
Hearing on Committee Print Regarding Patent Quality Improvement

Testimony of

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on behalf of

Genentech, Inc.

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Subcommittee on Courts, the Internet and Intellectual Property

of the

House Judiciary Committee

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Mr. Chairman and distinguished Members of the Subcommittee,

My name is Jeff Kushan. I am a partner in the Washington office of the law firm of Sidley Austin Brown and Wood, LLP. I am also a registered patent attorney, and specialize in the areas of biotechnology, pharmaceuticals and software-related inventions.

Today, I have the privilege of offering testimony on behalf of Genentech, Inc. Genentech was the first biotechnology company, founded in 1976, in South San Francisco, California. Genentech's mission is to be the leading biotechnology company, using human genetic information to discover, develop, manufacture and commercialize biotherapeutics that address significant unmet medical needs. Genentech presently markets 13 products, with

more than 30 more in development.

Genentech very much appreciates the opportunity to provide testimony to the Subcommittee today on the topic of patent law reform. We commend you, Mr. Chairman, for your initiative in opening this legislative dialogue on the topic of patent law reform. We also want to recognize the past efforts of your colleagues on this topic, including Mr. Berman and Ms. Lofgren.

Genentech is a company that was founded on innovation. It should come as no surprise that patent protection and the health of the patent system are thus crucially important to Genentech. The availability of patent protection for its inventions is an important consideration to Genentech in its research and product development activities. Assured patent exclusivity encourages the investment of hundreds of millions of dollars each year on efforts to research and develop new biotherapeutics.

Genentech also recognizes that the patent system faces several serious challenges.

First, the Patent and Trademark Office (PTO) faces serious challenges in performing its statutory function of issuing valid patents in a timely fashion. The primary cause of this problem is the ongoing problem of fee diversion. The unpredictable nature of patent fee diversion has made it difficult for the PTO to engage in the long-term restructuring of its operations that is necessary to make the patent examination process more reliable and efficient. We cannot stress more emphatically that the most important legislative deliverable for Congress in the effort to improve the patent system is to ensure predictable and adequate funding for PTO operations.

Second, the current model used by the PTO in conducting examination of patent applications needs to be seriously reevaluated. Presently, every application that is filed today is placed into the queue for examination. This requires the PTO to budget for and engage in an unnecessary examination of many thousands of patent applications. The United States is unique in the world in this respect ? every other major office conducts examination of applications only upon request and payment of a fee. Exacerbating this problem is the approach the PTO employs in "restricting" patent applications. The PTO requires applicants to file additional patent applications when it believes a first application has claimed more than one patentably distinct invention. The PTO examiners, however, use an exceedingly narrow and strict standard for restriction, which has led to a multiplicity of unnecessary filings in the biotechnology area. These extra applications make coherent and efficient examination of inventions very difficult, and contribute to an artificial backlog of unexamined applications. Restructuring the patent examination process to address these two problems would result in examiners having more time to examine each invention, and would thus significantly improve patent quality. We encourage Congress to pursue such legislation in conjunction with the current legislative effort.

Finally, the process of resolving disputes over patents through litigation in the Federal Courts produces a high degree of uncertainty for businesses such as Genentech. Although the Court of Appeals for the Federal Circuit has done much over the years to clarify the requirements and standards for patentable inventions, there still remains a significant amount of uncertainty in how those requirements and standards will be applied to biotechnology inventions by trial courts and juries. As a result, it remains difficult to predict if a patent will be held valid, if it will be infringed or if it will be held unenforceable.

Similarly, it is often impossible to predict what damages a company will face if it is found to infringe a patent. The uncertainty in today's patent litigation environment, unfortunately, is being exploited by certain patent owners to distort the value of their patent rights and to undermine the legitimate use of patents. Reforms to the patent system—both as to the standards governing patent validity and as to outcomes and consequences in litigation—are necessary and timely.

Your hearing today provides a timely opportunity to engage on the issue of legislative reform to our patent system. We welcome your initiative in starting this discussion, and believe it will yield fruitful results.

The draft committee print proposes reforms across a broad spectrum of elements of the patent system. Our comments today will focus on those areas of greatest importance to Genentech; namely, proposed reforms to the rights and remedies provided with the grant of a patent, standards governing patentability, reforms to the inequitable conduct doctrine, and post-grant opposition procedures.

