Legal Backgrounder

Washington Legal Foundation
Advocate for freedom and justice®
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Vol. 19 No. 7 April 16, 2004

ALTERING PATENT SUIT PROOF BURDEN WOULD CHILL INNOVATION

by

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American ingenuity is encouraged by a patent system that provides incentives for inventors to disclose their inventions in exchange for a period of exclusivity. These disclosures, given in exchange for exclusivity, provide a foundation onto which other innovators build, advancing technological development. Patent claims define the scope of the exclusivity awarded to an inventor in exchange for disclosure.

The patent system has built-in checks and balances that seek to insure fairness. On one level, the rules for obtaining a patent require that the specification include a written description of the invention, teach how to make and use the invention, and disclose the best mode known to the inventor for practicing the invention. 35 U.S.C. § 112. These usually are referred to as the "written description," "enablement," and "best mode" requirements. Claims issued by the patent office must be supported by a corresponding written description of the subject matter within the patent specification. Similarly, the scope of the issued claims must correspond to the scope of enablement taught in the specification. The written description and best mode requirements serve as a check against overreaching by preventing the issuance of claims whose scope exceed the specification's disclosure. The best mode requirement ensures that an inventor not hide from the public the best way to practice the claimed invention.

Patent examiners also are charged with making sure that issued claims define subject matter that is inventive over what has come before (i.e., the "prior art"). An examiner therefore searches the prior art to identify references that may disclose, in whole or in part, the claimed invention. During prosecution of the application, claims may be rejected if they fail to define novel subject matter, or if the patent examiner determines that there only are obvious differences between the claimed subject matter and the prior art. 35 U.S.C. §§ 102, 103.

An applicant may respond to a claim rejection by changing (i.e., amending) the claim, by arguing against the rejection, by submitting evidence that the claim is novel and non-obvious, or with some combination of these approaches. United States Patent and Trademark Office (USPTO) policy requires examiners to accept as true an applicant's statements during prosecution, unless there is an objective reason to doubt their truth. 37 C.F.R. §§ 1.4, 10.18; Manual of Patent Examining Procedure (MPEP) (8th Ed., Rev. 1 Feb. 2003) § 410. The examiner weighs the response and allows the claim if she determines that a preponderance of the evidence supports allowance.

Patent claims enjoy a presumption of validity once issued. 35 U.S.C. § 282. A party seeking to invalidate a patent claim must provide a high degree of proof to overcome this presumption. The legal standard for this proof is "clear and convincing" evidence of invalidity, more stringent than the

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"preponderance" standard used by the examiner during prosecution. *Eibel Process Co. v. Minnesota & Ontario Paper Co.,* 261 U.S. 45, 60 (1923); *see also* 1D.S. Chisum, CHISUM ON PATENTS, § 3.05 (2004).

As the pace of technical change has quickened, the number of patent applications filed at the USPTO has grown. Between 1998 and 2000, the number of patent applications filed by U.S. corporations doubled. The USPTO currently receives new patent applications at the blistering rate of about 300,000 applications per year. Http://www.ftc.gov/opp/intellect/lernerjosh.pdf. Overburdened patent examiners have extremely limited amounts of time to search the prior art and examine the applications. Understandably, time-pressed examiners (whose prior art searches may not turn up the most relevant prior art) issue some patents of questionable validity.[1]

What effects have such questionable patents had on the balance between competition and innovation? In its October 2003 report,[2] the Federal Trade Commission (FTC) suggests that innovation is deterred by the issuance of too many questionable patents. Patent litigation is expensive. Potential competitors may decide to avoid innovating if they perceive unacceptable levels of patent litigation risk. The FTC report also points out that questionable patents are inconsistent with the constitutional mandate of using the patent system to promote the progress of science and the useful arts because the scope of protection awarded exceeds the contribution the patent specification makes to advancing the state of the art.

The FTC makes numerous suggestions in its 300 page report as to how the patent system should be modified to change the balance between competition and innovation. The rest of this LEGAL BACKGROUNDER examines the impact of the FTC's proposal to restore balance by diminishing the presumption of validity issued patents currently enjoy. Specifically, the FTC's report suggests lowering the standard for invalidating patents from the current "clear and convincing" to the lesser "preponderance of the evidence" standard. Lowering the standard for invalidating issued patents will shift the balance in favor of competition, the FTC reasons, because it makes it easier for a patent litigation defendant to invalidate a patent. According to this reasoning, diminishing litigation risk encourages innovators to enter fields they otherwise might not, and reduces the chilling effect questionable patents may have on innovation.

