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Committee on the Judiciary
United States House of Representatives
On
H.R. 1908, "The Patent Reform Act of 2007"
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Mr. Chairman, Congressman Smith and Members of the Subcommittee, thank you for the opportunity to testify today. My name is Kevin Sharer and I am CEO and Chairman of the Board of Amgen, one of the world's leading health care biotechnology companies. We are headquartered in Thousand Oaks, California, operate in more than 30 countries world wide and have more than 20,000 employees.

Amgen's mission is to serve patients. As the world's leading biotechnology company, we use scientific discovery, research and innovation to produce medicines that dramatically improve people's lives. For more than 25 years, the company has harnessed the powerful tools of cellular and molecular biology and medicinal chemistry to discover, develop, and commercialize proteins, antibodies, and small molecules that can extend the reach of medicine. Started as a small business with assistance from the US Small Business Administration (SBA), Amgen was inducted into the SBA Hall of Fame in 2005.[1] We are one of over 1,500 biotechnology companies in the United States.[2]

Originally founded in 1980, Amgen pioneered the development of novel and innovative products based on advances in recombinant DNA and molecular biology. More than a decade ago, Amgen introduced two of the first biologically derived human therapeutics, EPOGEN® (epoetin alfa) and NEUPOGEN® (filgrastim), which became the biotechnology industry's first blockbuster products and provided treatment for hundreds of thousands of patients suffering from conditions of anemia related to chronic kidney disease and neutropenia caused by chemotherapy.

Today, Amgen is a Fortune 500 company whose business has expanded to serve patients around the world in the treatment of anemia, rheumatoid arthritis, supportive cancer care, new therapies for cancer and other life- threatening and debilitating diseases such as psoriatic arthritis and ankylosing spondylitis[3]. The ability to invent, develop and market these medical breakthroughs

[1] "Four Exemplary Businesses Inducted into the SBA's Hall of Fame", United States Small Business Administration press release, April 27, 2005 (accessed 7/22/05 at http://www.smallbusinessnotes.com/fedgovernment/sba/sbanews/sbanews042705d.html)
[2] Biotechnology Industry Facts (accessed 7/22/05 at http://www.bio.org/speeches/pubs/er/statistics.asp)
[3] Ankylosing spondylitis (pronounced ank-kih-low-sing spon-dill-eye-tiss), or AS, is a form of arthritis that primarily affects the spine, although other joints can become involved. It causes inflammation of the spinal joints (vertebrae) that can lead to severe, chronic pain and discomfort. In the most advanced cases (but not in all cases), this inflammation can lead to new bone formation on the spine, causing the spine to fuse in a fixed, immobile

was made possible by the promise of strong patent protection and an effective patent enforcement system.

Biotechnology is revolutionizing the war against disease and boosting the American economy – but this revolution depends upon strong and reliable patent protection.

Saving Lives
Biotechnology is saving lives and holds the promise of breakthrough solutions for many devastating diseases and conditions for which there is currently inadequate treatment or no treatment. Enormous investments in biotech have made possible the industry's medical breakthroughs, including

- new cancer drugs that take specific aim at tumor cells,
- "clot-buster" drugs that dissolve clots that cause heart attacks and strokes, dramatically reducing disability and death from these health episodes,
- a drug that can help inhibit the progression of joint damage and dramatically improve the health and well-being of patients suffering from rheumatoid arthritis and juvenile rheumatoid arthritis, and
- products that stimulate red and white blood cell production and reduce disability and death from anemia and infection associated with chemotherapy and kidney disease.

Over 325 million people worldwide have been helped by the more than 155 biotechnology drugs and vaccines available today.[4]

Benefiting the Economy.
The biotech medicines industry is also a major economic and job-producing asset for the US at a time when concern about losing jobs to low-wage countries is growing.

- Medical biotechnology companies directly employed more than 400,000 Americans in 2003. Jobs in this sector tend to be skilled positions that pay more than $25,000 per year above the average wage.
- For every job in a biotechnology company, on average, 5.7 additional jobs are created in other businesses that support the industry and the daily needs of their employees. and families. This multiplier is substantially above the average for all industries.
- In 2003, the industry was responsible for 2.1 percent of total employment in the nation.
- The medical biotechnology sector is among the most productive of the U.S. economy. It was directly responsible for $63.9 billion in real output in 2003.

