

Testimony
United States Senate Committee on the Judiciary
Perspectives on Patents: Post-Grant Review Procedures and Other Litigation Reforms
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Prepared Statement of Philip S. Johnson

Mr. Chairman and distinguished Members of the Subcommittee: I wish to thank you for the opportunity to testify on various aspects of patent law reform. Although I am active in a number of professional organizations with interests in patent law reform, I am appearing today only in my capacity as Chief Patent Counsel of Johnson & Johnson.

Introduction

By way of introduction, I am a registered patent attorney with 33 years of experience in all aspects of patent law. In addition to drafting and prosecuting patent applications, I have tried patent cases to both judges and juries, and have advised a wide variety of clients in many industries ranging from semi-conductor fabrication to biotechnology. Over the course of my career, I am pleased to have represented individual inventors, universities, start-ups, and companies of all sizes. In January of 2000, I left private practice to join Johnson & Johnson as its Chief Patent Counsel, which is the position I hold today.

Johnson & Johnson is a family of more than 200 companies, and is the largest broad-based manufacturer of health and personal care products in the world. Collectively, Johnson & Johnson companies represent this country's largest medical device business, its third largest biotechnology business, its fourth largest pharmaceutical business, and very substantial consumer, nutritional, and personal care businesses. Johnson & Johnson companies employ over 55,000 people within the United States. Johnson & Johnson's companies are research-based businesses that rely heavily on the U.S. patent system and its counterpart systems around the world. In 2006 alone, Johnson & Johnson's businesses invested \$6.3 billion in R&D.

As the manufacturer and marketer of thousands of products, the freedom to make and sell products in view of the patents of others is always a concern of Johnson & Johnson businesses. They therefore routinely review hundreds of patents during their product development processes, make appropriate design changes to avoid the patents of others and/or obtain appropriate licenses or legal opinions prior to launching their products. Nonetheless, Johnson & Johnson companies do from time to time become involved in patent litigation, finding themselves to be defendants about as often as they are plaintiffs. Most of these litigations involve competitors or would-be competitors, although some involve non-manufacturing patentees.

General Policy Considerations Driving Patent Reform

Patent law reform means different things to different people. For example, some proponents focus on enhancing the quality of patents issued by the U.S. Patent and Trademark Office. Other proponents have focused on litigation reform. The recent reports issued by the Federal Trade Commission (“FTC”) and the National Academies’ Board on Science, Technology, and Economic Policy (“NAS”) surveyed the landscape and made many thoughtful recommendations.

While patents are a principal driver of innovation in many technologically-based industries, they are perhaps most important in the pharmaceutical and biotechnology industries. In industries in which it takes 8 to 10 years or more, and hundreds of millions of dollars, to develop, test and obtain approvals for a single product, patents are critical. No pharmaceutical company wants to commit this magnitude of investment to the development of a drug product only to later find that the patent was invalid or unenforceable due to an error in its examination, or because of previously undiscovered prior art.

The perceived predictability and reliability of patent protection weighs heavily on business planners in deciding whether to go forward with the investments needed to develop potentially promising new drugs. As a matter of sound public policy, we urge the Subcommittee to support changes that encourage investment decisions to be made based upon the potential importance of the new technology rather than on whether the patent examination process is or has been flawlessly conducted. As Chief Judge Sue Robinson of Delaware recently noted in her speech to the Association of Corporate Patent Counsel, patent litigation has become more a matter of semantics than of science. In Johnson & Johnson’s view, this trend is taking patent law in the wrong direction. Instead, we believe that the rewards promised by the patent system should closely track the value of the invention’s contribution to society, not the skills of those who happen to have been involved in drafting, prosecuting or examining the patent application. Just as plainly invalid patents (i.e., those purporting to cover that which contribute nothing to society) are a drag on the patent system, so too are rules that elevate the consequences of harmless administrative error to the point of depriving a worthy inventor of the protections to which he or she is otherwise entitled.