In general, Genentech supports reforms in many of the areas addressed in the Committee Print. However, certain proposals, particularly those that could operate to deprive the owner of a valid U.S. patent of its ability to prevent the unauthorized use of a patented invention, would seriously alter the nature of the patent right. Genentech opposes reforms of this nature, as they would undermine the foundation upon which many of this company's business decisions have been based; namely, the guarantee of exclusivity.

Proposed Reforms to the Standards Governing Injunctive Relief

Section seven of the Committee Print would fundamentally alter the nature of a United States patent by altering the standards governing entitlement to permanent injunctive relief under section 283. While Genentech is sympathetic to the problems associated with the unpredictability of patent litigation, it cannot support legislation that would call into question the basic premise under current law that infringement of a valid patent can be enjoined.

Section 7 begins by incorporating into section 283 in express terms the standard governing entitlement of any litigant to injunctive relief. However, section seven then would prohibit a court from presuming that there will be irreparable harm to the patent owner as a consequence of a finding of infringement of the patent. The proposed legislation also directs courts to consider evidence that would support or negate any of the equitable factors governing the award of injunctive relief, including whether or not the patent owner makes use of the invention.

Section seven of the Committee Print thus would overrule the well-established and long-standing precedent that the owner of a patent is presumed to be irreparably harmed by an infringement of a valid United States patent. The existing presumption is based on sound public policy reasons, and we see no justification for altering this existing precedent. The

reason is simple ? the value of a patent derives from its status as a property right. There is nothing more essential to the character of the patent as a property right than its capacity to prevent unauthorized use of the patented invention.

More than a century ago, our courts recognized that the capacity of a patent to prevent the unauthorized use of the patented invention was the fundamental attribute that gives the patent its economic value. This premise has been repeatedly affirmed by courts since that time. See, for example, *Polymer Technologies, Inc v. Bridwell*, 103 F.3d 970 (Fed. Cir. 1996) ("The right to exclude others from a specific market, no matter how large or small that market, is an essential element of the patent right"). The recognition that the right to exclude is the essential attribute of the patent right gave rise to the legal presumption that is a foundation of the U.S. patent system; namely, that the owner of a valid United States patent is irreparably harmed by an infringement of that valid patent, in the absence of any further evidence. There is no sound reason for not continuing to rely on this premise. Genentech also sees no reason why the burden should not be placed on the shoulders of the infringer of a valid United States patent to show why that infringer should not be enjoined from its continued infringement of the patent.

The specific issue implicated by the proposed modifications to section 283 is who bears the burden of putting forward evidence to establish that an injunction is appropriate once the patent has been fully adjudicated and found to be valid and infringed. The standard thus speaks to valid patents, not to patents that are of questionable validity. It also concerns the question of permanent injunctive relief, not preliminary injunctions that may be awarded pending resolution of the litigation over whether the patent is valid or infringed. As a standard governing the burdens that are to be applied with respect to valid and infringed patents, it is appropriate to maintain the standard in the form it exists today. Genentech believes the law appropriately places the burden on the shoulders of the infringer to establish why an injunction should not be granted. Whether that infringer is able to do so or not will turn on the facts and circumstances of each case.

Genentech is not insensitive to the concerns expressed by many over the disruption of ongoing business activities as a consequence of the grant of a permanent injunction. Genentech certainly has its fair share of defensive patent litigation. The question of permanent injunctive relief, however, is one that is best left to the courts upon the body of precedent that exists today. Genentech remains open, of course, to measures that remove some of the uncertainty of patent litigation, or which address the truly unique situations faced by those who advocate for change of the law.

In this respect, Genentech encourages the Congress to focus on the specific and unique concerns being expressed that have led to this proposal. For example, one scenario that has been identified is the potential grant of a permanent injunction in favor of a patent owner that has taken no steps to bring a competing product to market, or who has extensively licensed the patent on a non-exclusive basis to other parties, and who can be fully compensated through money damages. Genentech believes courts presently do consider such factors in determining whether to award a permanent injunction. Similarly, some concerns arise from the situation of a company facing the requirement to immediately comply with an injunction issued by a District court. In many instances, courts will stay the effect of the injunction pending appeal of the judgment on validity or infringement, which provides the infringer the time needed to alter its product or take other steps.