Biotechnology innovation contributes significantly to improve the health and welfare of the world. However, strong patent protection and a rational, predictable, and efficient patent system are essential to continued biotechnology innovation.

Biotechnology is Uniquely Sensitive to Changes in Patent Law.
Innovation in biotechnology, more than any other industry, depends upon strong patent protection. Discovering and producing safe and effective biologics is uniquely difficult, uncertain, and expensive. Developing biologic drugs requires extensive technical expertise and

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position, sometimes creating a forward-stooped posture. Spondylitis Association of America website (accessed 7/22/05 at http://www.spondylitis.org/about/as.aspx)
[4]EuropaBio, "Comments on WHO Priority Medicines Project," September 15, 2004 (accessed 10/25/04 at http://www.europabio.org/positions/WHOPriorityMedicines.pdf)

financial resources. Overall, the cost of drug development is approximately $800 million to $1.2 billion per successful drug.[5] Biotech products can take a very long time – for some products 12 to 15 years – to move from the laboratory to patients.[6] The vast majority of potential products fail. From pre-clinical discovery to FDA approval, biotech has a 10 to 30% success rate.[7] Manufacturing is very complex and expensive. It takes approximately 5 years and $1 billion to build a factory to produce biotech medicines - this time and money must be invested before the company knows if the product works, whether it will be approved by the FDA, or what the size of the market will be. Only three of ten marketed drugs produce revenues that match or exceed average R&D costs.[8]

Investors take significant financial risk to fund the research and development of these life-saving treatments and they rely on laws protecting patents to recover their investment if the product is approved for market. It is impossible to tell prior to making significant R&D investment which of the thousands of promising ideas will become a successful future treatment or cure. Once such success occurs, that product must then fund R&D to create new drugs and therapies that will reduce human suffering, improve quality of life, and save lives.

Without sufficient incentives to invest in life-saving R&D, we will have:

- Fewer cures and treatments discovered,
- Fewer promising discoveries making it to market,
- Slower access to cures and treatments by patients,
- Less product choice for patients, and
- Fewer jobs in the biotech and other sectors and therefore a less vibrant economy.

Patent Reform Must Support Innovation

Innovation is good for society; it is the single biggest factor determining the rate at which a society improves its ability to deliver longer, healthier, more comfortable lives to its citizens. US IP today is worth between $5 trillion and $5.5 trillion. This is the equivalent of 45% of US GDP and greater than the GDP of any other nation in the world.[9]

An effective patent system encourages innovation by providing economic incentives to invest in innovation and to take the risks needed to do the research and development to bring new and meaningful products to the market. To be effective in this regard, the patent system must have the public's confidence that patents of appropriate scope can be obtained and enforced to provide exclusive rights to inventions. A strong patent system that is transparent, reliable, predictable and enforced will foster public confidence and capital investment. Biotech, more so than other high tech sectors, needs access to huge levels of venture capital. Biotechnology companies and their investors rely on a patent system that, although not perfect, has developed some consistency

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[5] Boston Consulting Group, "A Revolution in R&D – the impact of genomics," *BCG Focus*, June 2001.

[6] Biotechnology Industry Organization, "Biotechnology Industry Facts" (accessed 10/25/04 at http://www.bio.org/speeches/pubs/er/statistics.asp); Joseph A. DiMasi, "The Price of Innovation: New Estimates of Drug Development Costs," Journal of Health Economics, Volume 22, Issue 2, March 2003, Pages 151-185 (accessed 10/25/04 at http://www.cptech.org/ip/health/econ/dimasi2003.pdf)

[7] Milken Institute, "Biotechnology Valuations for the 21st Century," April 2002 (accessed 10/25/04 at http://www.dist.maricopa.edu/bwd/biotechpb.pdf)

[8] Pharmaceutical Research and Manufacturers of America, "Why Do Prescription Drugs Cost So Much and Other Questions About Your Medicines" (accessed 10/25/04 at http://www.phrma.org/publications/publications/brochure/questions/questions.pdf)

[9] "The Economic Value of Intellectual Property" by Robert Shapiro and Kevin Hassett, October 2005, p. 3.

in its approach to patenting biotech inventions and a measure of efficiency and certainty concerning the enforcement of those patents in the courts.