Policy changes that are perceived to lessen the economic value of patents, or their certainty of enforcement, have an immediate impact on investment decisions, and a long-term impact on the quality of innovation itself. While some might be tempted to encourage infringement, or to lessen its financial consequences, in the name of short-term competition, any such savings are likely to be heavily outweighed by the cost to society of foregoing future innovation that would lower costs and improve quality of life.

Johnson & Johnson’s interest in patent law reform is to insure that the patent system fairly rewards those who contribute to our society through the invention and development of new and useful products and processes. A fair, efficient and reliable patent system will continue to stimulate the investment in innovation that is necessary in today’s technologically complex world to create the new products and processes that will lead to

better lives for Americans and the rest of the world. In addition, the best promise for preserving and enhancing our place in an increasingly competitive global marketplace will be to stimulate U.S. investment in research-based industries.

Prompted in part by the recent studies by the FTC and NAS, attention has recently been focused on ways to improve our patent system. For the past two years, Congress appropriately provided increased funding to the U.S. Patent & Trademark Office in support of its 21st Century Strategic Plan to improve both patent quality and patent pendency. This was an excellent first step towards upgrading our patent system, and one that, if continued, should bear fruit in the years to come.

21st Century Coalition for Patent Reform

Johnson & Johnson is a member of the “21st Century Coalition for Patent Reform,” a group of interested companies from a wide variety of industries that have worked together to develop consensus patent reform language. Thus far, some 39 major companies and organizations have announced their support for a “Coalition Text.” An electronic copy of the Coalition Text is attached, as is cited to hereinafter as “CT.” Included among these are supporters of this text are the American Intellectual Property Law Association (“AIPPLA”) and the Intellectual Property Owners Association (“IPO”).

The Coalition Text should be viewed as a “package.” Unlike other packages, however, this package evolved through changes designed to garner the support of as many diverse stakeholders as possible. Thus, as in any legislation involving compromise, there may be some changes that are included in the spirit of creating a consensus regarding at least some of the goals of patent law reform. In supporting the Coalition Text, many companies have accepted significant compromises in the expectation that this text would garner support from companies in other industrial sectors, such as IT and software companies that have most recently shown interest in provisions relating to transfer of venue and to “damages apportionment.”

Companies that support the Coalition Text, as Johnson & Johnson does, generally view this compromise as a balanced and achievable approach to patent reform. This coalition package would provide significant advantages for owners of valid patents, while providing an opposition procedure that will provide a meaningful check on the quality of recently-issued patents. Subjective and intent-based invalidity issues would be largely removed from patent litigation, while ensuring that, like today, knowledge that is publicly accessible may still be used to assert that a patented invention is obvious.

Existing Posture of Pre- and Post-Grant Examination Procedures

One impetus for patent reform is the perception that the United States Patent and Trademark Office (USPTO) is neither conducting its examinations expeditiously, nor exercising a sufficient level of quality control over those examinations. Fortunately, the root cause of this problem, chronic under funding, has been alleviated at least for the moment by legislation providing funding sufficient to support the USPTO’s 21st Century

Strategic Plan and the action by Congress to appropriate all of the fee revenue to the Office. Unfortunately, it will take several years of continued full funding for the USPTO for this plan to result in improvements in both patent quality and pendency. In the meantime, Congress should be cautious not to enact reforms that will place undue demands on USPTO, or that are only responsive to the USPTO's current, transient problems.

Because no patent office, including ours, can ever find and consider every prior art patent or publication that might be relevant to a patent's validity, two post-grant procedures have been established to allow the USPTO to consider subsequently located patents and publications: *ex parte* reexamination and *inter partes* reexamination. These reexamination procedures are available to the public and are relatively inexpensive as compared to litigation. Because these are limited proceedings intended only to evaluate the impact of these documents on a patent's validity, discovery is not permitted and other validity issues, such as enablement, written description, best mode, claim indefiniteness, prior sale, prior public use and prior invention may not be challenged.