The most significant concern, however, appears to be the use by a party that is not in the market of the accused infringer of the threat of an injunction solely for the purpose of increasing the risk of liability to a manufacturer, and to increase the amount of a potential settlement. In that setting, significant questions of validity or enforceability of the patent often exist. These problems have led to more refined jurisprudence addressing issues such as prosecution laches, enhanced obligations for written description and the like. Certainly, if a patent owner elects to seek injunctive relief against an accused infringer, and causes harm by such an assertion, that party should face some consequences if the patent is shown to be invalid, unenforceable or not infringed. One approach may be to simply alter the amount of discretion given to courts to award fees and costs incurred in defending against such a claim, and to ensure that such liability extends to all parties that stand to gain economically from the infringement action. Congress also may wish to consider legislative solutions that specifically address the unique circumstances faced by specific industries, but which will leave intact the well-established body of law that ensures that a patent owner can rely on the presumption of irreparable harm stemming from proven infringement of a valid U.S. patent to establish entitlement to permanent injunctive relief. Genentech believes such approaches may prove to be a more fruitful avenue in deliberations for reform than the approach taken in section seven of the Committee Print.

Proposed Reforms to the Standard for Willful Infringement

In contrast to its views on proposals that would alter the standard for injunctive relief, Genentech does support reforms to the law governing the doctrine of willful infringement. The Committee Print proposes to alter the standard by identifying three specific types of actions as being indicative of situations of "willful" infringement of a patent that are sufficient to justify the award of enhanced damages.

Genentech believes that the articulation of the three scenarios found in the legislation is a sound basis for proceeding. Genentech, however, believes that these scenarios should be the only situations that warrant a finding of "willful" infringement. Part of the problem with the existing standard is that it is difficult to ascertain what will constitute willful infringement under present law. Making a more specific and explicit definition of those acts that will constitute willful infringement will help address part of the problem. Genentech also supports the approach in proposed legislation that precludes a court from drawing an inference of willful infringement from the absence of opinion of counsel, and that willful infringement may not be established solely upon proof of knowledge of the patent by the defendant prior to suit.

The changes proposed by section six of the Committee Print, however, do not go far enough. A significant problem with the existing willful infringement doctrine is that parties often claim willful infringement simply as a litigation tactic. The claim then manifests itself in demands for production of opinions of counsel as to the validity or infringement of the patent, and efforts to place into evidence information that is unnecessary and irrelevant to the question of infringement. Genentech believes that in addition to establishing more objectively defined standards for willful infringement, three additional measures are needed.

First, the law should preclude a court from addressing the question of willful infringement until after a party had been found to have infringed the patent. Taking up the question of willfulness only after a party has been found in a final unappealable judgment to have infringed the patent will go far in helping to curb some of the abuses that exist in today's modern litigation environment. Second, the question of willfulness should be addressed only by the court, and not by a jury. Finally, the law should preclude a party from attempting to obtain discovery of opinions of counsel incidental to a claim of willful infringement until after the court has first determined that infringement was established. With these additional changes, Genentech can support the reforms to willful infringement being proposed in section 6 of the Committee Print.

Reforms to Preclude Late Claiming of Inventions

Section 8 of the Committee Print would treat as unpatentable certain types of claims that are presented at a certain point in time. The legislation appears to be focused on the problem of parties that present broad claims long after an initial application has been filed, with the intent of capturing the intervening market entry by a competitor who believed that there would not be a patent obstacle. While Genentech is sympathetic to some of the concerns raised with respect to late-presented claims, it does not believe the proposed legislation will provide a practical solution, and instead will create significant problems for legitimate patent applicants.

Genentech notes that under existing PTO practices, biotechnology patent applicants are often subjected to extensive restriction requirements. This means that for each invention that is pursued in a first application, Genentech often must file dozens of additional applications to obtain meaningful and sufficient claim coverage. Under existing law (35 U.S.C. 121), Genentech has the right to defer the filing of these additional applications. If the law required the immediate filing of dozens of voluntary divisional applications, as proposed in the Committee Print as a solution to the late-claiming problem, it would place unjustified additional expenses on biotechnology applicants such as Genentech. More significantly, in many cases, new questions of law or practice arise during the examination of an application. These new standards not only cause applications to undergo a protracted examination process, they also clarify what types of claims a patent applicant may pursue.