Amgen urges the Congress to carefully consider the impact each proposed patent reform change would have on the current patent system before altering what is widely considered to be the most effective patent system in the world. Congress's first commitment must be to enact measures that advance the public good. A central component to securing this goal is to do no harm to innovative and economically productive industries, like biotechnology, that are effectively served by the current patent laws. It is these risk taking entities that produce beneficial new products and advance the human condition. Where the system is not broken, it should not be changed.

We recognize that the software, financial services industries and others have identified legitimate problems with the way the system impacts business activities *in those sectors*. We appreciate the tireless efforts made by Chairman Berman and Conyers as well as Congressman Smith, Sensenbrenner, Issa and this entire subcommittee to proceed cautiously and attempt to secure consensus before embracing wholesale change.

Some Parts of Patent Reform Will Deter Innovation

While we commend some aspects of the recently introduced bill (H.R. 1908), [see, pages 8 and 9, infra, commenting on several important measures that Amgen supports that are contained in the bill] this testimony will focus, initially, on the parts of the legislation that concern us.

Two aspects of patent reform embodied in the companion bills introduced in the House (HR 1908) and Senate (S 1145) have the potential to undermine the value of patents and therefore hinder innovation in biotechnology and other resource-intensive industries. The first is the proposal to establish a so-called post-grant opposition procedure that provides an additional administrative procedure in the PTO through which patents can be challenged throughout the life of a patent. This proposal is based on a concern with patent quality and the desire to provide a more efficient path to challenge bad patents. While we agree that there are some bad patents that have issued, overall we believe that in general the PTO does a good job of examining and issuing patents given its ever-increasing workload. We believe that creating a post-grant opposition procedure will do little to address these intended objectives, and we have concerns that it could become a vehicle to harass legitimate patent owners and make it difficult for them to enforce their patents. The "second window" in the pending legislation allows patents to be challenged repeatedly in the PTO throughout the life of the patent, resulting in more uncertainty-- not less -- and more litigation. Amgen urges Congress to follow the National Academy of Science recommendations and provide one single 9-month window for a post-grant system.

The second problematic proposal relates to the remedies available to redress the injury caused by patent infringement. The fundamental right bestowed by a patent is the patent owner's right to exclude others from practicing the invention. Without this right, and without fair compensation for trespass upon this right, patents would have little value. As a result of the recent Supreme Court decision in the E-Bay case [10], for some patent owners, obtaining an injunction after a patent is found to be valid and infringed is no longer certain. Coupled with that, the current legislation could make it difficult for a patent owner to effectively recover damages for patent infringement. Would-be patent infringers have little to deter them if all they have to do is pay a

[10] eBay Inc. v. MercExchange L.L.C., 126 S. Ct. 1837 (US 2006)

small amount for the use of someone else's invention without permission and without fear of an injunction to stop them. Where there is insufficient protection for intellectual property rights, innovation and innovation-based industries could suffer because there would be insufficient reward for the risk-taking needed to innovate. Amgen opposes these proposed changes in the calculation of damages (as currently drafted) and urges the Congress to embrace alternative reform proposals, as outlined below, for improving patent quality and encouraging innovation.[11]

Post-Grant Opposition

We recognize that many observers of the patent system have concerns about the quality of issued patents in the United States.[12] Many have suggested that a post-grant opposition system would provide a quick and less expensive solution to this problem. Respectfully, we disagree. Our experience with post-grant opposition procedures in other countries has shown that they are neither quick nor inexpensive and that they can become a useful tool for infringers to prevent patent owners from being able to enforce their rights in a timely manner. Also, if a similar percentage of patents are challenged in the US as are challenged in Europe, it could overwhelm the already strained resources of the PTO. [13] Biotechnology patent applicants already have to wait too long to get their applications examined and patents issued in the US, and a post-grant system would only make the situation worse, as well as lead to other serious policy problems as outlined below.