If implemented, what effect would such a proposal likely have on innovation? While reducing the presumption of validity accorded issued patents might spur innovation in the short term, the long-term effects would quite likely be opposite. Reducing the presumption of validity makes patent holders less willing to enforce their patents because of the increased risk they face in losing on an invalidity counter-claim. The patent system is based on the disclosure-for-protection bargain between the inventor and the government. One problem with this aspect of the FTC's proposal is that it deters innovation by undercutting the patent system's incentive to disclose. Faced with the choice of disclosing an invention in a patent that provides relatively thinner protection under a preponderance standard, or guarding an invention as a trade secret, more innovators will find the balance tipped in favor of trade secret protection. Under the FTC's proposed preponderance standard, patent challengers become more willing to risk litigation, and less willing, once in litigation, to settle. Increased patent litigation therefore seems to be a likely near-term consequence if the FTC's proposal were adopted.

Unfortunately, trade secret protection is not a viable option for many of the industries that currently rely on the protections the patent system provides. Because trade secret protection does not prohibit reverse engineering of an invention, it is unavailable to industries that rely on filings with government agencies to obtain marketing approval, since the public ultimately can obtain portions of filings. For these reasons, the biotech and pharmaceutical sectors are examples of industries that would be hard-pressed to make effective use of trade secret protection. Long lead times and heavy capital investments are needed to bring new biologics and pharmaceuticals to market. These industries rely heavily on patent protection to keep others from free riding on their research and development investment. The FTC's proposal, if adopted, would have a strong impact on these sectors.

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[1]Note that under 37 CFR §1.56, individuals associated with the filing and prosecution of a patent application have a duty to disclose to the patent office prior art known to the individual that is material to the patentability of the claims. However, the duty of disclosure does not require these individuals to search for such art.

[2]*To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, report by the Federal Trade Commission, Oct. 2003.

  ISBN 1056 3059

The FTC's proposal also would likely have a strong impact on industries that file large numbers of patents on incremental or marginal improvements. The likelihood that the FTC's proposed standard change affects outcome in a validity challenge depends on the initial strength of the patent. The validity of seminal foundational patents is less likely to be altered by a change in standard as compared to that for patents covering incremental or marginal improvements to existing technology. The FTC's proposed change is thus likely to strongly impact the high tech, software and medical device industries. Should the FTC's proposed change be adopted, these industries would likely reduce the number of patents filed on small improvements.

How likely is Congress to act on this proposal? It is difficult to assess, but an analysis of a variety of factors suggests the likelihood is low indeed. The current clear and convincing standard is well-entrenched.[3] Given its longevity, it seems unlikely that Congress will alter it. Furthermore, when scrutinized, the FTC's proposal appears logically flawed. The FTC argues that rushed examination is causing patent examiners to allow patents that would not issue if given more scrutiny during examination. For example, given the intense time pressure patent examiners face, a patent claim might be examined without the examiner being aware of the most relevant prior art. In adversarial litigation, a challenger is highly motivated to find such art and prove that the claims are invalid in light of the newly-discovered art, or put forth other reasons for finding the patent invalid. Truly shoddy patents should be easy to invalidate during litigation, even under the current clear and convincing standard.

Statistics compiled by the University of Houston Law Center report the number of times patent owners and accused infringers prevailed on various validity issues. Http://patstats.org. During the three-year period from 2000 through 2002, accused infringers prevailed overall 38% of the time in proving invalidity (under the current "clear and convincing" standard). When the data are parsed more finely to look at invalidity issues susceptible to scrutiny by examiners during prosecution[4], accused infringers prevailed almost as often (i.e., on 36% of these issues). A few points bear mention. The data provide no evidence to support the FTC's hypothesis that poor examination quality is causing the USPTO to allow invalid claims. If this were the case, the data would be expected to show accused infringers prevailing on the invalidity issues that examiners scrutinize more frequently than on issues examiners cannot easily review.

Even under the clear and convincing standard, litigated patents were invalidated in 38% of the cases. Reducing the burden of proof to the FTC's proposed preponderance standard would be expected to raise this percentage. As the percentage of patents invalidated during litigation rises, the value of patents diminishes, and the incentive for disclosure decreases. Given the current statistics, it seems unlikely that Congress will respond positively to the FTC's proposed change.

The FTC's proposed change is too blunt an instrument for fixing the problem it purports to address, i.e., minimizing the anti-competitive impact of poorly-examined patents. Lowering the standard for invalidating patents increases the risk that even well-examined patents become invalidated during litigation. This risk also should lead Congress to reject FTC's proposed change.

The industries most likely to be affected by this proposal are important drivers of the country's economy. Changing the rules as the FTC proposes, to call into question the strength of issued patents, creates uncertainty and destabilizes markets served by those industries. The U.S. Supreme Court recognized this problem in its 2002 *Festo* decision. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*, 535 U.S. 722 (2002). In deciding not to endorse a change in the scope of patent protection adopted by the Federal Circuit, the Supreme Court pointed out that "[f]undamental alterations in these rules risk destroying the legitimate expectations of inventors in their property... To change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous patents that have not yet expired and that would be affected by our decision." *Festo*, 535 U.S. at 739 (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 32 (1997)). That reasoning applies with equal force to the FTC's proposal to lower the standard for invalidating patents. In view of these factors, it seems unlikely that Congress will adopt the FTC's proposal.