The proposed solution also suffers from the practical problem of determining when a claim is "broader" than a claim that was published, issued or presented in a priority application. In most instances, claims will be both broader and narrower than previously presented claims. Forcing the patent examiner, and then the courts, to determine if sets of claims are broader or narrower than earlier filed claims will present immense challenges. Moreover, while many other provisions in the legislation would go far in eliminating uncertainty in the standards governing patentability, this measure would have precisely the opposite effect.

For these reasons, Genentech generally opposes the approach reflected in section 8 of the Committee Print, and encourages the Committee to explore other ways of curbing the problem of late claiming. Genentech also notes that courts are taking steps to address late-claiming situations. See, e.g., *Symbol Technologies v. Lemelson*, 277 F.3d 1361, 161 Ed. Law Rep. 57, 61 U.S.P.Q.2d 1515 (Fed. Cir. 2002).

Reforms to the Standards Governing Enforceability of Patents

Section five of the Committee Print proposes to reform the doctrine governing inequitable conduct. Genentech strongly supports legislative reforms in this area.

Section 282 provides that a party accused of infringement may raise a defense that the patent is unenforceable. Unenforceability is a defense distinct from invalidity of the patent or from non-infringement. It operates to preclude the patent owner from enforcing a patent that is otherwise meritorious ? meaning that the invention claimed in the patent is novel, not obvious, useful, and adequately described. It has evolved over the years from several equitable doctrines, the most dominant of which is the assertion by a defendant that the patent is unenforceable because the patent owner committed a fraud on the PTO in the process of obtaining the patent. From this legitimate foundation, the doctrine of "inequitable conduct" has arisen and flourished to an inappropriate degree.

As several courts have observed, claims of inequitable conduct have become what is justifiably labeled as a "plague" on modern patent litigation. Inequitable conduct is routinely raised in patent cases, and often is based on the flimsiest of assertions. The reason is simple ? by pursuing this defense, a patent on an invention that is otherwise meritorious can be nullified by making it impossible to enforce.

The inequitable conduct doctrine, however, has created significant problems for patent applicants and for the PTO during the examination of applications. The most significant is that communications between the patent applicant and the patent examiner are now a contorted and restricted dialogue, primarily because of the risk that these communications made honestly and in good faith will be turned into a story of inequitable conduct when the patents are put into litigation in the future. Concerns about creating a foundation for a claim of inequitable conduct may cause applicants to be overly inclusive in citing information to the PTO. This often results in situations where the patent examiner is given an immense amount of information solely for the purpose of foreclosing a claim that the applicant was concealing information from the examiner, thereby imposing unnecessary burdens on the patent examination process. Moreover, applicants can be put into a "Catch 22" situation in that they can later be accused of "burying" a reference if they cite many references to the PTO to satisfy their Rule 56 obligation as defined by the courts.

Plainly, reforms to this doctrine are necessary. In general terms, Genentech would support reforms that provide that a party could not raise an assertion of inequitable conduct in respect of a patent unless at least one claim of the patent were shown to be invalid on the basis of the disputed prior art or information. Such a change would establish a more objective threshold finding of significance for the disputed subject matter and would supplant the existing "materiality" standard. Genentech would also support retaining the requirement in present law that there be a distinct finding of a specific intent of the applicant to mislead the PTO. Such reforms would change how parties could raise inequitable conduct assertions in litigation, and would reduce the opportunistic uses of such pleadings in litigation.

Genentech also would support enactment of measures to ensure that patent applicants are forthcoming during the original examination of patent applications. For example, Genentech would support measures that provide the PTO or the courts with some authority to sanction parties which it had determined had engaged in misleading or inappropriate conduct before the PTO. The sanction of unenforceability of the patent is not the only type of sanction that can be employed to ensure that parties act with good faith and candor in the PTO. The approach taken in the Committee Print reflects the type of authority that may prove useful in this regard, although Genentech believes the present language of section 6 can be substantially improved.

Genentech also believes that a more transparent examination process can also be pursued in conjunction with these reforms. Genentech notes that the United States patent system is structured to deliver reliable results in a cost-effective and timely manner. Examination is conducted on an "*ex parte*" basis ? meaning that the PTO and the patent applicant are the only participants in the examination process. The advent of publication of patent applications prior to grant from the 1999 American Inventors Protection Act (AIPA) has shed some light onto ongoing examinations, but, fundamentally, the patent examination process remains closed to substantive participation by parties other than the patent applicant.