Single (9 Month) Window Post-Grant Opposition Proposal

In conjunction with other patent reforms, it has recently been suggested to allow third parties to more broadly challenge the validity of an issued patent before the USPTO. The Coalition Text contains a package of changes that would permit third parties to submit relevant prior art to the USPTO during the initial *ex parte* examination process (CT Sec. 8), and to institute an *inter partes* opposition within nine months of the grant of a patent (CT Sec. 7(f)). Unlike reexamination, in an *inter partes* opposition, essentially all validity issues may be raised (CT § 324). Unlike a federal court proceeding, where the challenger must prove invalidity by clear and convincing evidence, in the proposed *inter partes* opposition, a challenger need only prevail by a preponderance of the evidence (CT § 332(a)). Moreover, unlike *inter partes* reexamination, collateral estoppel will be limited only to those issues of fact or law "actually decided by the panel and necessary to the determination of the issue." CT, § 336 (a)(1).

Several important intellectual property stakeholders nonetheless oppose establishment of any post-grant opposition procedure, including "first window" oppositions. Individual inventors, universities, small businesses and start-ups (especially biotechnology start-ups) are particularly concerned about adding the burden of an additional proceeding to the existing *ex parte* examination. These stakeholders believe that the lowered standard of proof that would apply to these proceedings is unfair to patentees who have convinced an impartial government agency of their right to a patent, and that the weakened collateral estoppel provisions that would apply will prevent them from enjoying "quiet title" to their patents. Additional concern has been expressed, based on experience in similar European oppositions, that thousands of U.S. oppositions may be filed each year. If so, these could easily overwhelm the USPTO's already-stretched resources.

Because the term of a patent is fixed, lengthened uncertainty concerning the nature of the patent grant inherently diminishes its perceived value. Stakeholders whose business

models depend on the issuance of patents to raise much needed capital, and to justify the continued investment that is necessary to bring modern, high technology inventions to the marketplace, are therefore particularly vehement in their opposition to any post-grant opposition process. In some cases, they fear that the continued uncertainty created by additional years of post-grant oppositions will cause their new ventures to fail.

Others, including Johnson & Johnson, see single, 9-month-window oppositions as a procedure whose costs will be outweighed by resulting improvements in patent quality and enforceability. In increasingly complex technologies, such as pharmaceuticals, biotechnology and drug-device combinations, it can take many years and hundreds of millions of dollars to bring a single product to market. For these investments to be made, it is imperative that the patent covering the product to be developed be valid and reliably enforceable against anyone who might try to expropriate the invention at the expense of the innovator. The availability of an opposition procedure to serve as an initial quality control check is seen by these supporters as a price worth paying to ensure that they are investing in patents of high quality and reliable enforceability. Included within this calculus is the perception that the weakened collateral estoppel standard and the lowered burden of proof will induce third parties to actively participate in this limited extension of the patent examination process.

Subsequent (Life-Of-The-Patent) Post-Grant Opposition Proposal

H.R. 2795, introduced in the House last year, proposed to further create a second window for bringing oppositions. This second window, which would be available throughout a patent's life, would open once a charge of infringement was received from the patent holder. The concept of the second window was that accused infringers could opt to institute a second window opposition instead of challenging validity in court.

Outside of the software/semiconductor industries, the idea of "second window" post-grant oppositions was immediately opposed as unfairly burdensome to patentees, as counterproductive, as undermining the reliability of the patent grant, as unfairly providing a "second bite at the apple" to accused infringers, as unnecessarily adding to the time and expense of patent enforcement, and as beyond the currently foreseeable capability of the USPTO. The opposition to this concept came not only from those who opposed first window oppositions, but from a far broader spectrum of intellectual property (IP) stakeholders, including the AIPLA, IPO, ABA-IPL, PhRMA, BIO, and many others, including Johnson & Johnson. In any event, in the "Amendment in the Nature of a Substitute to H.R. 2795" offered by House IP Subcommittee Chairman Smith, the proposal for a second window for oppositions was dropped.