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[3]The roots of the current standard can be traced back to the late 1800s. *See* 1 D.S. Chisum, CHISUM ON PATENTS, § 3.05 (2004); *Barbed Wire Patent Case*, 143 U.S. 275, 284 (1892); *Loom Co. v. Higgins*, 105 U.S. 580, 591 (1881).

[4]Prior public knowledge or publication under 35 U.S.C. § 102(a), time-bar publication or patent under 35 U.S.C. § 102(b), earlier-filed U.S. patent of another under 35 U.S.C. § 102(e), or problems with the specification or claims under 35 U.S.C. § 112.

  ISBN 1056 3059

If the FTC's premise is true and the rise in patent filings is leading to a fall in patent quality, it seems sensible to address the problem at the examination level so that poor quality patents are not issued by the patent office. This approach avoids the risks created by lowering the invalidity standard. In December 2001, James Rogan, then director of the USPTO, issued a five-year strategic plan for reforming the patent system. *USPTO 21st Century Strategic Plan*. That plan addresses many of the examination quality concerns that motivated the FTC's proposal, and includes user fee increases in the range of 15 to 25 percent, depending on the service. Fee increases are helpful if the added fees remain within the USPTO to support the hiring, training and retention of the examiner corps. President Bush's Department of Commerce proposed budget for FY 2005 provides for no user fee diversion in 2005, and should allow for the hiring of 900 new highly-qualified patent examiners. HR 1561, which already has passed in the House of Representatives, and is pending in the Senate, codifies the elimination of the fee diversions from the UPSTO.

Additional ways to address patent quality also under consideration include adopting a European-style opposition procedure in which the validity of recently issued patents can be challenged and resolved administratively at low cost. Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577 (1999) (http://papers.ssrn.com/sol3/delivery.cfm/99092717.pdf?abstractid=180748). Quality issues also can be addressed using new and improved *inter partes* reexamination proceedings. H.R. 2215, signed into law on November 2, 2002, enacted by Public Law 107-273, amending 35 U.S.C. §§ 303(a) and 312(a). Because reexamination puts the patent back into examination at the USPTO, the "preponderance" standard is applied once more to the patentability determination. Under the revised procedures, third parties can request reexamination of an issued patent to argue that the claims are not patentable in view of prior art, including prior art considered by the examiner during prosecution. Importantly, the revised *inter partes* reexamination rules allow a third party to appeal an adverse determination to the Federal Circuit. Under the old rules, third party requesters faced the difficult choice of giving up their right to a full hearing in court on issues raised (or that could have been raised) during reexamination in exchange for using the more cost-effective reexamination approach claims. Permitting appeals following reexamination encourages use of this lower cost administrative proceeding to weed out potentially invalid patent claims.

In the biotechnology and pharmaceutical arts, courts focus on the written description requirement as a way of cutting back claim scope to match what an inventor has actually reduced to practice.[5] The court's focus on written description in these areas is in tension with more traditional analyses of written description, that allow an inventor to claim subject matter that is described in "prophetic" examples, i.e., examples that describe work that has not yet been carried out. *See* discussion re *Rochester* decision in Shuster, Su and Blaug, NATURE BIOTECHNOLOGY 21(6):701-703 (2003). As recent developments in the written description case law are digested by the USPTO, the scope of claims issued will contract to more closely match described experimental work, or close extensions of what actually was done. Inadequate written description provides a good basis for challenging the validity of issued patents, as accused infringers prevailed on written description issues in 46% of cases litigated in the three-year 2000 through 2002 time period. http://patstats.org.

In summary, the FTC's proposal to lower the burden for invalidating patents from the current "clear and convincing" to the less stringent "preponderance" standard seems to be ill suited for fixing a perceived imbalance between innovation and competition. The proposed change would likely cause a spike in litigation, and ultimately reduce innovation by removing incentives for inventors to disclose their inventions in patent applications. For these reasons, it seems more sensible to address problems with examination quality. Encouragingly, elimination of fee diversions from the USPTO, seems likely and should allow the office to address the issues of examiner hiring, training and retention. Time should be given to allow the impact of these and other changes on patent quality before serious consideration is given to proposals that make major changes in the patent laws.

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[5] *See* Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement, Fed. Reg. 66(4): 1099 Jan. 5, 2001 (available at http://www.uspto.gov/web/offices/com/sol/og/2000/week30/patguid.htm); *Regents of Univ. of Cal. v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d (BNA) 1398 (Fed. Cir. 1997), *cert. denied*, 523 US 1089 (1998); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d (BNA) 1609 (Fed. Cir. 2002); and *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004).