Practical considerations mandate that this model continue. The PTO, given its resource constraints, simply cannot administer a system that permits third parties to intervene in the examination of pending applications. Experiences in other countries that do permit substantive intervention in the examination of applications are uniformly negative. These experiences show that in many instances, third parties intervene to simply delay the issuance of a patent, which disrupts business expectations of patent applicants and consumes limited patent office resources. Allowing that type of public intervention in the examination of pending U.S. applications would create immense practical problems, given the volume of applications now pending before the PTO, and the limited amount of examination resources that are available.

However, there is no good basis for not publishing all applications 18 months after they have been filed. Publication provides access to the public of the contents of the application during the examination process. Genentech thus would support amendments that would mandate 18-month publication of all applications, and which enable third parties to submit information, accompanied with a brief explanation of the relevance of the information, on issues implicated during the examination of the application. Of course, that right to submit information must not entitle the third party to disrupt the examination process, or to formally oppose the grant of the patent. Genentech believes that such safeguards as 18-month publication of all applications and limited third-party submissions during *ex parte* examination, combined with the opportunity of more third-party involvement during post-grant opposition proceedings, warrant revisions to the inequitable conduct standards that give rise to so many baseless claims today. Such reforms also would place the U.S. more on par with the practices of other major countries including those that are members of the European Patent Convention and Japan.

Reforms to the Standards of Patentability

Sections 2 to 4 of the Committee Print would make substantial changes to portions of title 35 that govern patent eligibility. In principle, Genentech supports the approach taken in these sections, with certain exceptions.

Genentech supports reforms that would implement a "first inventor to file" standard in the U.S. patent system. Such a standard would address what many improperly perceive to be an assured right of a first inventor to obtain a patent. For reasons articulated well by the National Academies of Science in their 2004 report on the patent system, the existing "first to invent" standard creates immense challenges for patent applicants and the public, in part, because it requires the incorporation of many subjective criteria for patentability into the patent system. It also necessitates inventorship contests, known as interference proceedings, which are expensive, complex and usually result in award of the patent to the first inventor to file an application. Given the low frequency of these types of conflicts, the expenses associated with them, and the immense record keeping requirements they implicate, there is no sound reason for not shifting to a first inventor to file standard.

The reforms being proposed would retain a requirement that any applicant for a United States patent be filed by or on behalf of an inventor of the subject matter being claimed. This approach will ensure that the interests of inventors will be effectively protected. Genentech supports these types of safeguards in the patent system. With such a standard, however, conflicts may still arise over entitlement to a patent. Section two of the Committee Print would propose to address these conflicts through an interference proceeding. Such proceedings, as proposed under a modified section 135(a), would be based on "disputes" over who is an inventor. Genentech believes a more precise and specific standard, with specifically articulated outcomes of such a proceeding, is needed, rather than what has been proposed for section 135(a). In particular, a dispute over entitlement of a true inventor to a patent should be based on a proof of derivation of the invention by the first party to file from the inventor. The proceedings should result either in an entitlement to joint and several ownership of the patent in dispute, or in the award of a patent to the second inventor that files an application. Genentech is prepared to work with the Committee to devise an appropriately focused and limited procedure for resolving such disputes.

The conversion to a first-inventor-to-file patent system necessitates reforms to sections 102 and 103 of the patent statute, among other provisions. The approach taken in section two of the Committee Print is a good start toward these reforms. A number of specific issues, however, are not satisfactorily addressed in the proposed legislation.

- The revised law should confirm that subject matter in a published patent application or in a patent shall have prior art effect as from the actual or effective filing date of the patent or published application only if that subject matter has been described in a manner that complies with section 112, first paragraph. This will maintain the existing law that provides that the "secret" prior art effect of a patent or published patent application (i.e., for the period before the contents of the patent application are publicly known) is

to be limited to that subject matter that has been described in a manner sufficient to justify the grant of a patent on that subject matter. Revisions to proposed section 102 (d) of title 35 are required to give effect to this change.

- The standard for public accessibility of information to qualify that information as prior art should be specifically exemplified using more objectively defined criteria. In particular, Genentech would support revision of proposed section 102(c) to incorporate more precise and objective language for the concepts of "reasonable and effective accessibility" of prior art. Genentech also believes it will be important to exemplify these concepts in the legislative history of the proposed legislation.