A life-of-the-patent period for bringing oppositions would also undermine the benefits otherwise achievable from a single window post-grant review. The public interest strongly favors a patent system that issues high quality, reliably enforceable patents. Were it possible to bring an opposition throughout the life of a patent, competitors knowing of invalidating art or some other validity defect would have no incentive to bring an opposition during the initial period for doing so. The result would be to

unnecessarily prolong the economic impact of a defective patent, while reducing the perceived incentives for patentees to invest in developing their inventions for market. Finally, in the absence of any demonstrated capability that the USPTO can effectively implement a single window opposition procedure, to add second window oppositions would, at best, seem premature.

It must be noted, however, that would-be competitors are not without recourse should they conclude years after a patent is granted that it is invalid in view of the teachings of prior art references not previously considered by the USPTO. Both *ex parte* and *inter partes* reexamination procedures will continue to exist to allow members of the public to conveniently and expeditiously challenge a patent's validity.

Inequitable Conduct Reform

Numerous patent litigation reforms have been suggested in connection with the debate over patent reform. Chief among them is the need for inequitable conduct reform. A judicial creation dating back to at least the 1960's, when neither *ex parte* nor *inter partes* reexaminations were available, the doctrine was developed in response to a few egregious cases where patent applicants either intentionally withheld highly material prior art from the patent examiner, or lied to the examiner in order to gain allowance of their patents. Where the prior art was intentionally withheld, the courts saw themselves (and the public) as having been deprived of the expertise and opinion of the USPTO on issues material to patentability. Where affirmative misrepresentations were made, the applicant was seen as taking advantage of the *ex parte* nature of the proceedings, as the patent examiner is not otherwise active in the field, and lacks the resources needed to investigate, test and rebut an applicant's factual contentions. Thus, when it was shown by clear and convincing evidence that the information that was withheld or misrepresented was material to the examination and that the applicant had the specific intent to deceive the USPTO, the courts responded by holding the patent unenforceable.

In the ensuing four decades, the doctrine of inequitable conduct has evolved to be the defense of last resort for infringers. It is now raised in almost every case, and is sometimes successful even when all of the patent's claims are otherwise adjudged to be valid, and/or even when it is agreed that the information presented to the USPTO was entirely accurate. Recently, for example, the Court of Appeals for the Federal Circuit affirmed summary judgment of inequitable conduct under what appears to be a new duty of candor, applying a *might-have-been-asked-should-have-been-answered* standard, for deciding what must be told to a patent examiner. In *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181 (Fed. Cir. 2006), the patent at issue was found unenforceable due to the submission of the entirely truthful declarations of non-inventors requested by the patent examiner to corroborate the art-recognized dictionary definition of a commonly used claim term ("peroral," meaning through the mouth). Notwithstanding the truthfulness of the declarations, the patent was held to be unenforceable because the USPTO had not been told that some, but not all, of the non-inventor declarants were people who otherwise had consulting or other business relationships with the applicant's employer.

Because not all information pertaining to an invention and its related prior art can be (or should be) submitted to the USPTO, accused infringers now resort to taking issue with virtually anything said to the Office during prosecution and/or the manner in which the patentee chose to say it. Inequitable conduct issues have become a scourge on the patent system, increasing and prolonging patent litigation, and confounding and chilling communications between patent applicants and the USPTO.

It is arguable that the establishment of opposition proceedings should obviate any further need for the inequitable conduct defense, as competitors are well situated to submit additional material prior art and rebut any incomplete or misleading arguments that may have been made during the ex parte phase of patent examination. Nonetheless, the Coalition Text preserves the defense of inequitable conduct, but proposes to impose two threshold limitations: (1) a pleading threshold requiring that at least one asserted claim of the patent be found invalid, and (2) an evidentiary threshold requiring that the challenger show that but for the patentee's conduct, the invalid patent claim would not have been allowed. (CT § 5). Both of these are widely seen to be necessary to restore rationality to the inequitable conduct defense, and to remove the chill that currently exists during patent examination. Coupled with 9-month post-grant oppositions, these reforms should facilitate more open dialog between the examiner and applicant, and should improve patent quality.

