by NIH incorrectly refers to the '554 application as "the '554 patent".

If the PTO believes that communication with Petitioner will expedite handling of this petition, the PTO is requested to contact the undersigned at the number provided.

Respectfully submitted,

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Attorney for Petitioner

Date: April 27, 1998

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