- Genentech supports elimination of the "best mode" requirement of section 112, first paragraph. This measure has proven unnecessary and unhelpful in the patent system, particularly in view of the enhanced obligations on disclosure imposed by modern judicial interpretation of the requirements for written description and enablement under section 112. Genentech encourages the Congress to affirm the independent and distinct nature of these two remaining elements of section 112, first paragraph, as part of the legislative history explaining the reform that would be made to this provision of title 35.

Certain changes being proposed, however, are unnecessary to implement a first-inventor-to-file system. For example, Genentech would oppose amendments to section 101 of title 35, which are unnecessary to give effect to a first-inventor-to-file system. Genentech also encourages the Subcommittee to further evaluate all of the changes being proposed to ensure that the most efficient path is taken to implementing these reforms. Changes that are not necessary to give effect to the new standard should be avoided, particularly when they may disrupt long-established concepts and definitions.

Post-Grant Opposition Procedures

As we have previously testified before this Subcommittee, Genentech strongly supports legislation that would create a cost-effective, vigorous and fair procedure to review the validity of issued patents. Our experiences teach us that claims of infringement of invalid patents are increasing, and have the potential for causing significant, unwarranted business disruptions. A cost-effective procedure that allows for robust participation by third parties yet is appropriately limited to avoid prejudice and the problems of litigation before a Federal court, would provide immense value for patent owners and the public alike. Genentech thus supports the effort of the Subcommittee to establish an effective and efficient post-grant opposition procedure, and to revise the *inter partes* reexamination authority to make that system viable.

As Congress begins its deliberations on section 9 of the Committee Print, it should keep certain fundamental principles in mind. First, there is no right of a member of the public to retain and enforce an invalid patent. It also is not appropriate to permit entities to use the high cost and complexity of patent litigation to forestall discovery of the invalidity of a patent. Invalid patents impose an immense and unjustified cost on American businesses, including companies in the biotechnology industry.

Second, we believe a properly designed system must incorporate safeguards to ensure that it will not be abused by third parties. As noted in our prior testimony, the devil is in the details. The challenge is for Congress to create a procedure that provides a rigorous and balanced inquiry into the validity of a patent, and to make that procedure feasible for the PTO to administer. A system that permits a third party to paralyze a patent by initiating an open-ended administrative proceeding would seriously undermine the incentives and purpose of our patent system. Likewise, a proceeding that becomes comparable in complexity, burden and cost to litigation in the Federal courts would yield no benefits.

Finally, a patent review system administered by the PTO must remain focused on those issues that the PTO has special expertise in evaluating, and work within the practical constraints of an administrative proceeding that is designed to be efficient but thorough. In particular, the system should avoid having the PTO evaluate questions of compliance with the "best mode" requirement of 35 U.S.C. §112, or compliance with the duty of disclosure under 37 CFR §1.56. The system should also build on the recognition that the PTO can bring a special technical expertise to independently evaluate scientific and technical questions that bear on patentability. At the same time, the PTO is not well-equipped to manage contentious proceedings that will turn on critical evidentiary questions. As such, we encourage the Congress to incorporate safeguards that take account of these limitations, and to not create a system that the PTO is incapable of effectively managing, or which leads to unjustified costs.

It is appropriate for this Congress to take up the task of devising and implementing an effective post-grant opposition system. Options that exist today ? so-called *ex parte* and *inter partes* reexamination ?do not present a viable alternative to litigation in the Federal courts, primarily because these procedures do not provide third parties with a fair and balanced degree of participation relative to patent owners. The fact that only a handful of patents have been the subject of *inter partes* reexamination proceedings, despite the existence of thousands of eligible patents, is a telling indication of the problems with the current system. The absence of a fair and efficient administrative procedure to review patent validity makes it possible for owners of invalid patents to use the often enormous expense of patent litigation to effectively shield invalid patents from challenge. An improperly granted

patent that cannot be reviewed in a cost-effective manner creates unjustified burdens and risks for American companies, including those in the biotechnology industry.

Genentech believes that the availability of an appropriately structured post-grant review system will enhance public confidence in the patent system, and provide the public with a much needed administrative alternative for resolving questions of patent validity. The recent reports from the Federal Trade Commission (FTC) and the National Academies of Science (NAS) reinforce this conclusion. Each organization recognizes that the PTO has a special expertise in evaluating certain patentability issues, such as anticipation, nonobviousness, enablement, written description and utility and that an administrative patent validity review proceeding can be conducted more rapidly than litigation in a Federal court. They correctly find that the public would significantly benefit from the availability of a procedure that does not present the burden, duration and associated expenses of patent litigation. These organizations also appreciate that any new system should not permit third parties to harass patent owners, or initiate groundless attacks on patents.

