



RESPONSE OF
THE BIOTECHNOLOGY INDUSTRY ORGANIZATION
TO
THE FEDERAL TRADE COMMISSION'S
PATENT SYSTEM REFORM RECOMMENDATIONS

APRIL 26, 2004

BIOTECHNOLOGY INDUSTRY
ORGANIZATION
1225 EYE STREET, N.W., SUITE 400
WASHINGTON, DC 20005
(202) 962-9200
www.bio.org

SUMMARY

The Biotechnology Industry Organization (BIO) shares the desire of the Federal Trade Commission (FTC) to maintain a healthy and fair patent system to promote research and development in all fields, including biotechnology. Moreover, BIO is in favor of reforms that would strengthen, streamline and make more efficient the patent system. We believe, however, that modifying the fundamental basis of patent laws, such as standards for patentability and patent validity, would be devastating to the biotechnology industry. These standards have been shaped by the courts throughout the history of the U.S. patent laws. Changes to the patent system's basic standards would set a dangerous precedent and disrupt biotechnology companies' ability to make business decisions.

BIO is a trade association of more than 1,000 companies, universities, research institutions and affiliated organizations engaged in biotechnology research on medicines, diagnostics, agriculture, pollution control and industrial applications. The biotechnology industry spent over \$10 billion on research and development in 2000 and is currently spending on R&D double what the pharmaceutical industry is spending, both on a per-employee basis and as a percentage of sales revenue. The majority of biotechnology companies are not profitable; many have yet to even bring a product to market.

Before generating its first dollar of product revenue, a biotechnology company typically spends more than \$800 million over the course of 10 to 14 years for product development.¹ Biotech companies rely primarily on private investments for financing, and investors recognize patents as important benchmarks of progress in developing product lines and revenues. Thus, biotechnology companies are heavily dependent upon strong intellectual property protection.

This document provides BIO's response to the FTC's recommendations in an October 2003 report entitled "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy." In this report, the FTC makes 10 principal recommendations for ensuring a proper balance between competition and patent rights. While BIO agrees with five of the principal findings detailed in the FTC report, we have concerns about other recommendations.

FTC RECOMMENDATIONS: AREAS OF AGREEMENT

As the PTO Recommends, Enact Legislation to Create a New Administrative Procedure to Provide Adequate Funding for the PTO. (FTC Recommendation 4)

¹<http://enews.tufts.edu/stories/120401BallooningCosts.htm>

BIO agrees with the report's recommendation that Congress should provide adequate funding to the U.S. Patent and Trademark Office (PTO). BIO believes this is of paramount importance and is pleased with Congress' recent activity on reforming the PTO fee and appropriations structure in that regard.²

Enact Legislation to Require Publication of All Patent Applications 18 Months After Filing. (FTC Recommendation 7)

BIO agrees that "submarine" patents can be detrimental to the progress of research and innovation, and that publication of patent applications effectively addresses the problem of submarine patents. Thus, as the report recommends, it may be beneficial for Congress to investigate revisions to the current publication scheme.

As the PTO Recommends, Enact Legislation to Create A New Administrative Procedure to Allow Post-Grant Review of and Opposition to Patents. (FTC Recommendation 1)

While there are diverging opinions within BIO's membership, BIO is willing to investigate the creation of a viable post-grant review proceeding within the PTO. Some BIO members believe that the solution to the number of "questionable patents" referred to in the FTC report lies in improving the quality of examination during the patent examination process, rather than through the use of a post-grant review system. Others believe that the current system of re-examination is inadequate and is rarely a reasonable option for our members. BIO recognizes the possibility of establishing a viable, non-duplicative and efficient post-grant administrative proceeding to contest the validity of a patent without the expenses and delays associated with district court litigation. BIO believes that certain procedural safeguards, such as limiting the time within which an opposition may be filed, should be a part of any post-grant opposition process.

Enact Legislation to Require, As a Predicate for Liability for Willful Infringement, Either Actual, Written Notice of Infringement from the Patentee, or Deliberate Copying of the Patentee's Invention, Knowing it to Be Patented. (FTC Recommendation 9)

The report recommends revising the current standard for willful infringement. BIO agrees that the standard for willful infringement causes unusual repercussions, such as businesses having a policy of not reviewing patent literature for fear of gaining knowledge of a competitor's patent, the need to generate costly legal opinions solely to defend against allegations of willful infringement and the potential for treble damages. The Federal Circuit is currently reviewing *en banc*³ this area of the law. BIO remains

²See H.R. 1561 passed by the House of Representatives and S. 1760 currently pending in the Senate, 2nd session.