Damages Apportionment/Whole Market Value

To most IP stakeholders, including Johnson & Johnson, there is simply no need to reform the current approach that is taken by the courts in the award of damages. The fact that the courts "pretty much get it right" is evidenced by the fact that critics of patent damages law have produced few if any cases where the courts "got it wrong." The Coalition Text nonetheless proposes compromise language that is intended to codify Georgia Pacific damages factor #13 in response to what was understood to be the original goal sought by members of the software/semiconductor industry. Where lost profits are not involved, and a reasonable royalty is to be determined, the key remains to link the determination of that royalty to the economic contribution of the claimed invention to the adjudged infringing product or process. As long as there is a sufficient nexus between demand for the infringing product or process and the characteristics, attributes or advantages conferred by the claimed invention, it remains entirely appropriate to award damages calculated on a royalty base that includes the entire value of the infringing product or process, as opposed to a sub-part or component thereof.

Unfortunately, the damages proposal in the Coalition Text has yet to gain widespread acceptance in the so-called "tech" community. These stakeholders instead suggest parsing the claimed invention into its elements to look for the so-called "inventive contribution" and to award damages on that feature alone. Under this theory, elements found in the prior art, and contributions made by the infringer to the product, would be subtracted out of the invention for purposes of the damages analysis.

"Prior art subtraction" has met widespread opposition in the IP community, as unfairly

diminishing the value of patent damages. At some level, all inventions are combinations of old elements. As Chief Judge Howard Markey of the Court of Appeals of the Federal Circuit once observed, “virtually all inventions are ‘combinations,’ and . . . every invention is formed of ‘old’ elements’ . . . Only God works from nothing. Man must work with old elements.” Howard T. Markey, “Why Not the Statute?,” 65 P.Pat.Off.Soc’y 331, 333-34 (1983). Accordingly, in almost every instance, rigorous application of a prior art subtraction will leave little or nothing on which to award damages. Moreover, some inventions result from the elimination of prior art elements or steps in a process. Once again, using the prior art subtraction approach, no damages would be awarded to these inventions, no matter how economically valuable they may have been shown to be.

Venue

The Coalition Text includes a provision for transfer of venue in patent infringement actions that have been brought in jurisdictions without a substantial connection to the case (CT § 9). This contrasts with previous suggestions that would limit available jurisdictions to those where the defendant is found. This difference is important. Although there are significant policy reasons for limiting unfettered “forum shopping,” there are also significant policy reasons not to restrict patent owners from bringing actions in jurisdictions, such as the parties’ home jurisdictions or elsewhere, where important evidence relating to the case may be located. The proposed transfer provision would have the benefit of preserving the patent owner’s initial choice of venue if rationally connected to the parties or evidence, while permitting alleged infringers to transfer cases to more appropriate jurisdictions if the case has been brought in a jurisdiction without substantial connection to the matter to be decided. This provision will likely reduce forum shopping, and enhance the perceived fairness of our system of patent enforcement. This provision, although not a complete remedy to forum shopping, has received widespread support, including support from the Business Software Alliance (BSA).

Awarding Attorneys Fees to the Prevailing Party

Although not contained in any tabled proposal, it has also been suggested that a loser pays system similar to the English rule might be appropriate for application in patent cases, as it is in certain other areas of IP, such as copyright. Adoption of an English-type system would allow inventors with meritorious, but lower value claims to assert them without fear that attorneys fees might consume any damages award. Such a system would also deter parties with frivolous or highly questionable claims from bringing them for fear of having to pay their opponent’s attorneys fees.

While most agree that a loser pays system would discourage frivolous litigation, questions remain as to whether such a system is politically achievable. In addition, concern has been expressed that provisos such as a “substantial defense” exception might undermine the value of such a rule.

Johnson & Johnson appreciates the invitation to provide our views to the Subcommittee

on these and other patent reform proposals, and look forward to working with the Subcommittee on patent law reform and other matters.