Past Congressional efforts to establish a procedure by which the PTO can review the validity of an issued patent have been well-intentioned, but have not produced a procedure that is viable. The first such system adopted by Congress was the "*ex parte*" reexamination system, enacted in 1982. In the *ex parte* reexamination system, any person, including the patent owner, may commence a reexamination of any issued patent on the basis of a patent or a printed publication that raises a substantial new question of patentability. See, 35 U.S.C. §302. The *ex parte* reexamination procedure, like original examination, is a closed procedure ? only the patent owner and the PTO participate substantively in the proceeding. As a result, most third parties avoid use of this procedure for commercially significant patents, since it does not afford those third parties a meaningful opportunity to participate in the proceeding.

In 1999, Congress created an enhanced version of reexamination, termed "*inter partes*" reexamination. The *inter partes* reexamination procedure does provide more of an opportunity for third parties to participate in the proceeding. However, due to the limitations built into the system, this "enhanced" version of reexamination has fallen short of expectations. The limited number of *inter partes* reexamination requests that have been commenced ?despite the fact that hundreds of thousands of otherwise eligible patents have issued since enactment of the legislation ?suggests that the design of this procedure will continue to limit its use by the members of the public. The most significant deficiencies of the *inter partes* reexamination system can be summarized as follows.

- It is not possible to use the procedure to review patentability issues that are most commonly encountered in biotechnology patents and applications; namely, compliance with 35 U.S.C. §§101, and 112, first paragraph. It has been our experience that issues of compliance with the written description and enablement provisions of 35 U.S.C. §112, first paragraph, and the utility requirement of §101, frequently are significant inquiries affecting the validity of many

biotechnology patents and patent applications. Not permitting these grounds to be raised in a post-grant review procedure renders the system far inferior as an alternative to litigation in a Federal court.

- The law imposes two distinct "statutory estoppels" that in combination make the procedure unattractive as an alternative to litigation in a Federal court. The first, found in 35 U.S.C. §315(c), prohibits a requestor from raising in a Federal court *any* issues of validity that "could have been raised" at the time of the request for reexamination in view of art known to the requestor. This broad estoppel attaches by the mere filing of a *request* for *inter partes* reexamination. The second "estoppel" is found in an uncodified section of the AIPA (§4607 of the Intellectual Property and Communications Omnibus Reform Act of 1999, as enacted by §1000(a)(9) of Public Law 106?113), and is designed to prohibit a third party who participates in a reexamination proceeding from later contesting the legitimacy of any "facts" determined in the proceeding. These statutory estoppel provisions impose an unacceptable price on use of the *inter partes* reexamination procedure in almost all situations.

- The *inter partes* reexamination system does not permit third parties to use certain evidentiary procedures that would ensure that the procedure is sufficiently rigorous. For example, it is not possible to cross-examine expert witnesses used in the proceeding or direct questions to the opposing party.

- Finally, the system cannot be used to review issues of validity involving patents issued on applications filed before November 29, 1999. We note that this limitation, in particular, has rendered the system of marginal value to many companies in the biotechnology industry, in part because there still remain a

significant number of biotechnology patent applications pending before the PTO that were filed before this date.

These limitations in the *inter partes* reexamination system have made the procedure of marginal value to the public. It simply is not an effective alternative to expensive, unpredictable and protracted litigation in the Federal courts.

Genentech thus encourages the Congress to pass legislation now to create a viable, cost-effective, and fairly balanced post-grant administrative patent review procedure. The approach set forth in section nine of the Committee is a good starting point, but several important variables need to be revised to make that system acceptable.

- Threshold Showing to Initiate Procedure ? Genentech believes that an opposition system should require any party wishing to commence a proceeding to provide a cogent and well-supported showing that at least one claim in the patent is invalid, and require the PTO to make an independent determination that the showing meets a threshold level of question as to the validity of one or more claims in the patent. If the initial showing is not sufficient, the Office should not commence the proceeding. Genentech is flexible as to the specific standard employed to make this assessment. One possible standard is that the claim is "prima facie" invalid ? meaning that, assuming the cited evidence is accepted as true, the claim would be invalid. Other standards could be employed as an alternative to the *prima facie* standard. The approach taken in the legislation, however, is not viable. It would permit an opposer to commence an opposition upon any showing. The burden would then fall to the patent owner to prove that the opposition proceeding is groundless. Genentech believes this "initial proof" requirement is an important part of any post-grant review procedure that could result in invalidation of one or more claims of a patent. Without this initial determination, patent owners could be subjected to groundless challenges to their patents.