³BIO has filed in the Federal Circuit an *amicus curiae* brief regarding judicial clarifications to willful infringement precedent in *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, Docket No. 01-1357, -1376, 02-1221, -1256.

hopeful that the Federal Circuit will soon reform its precedent on willful infringement. However, if the Federal Circuit does not make the necessary changes to this area of the law, BIO will seek appropriate reform.⁴

Implement the PTO's Recommendation in its 21st Century Strategic Plan that it expand its "second-pair-of-eyes" review to selected areas. (FTC Recommendation 5c)

Although BIO agrees with the FTC that a second level of review may be helpful to PTO examiners in particular cases, we are concerned that the extra scrutiny could be inefficient in practice. Since biotechnology cases are among those suggested for "second pair of eyes" review, BIO must stress that an applicant's right to have its patent application examined promptly by the PTO is equally valid in all technological arts. To the extent that a second level of review would systematically delay the timely issuance of applications in biotechnology and other targeted technologies, restructuring the system would become necessary in order to minimize delays.

BIO has certain questions and concerns relating to the remaining recommendations in the FTC report. These questions and concerns are summarized below.

FTC RECOMMENDATIONS: AREAS OF CONCERN

Adoption of a "preponderance of the evidence" standard for challenging or enforcing patents (FTC Recommendation 2)

The FTC recommends weakening the standard of challenges to patent validity from the present "clear and convincing" standard to a "preponderance of the evidence" standard. BIO is concerned that eroding the presumption of validity granted to patents by statute would lead to an increase in expensive and protracted litigation. Such protracted litigation could substantially raise business costs that harm innovators in all industries, including the biotechnology industry. Current court precedent requires a patent challenger to prove invalidity or unenforceability of a patent by "clear and convincing evidence." This heightened standard supports the statutory requirement that patents are presumed to be valid,⁵ which many view as a reward to the patent applicant in exchange for having chosen to disclose the invention through the patent system and having demonstrated to the PTO that the disclosed invention is patentable.

BIO believes that a strong presumption of validity is crucial to the biotechnology industry given the time (10 to 14 years) and resources (more than \$800 million) that many of our innovator biopharmaceutical companies must spend in making significant

⁴BIO's *amicus curiae* brief on the *Knorr-Bremse* court decision is available at <http://www.bio.org/ip/KnorrBremse.pdf>.

⁵See 35 U.S.C. § 282 ("A patent shall be presumed valid").

discoveries and developing pharmaceutical products. BIO agrees with the FTC's reasoning that a heightened patent challenge standard is justified only insofar as the PTO is provided with adequate resources to sufficiently examine patent applications. In this regard, however, BIO is confident that the efforts of the PTO and Congress will continue to refine the application examination process to ensure patent quality by, for example, improving PTO funding,⁶ refining patent examination procedures⁷ and exploring a viable post-grant review process.

BIO fears that weakening the presumption of validity would dramatically increase the incidence of patent litigation in general, and would decrease incentives for settlement of patent disputes. The adoption of a "preponderance of the evidence" standard for patent challenges would disadvantage all innovators and, in particular, would disproportionately disadvantage smaller innovative companies and independent inventors by increasing their chances of experiencing litigation.

Consideration of harm to competition before expanding patentable subject matter (FTC Recommendation 6)

The FTC recommends that policy-makers consider harm to competition before expanding patentable subject matter. The report reasons that what qualifies as "statutory" subject matter has been expanded since 1980 through a series of federal court decisions. In the case of biotechnology-related inventions in particular, the Supreme Court in 1980 reviewed the patent statute and applied it to living matter inventions in a manner consistent with precedent.⁸ Computer software and related method inventions were likewise recognized as patentable by the Court of Appeals for the Federal Circuit under the current statute and following the precedent of the Supreme Court.⁹

The report is imprecise as to how the FTC recommendation would be implemented. The report seems to suggest that some type of competition review should be undertaken before "new patents" are issued on subject matter. BIO believes that it would be difficult to retain a primary benefit of the current U.S. patent system—technology neutrality—if the discretion of the courts and the PTO is restricted in interpreting and applying the current patent laws to ongoing developments in the area of "new subject matter." Implementing a special competition review in cases of emerging technologies may raise issues regarding technology discrimination restrictions imposed

⁶See, supra, note 2.

⁷Examination procedures are revised by the PTO regularly to improve examination quality. The PTO adopted new written description and utility examination guidelines in 2001. See 66 Fed. Reg. 1099 (Jan. 5, 2001) and see 66 Fed. Reg. 1092 (Jan. 5, 2001), respectively. Additionally, the PTO is considering the expanded use of management review (the so-called second set of eyes type review for difficult to examine technologies). See the PTO's "21st Century Strategic Plan," available at <http://www.uspto.gov/web/offices/com/strat21/index.htm>

⁸See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁹See *State Street Bank and Trust Co. v. Signature Financial Group Inc.*, 47 U.S.P.Q.2d 1596, 1600-01 (Fed. Cir. 1998) (following *Chakrabarty* as relevant precedent confirming the broad range of statutory patentable subject matter under 35 U.S.C. § 101.).

by international intellectual property agreements¹⁰ and may deny an inventor the appropriate scope of protection for pioneering subject matter.

Consideration of economics and competition concerns in patent law decision-making (FTC Recommendation 10)

The FTC report appears to advocate employing general policy considerations as part of patent law decisions without any statutory specificity. While the report states that the “Federal Circuit and the PTO (like courts in the area of antitrust law) may also benefit from much greater consideration and incorporation of economic insights in their decision making,” it is not clear how the FTC believes the current system could or should be changed to address such considerations. To the extent that the FTC indicates that it will seek to become more actively involved in challenging patents and in other interventions within the PTO or the courts, BIO believes that there is a substantial risk of confusion about the role and position of two federal agencies seeking to occupy the same field. If the FTC seeks to intervene to challenge patent validity after the PTO has applied its expertise, the issue of who speaks for the federal government on intellectual property matters would at best be confusing. Congress historically has been proactive in addressing any potential harm to competition introduced by federal court precedent or PTO rule-making, and BIO is confident that this legislative policy mechanism will continue to work effectively.

Creation of intervening or prior-use rights to protect against continuing applications (FTC Recommendation 8)

The report, while recognizing “legitimate reasons” for the use of continuing applications, suggests creating a form of intervening or prior-use rights to cure anticompetitive problems caused by applicants who extend the effective period of pendency of their patent application by filing various “continuing” applications. The report characterizes this as an unfair mechanism for patentees to ensnare competitors with claims of patent infringement. According to the FTC report, provisional rights would attach where products or processes are developed or used before an applicant publishes amended patent claims covering the specific products or processes.

BIO believes that existing doctrines and mechanisms adequately address situations that could be classified as “illegitimate” continuing applications and that legislative or administrative activity in this area would not clarify or resolve any anticompetitive issues. Currently, the law provides multiple mechanisms by which prior use can insulate an accused infringer from patent liability.¹¹ Further, there are

¹⁰The Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) portion of the WTO treaty, under Article 27, prohibits countries from discriminating between technologies by refusing to patent certain products.

¹¹See 35 U.S.C. §§ 102(a), 102(b), 102(g) (defining certain prior uses as constituting prior art); and 35 U.S.C. 273 (establishing prior use of a method in commerce one year prior to the filing of the application for patent as a defense to infringement).

mechanisms by which undue delays in the pendency of a patent application can cause any patents issuing from them to be unenforceable,¹² and the doctrine of double patenting prevents the extension of the term of patent protection on obvious variants of previous inventions. Further, the written description requirement prevents a patent applicant from later claiming inventions not disclosed adequately in its original application.¹³

BIO opposes the creation of new broad prior-user rights to the extent that they would interfere with the legitimate practice of amending claims and filing continuation applications to pursue the full claim coverage to which a fully disclosed invention is entitled. We believe that the current state of the law adequately distinguishes between legitimate and illegitimate reasons for filing continuing applications and amending claims.

Tightening of certain legal standards—for obviousness in particular— and review of the “commercial success test” and the “suggestion test” (FTC Recommendation 3)

The non-obviousness requirement in U.S. patent law requires that an invention not just be new, but also be more than a minor, “obvious” advance over prior technology when viewed by a person of ordinary skill in the art. The FTC report recommends revising two of the many tests used in non-obviousness inquiries.