- Estoppel. Participation in a post-grant

review system must not create any barrier for the participants to litigate patent validity on issues that were not actually raised and addressed in the post-grant review proceeding before the PTO. While Genentech believes Congress should not include express estoppel provisions in the post-grant review legislation, if included, those provisions should not be comparable to the codified and uncodified estoppel provisions applicable to *inter partes* reexamination proceedings. Instead, they should apply only to those issues actually addressed in the opposition proceeding, and which were necessary to the final determination of the Office.

- Time Limits to Initiate and Conclude Proceeding. A third party should be allowed to initiate a post-grant review proceeding provided it has made an appropriate preliminary showing only within a fixed period following issuance of the patent. In our view, the optimal period is nine months. Genentech believes a limited authority to commence an opposition proceeding if the patent owner consents may also merit consideration, if sufficient safeguards against "coerced" consent can be devised. To be viable, the post-grant proceeding must be concluded within a reasonable period, namely, 12 to 18 months. The legislation should confirm that this deadline will be respected by the PTO.

- Applicable to Any Patent that Can Be Enforced. The system should permit review of any patent that is capable of being enforced, subject to the threshold showings and limitations noted above.

- Limited Additional Evidentiary Procedures. Genentech believes a viable post-grant review procedure should permit use of evidentiary procedures that will provide a more rigorous review of issues pertinent to the validity of a patent than are permitted under the current *inter partes* reexamination authority. At the

same time, we recognize that if all the evidentiary procedures available in litigation before a Federal Court were allowed to be used in a post-grant review procedure, no benefits would be realized from using the PTO-based procedure. As a result, Genentech believes it would be appropriate to make available only certain limited additional procedures in a post-grant review procedure; namely, the right to cross-examine a witness who offers testimony in the proceeding, and, if the presiding authority finds it appropriate, limited requests for admissions and an opportunity for an oral hearing. Other measures, however, should be expressly prohibited in the law. In particular, parties to a post-grant proceeding should not be subject to document production, or forced to produce fact witnesses for depositions. Such restrictions are appropriate and will not undermine the effectiveness of the procedure. Proposed section 328 should thus be amended to foreclose discovery other than those types enumerated above.

- Prohibit inequitable conduct challenges based on actions of parties during post-grant proceedings. The inequitable conduct doctrine operates to ensure that patent applicants during *ex parte* examination of their applications are held to a higher standard of dealing with the PTO. A party that does not meet his or her duty of disclosure to the Office can cause that party's patent to be held unenforceable. The reason for this enhanced duty of disclosure is that the *ex parte* examination procedure is closed and the public cannot participate. Unlike *ex parte* examination, however, post-grant review procedures being proposed in section 9 of the Committee Print would be public and would include the active participation of one or more parties opposed to the patent owner. These factors eliminate the need for any enhanced disclosure standards comparable those imposed during original examination. Moreover, there is no comparable sanction that can be imposed

on third parties in such a proceeding (i.e., those parties will be free to litigate infringement, enforcement and invalidity in the future largely unfettered by their participation in the proceeding). In view of this, Genentech believes the legislation should impose identical obligations and responsibilities on parties to an opposition proceeding. This means, in part, that the legislation should include a provision which holds that a patent may not be held unenforceable due to those events that arise during the opposition proceeding. Such a provision should also confirm that if the PTO finds that one party has made a misrepresentation, it should have the authority to take actions to sanction that party appropriately. Where such misrepresentations are discovered after the patent emerges from the proceeding, courts may give due consideration to the actions of the party, but should not be allowed to hold the patent unenforceable.

Genentech stands ready to work with the Committee to improve section 9 of the Committee Print to create a well-structured and effective post-grant opposition procedure.

Conclusion

Genentech thanks the subcommittee for the opportunity to present its views on the topic of patent reform. As a significant user of the patent system, Genentech believes it is desirable to pursue legislative reform to improve this critically important system. We encourage Congress to work with all sectors of the patent community to ensure that the best package of reforms can be pursued and enacted into law.

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