The first such test addressed in the report concerns the weighing of various indicators of non-obviousness, with one indicia of interest being whether the invention has enjoyed demonstrable “commercial success.” BIO believes that the PTO currently applies a standard very similar to the FTC’s suggested test of “1) [evaluating] on a case-by-case basis whether commercial success is a valid indicator that the claimed invention is not obvious, and 2) [placing] the burden on the patent holder to prove the claimed invention caused the commercial success.” In particular, the PTO currently instructs its patent examiners to have the patent applicant demonstrate a “nexus” between the evidence of commercial success and the distinguishing features of the invention establishing that the commercial success was derived from the patentable features.¹⁴ Thus, the extent to which the FTC is advocating a change in the current standard is unclear.¹⁵

The second test identified in the FTC report concerns the requirement that, in order to combine distinct prior teachings or prior art references to render a patent

¹²See *Symbol Technologies Ltd. v. Lemelson Medical, Education, and Research Foundation LP*, 61 U.S.P.Q.2d 1515, 1518-19 (Fed. Cir. 2002) (recognizing the doctrine of prosecution laches to prevent enforcement of a patent following unjustified delays in prosecution).

¹³See *Gentry Gallery, Inc. v. Berkline Corp.*, 45 U.S.P.Q.2d 1498 (Fed. Cir. 1998) (invalidating patent claims stating that the “original disclosure serves to limit the permissible breadth of [the applicant’s] later-drafted claims”).

¹⁴See Manual of Patent Examining Procedure (“MPEP”), section 716.03 (2003).

¹⁵While the “nexus” requirement appears to be well laid out by the PTO, it may nonetheless be necessary for litigants to request specific proper jury instructions concerning the commercial success standard to avoid cases of juries broadening the application of this test.

obvious, those references or teachings must “suggest” their combination to one of ordinary skill in the art. The FTC report recognizes that the Federal Circuit’s more recent discussions of the “suggestion test” enables flexibility regarding exactly how much suggestion is required under any given circumstances depending upon the general level of skill in the art. BIO is therefore not certain to what extent the FTC is suggesting administrative or legislative action in this area. BIO accepts the current Federal Circuit articulations of the “suggestion test” as being an accurate articulation of the law. BIO is concerned that efforts to alter the “suggestion” standard to the detriment of inventors could enable examiners to make obviousness rejections in hindsight without supporting reasoning susceptible to administrative and judicial review, which reasoning is currently required by case law.

***Modification of rules on prior art submissions and examining procedures
(FTC Recommendation 5)***

The report recommends individual PTO rule modifications to implement some portions of the PTO’s 21st-Century Strategic Plan. These modifications include 1) empowering examiners to request “statements of relevance” from applicants concerning prior art references submitted for consideration, and 2) increasing the use of Rule 105 inquiries by examiners to obtain information from applicants (as well as modifying the rule to make it easier for examiners to do so).

BIO agrees that the ability of examiners to conduct an impartial and unbiased third-party review of the application and relevant prior art is necessary for our patent system to work efficiently. However, BIO has reservations regarding the extent to which expanding the current authority of examiners under Rule 105 to make inquiries of patent applicants and to request statements of relevance would assist in examiner review. It is unclear how such expansions of examiner authority would foster efficient and prompt examination of patent applications since examiners would still be required to review disclosed prior art on their own; it is likely that a substantial increase in the use of such statements and inquiries would cause delays in patent examination. In general terms, BIO agrees with the comments of the Intellectual Property Owners to the PTO¹⁶ relative to the pending proposed changes to Rule 105.

CONCLUSION

BIO commends the FTC’s efforts to review competition and patent policy and believes that many of the FTC’s recommendations to streamline and make more efficient PTO practices are creditable. BIO, however, strongly opposes the FTC’s recommendations that would alter the standards and principles that have long served as the basis for the patent system. These existing standards have resulted in the forward

¹⁶See November 24, 2003, IPO letter to former Director James E. Rogan, available at: http://www.ipso.org/Template.cfm?Section=IPO_Position_Statements&CONTENTID=12592&TEMPLATE=/ContentManagement/ContentDisplay.cfm

trajectory of cutting-edge technologies such as biotechnology, which in turn has yielded more than 155 biotechnology drugs, hundreds of medical diagnostic tests, biopesticides and industrial microbes. Our industry is dedicated to developing the most innovative products and processes to address the challenges before us in the 21st century. However, the industry cannot fulfill its promise if the underpinning of the patent system is shaken. It is the assurance of a strong and predictable patent system that drives our industry forward and enables entrepreneurs to take the risk of product development. Thus, our industry supports efforts to ensure adequate resources and funding for the PTO and efforts to streamline examination, which will ultimately enhance the strength and predictability of patents. BIO looks forward to working with the PTO and Congress on strengthening the U.S. patent system.