Proposals to establish a "post-grant opposition" procedure available throughout the life of a patent could decrease the efficiency of the patent system, increase the cost of patent prosecution and validity challenges, and add uncertainty to the patent system that could deter investment in innovation. Post-grant opposition is proposed as an additional administrative procedure for reviewing patent validity without court involvement. Under the new proposal, the validity of a patent could be challenged in the Patent and Trademark Office (PTO) through post-grant opposition within twelve months after the patent was issued (a "first window"), or anytime thereafter (the "second window") if the petitioner establishes that the patent causes or is likely to cause to the petitioner "significant economic harm," if the challenger has received a notice of infringement, or any time at the consent of the patent holder.

We are skeptical that implementation of post-grant opposition to challenge a patent can achieve the objectives of increasing quality and efficiency in the patent system and reducing litigation costs. The system already provides a mechanism (*i.e.*, reexamination) for interested parties to challenge patents after issuance by the PTO. Alleged infringers can also challenge the scope and

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[11] We believe that apportion of damages discourages innovation. However, a less onerous approach, should Congress chose to address this issue, is to focus on the value of the invention to the infringing product rather than the value of the invention over the prior art. In most cases, the result should be similar, but this approach is more consistent with how a fact-finder would approach the evidence and the damages issue after considering the inventive features of the claim.

[12] As the National Academy of Sciences noted in its 2004 report: "[n]ow is an opportune time e to examine the system's performance and consider how it can continue to reinvent itself." *A Patent System for the 21st Century*, National Academy of Sciences (2004), Executive Summary, p. 3.

[13] In 2003, 5% of all issued European patents were opposed, which translates to an actual number of 2634 oppositions filed. In 2003, the USPTO granted 173,072 patents. Taking the percentage of oppositions from Europe as indicative, this means that 13,845 oppositions would have been filed in the US in 2003 – a massive administrative burden by any standard. Performance and Accountability Report FY 2003, United States Patent and Trademark Office, available at www.uspto.gov.

validity of issued patents in litigation. The proposed post-grant system provides another mechanism that patent challengers can use. We submit that the patent system does not need three different ways to challenge issued patents. Because the pending legislation would allow oppositions to be filed throughout the term of the patent, it would be all but impossible to obtain "quiet title" to the patent.

For these reasons, we recommend that Congress proceed cautiously with regard to post-grant opposition. We believe a consensus could be reached to create a pilot program prior to wholesale implementation of a post-grant proposal, in order to be confident that the PTO can handle the additional workload and that the new mechanism will increase patent quality as intended. A pilot project could also assess the impact on any particular sector or set of industries. At the very least, we would urge members of this subcommittee to adopt the NAS recommendation and establish a post-grant system with a single window of limited duration (as Europe).

We oppose adopting a so called "second window" for challenging patents in a post-grant opposition system which would make this administrative mechanism available throughout the life of the patent. The "second window" would be inefficient and would undermine innovation in biotechnology and other resource-intensive sectors. Permitting patent validity to be challenged in the USPTO upon notice of infringement would require validity to be analyzed twice – once in the PTO and again in court when infringement is considered. Since these determinations are largely based on the same set of detailed and technical facts, this split would require two different judicial or quasi-judicial bodies to examine the same facts, significantly increasing the resources that both the patent holder and the alleged infringer must invest as a result of presenting the case twice, in two different forums.

The second window also negates what advocates argue is the merit of post-grant opposition, namely that it enables patent holders, challengers, and investors to learn at the beginning of the patent term the scope and validity of the patent. Infringers would have incentive to wait until threatened with a notice of infringement before bringing an opposition before the PTO, thus making the first window less effective in enhancing patent quality and certainty as claimed by supporters. Furthermore, allowing post-grant opposition challenges throughout the life of the patent would delay a patent owner's ability to enforce its patent, because the infringement suit could be postponed by the court until the opposition is completed and a decision is issued. This would significantly increase uncertainty for patent holders and investors, and therefore discourage investment in industries that rely upon strong patent protection. Finally, the second window would dramatically increase the number of oppositions likely to be presented to the PTO for consideration, before it is clear whether the post-grant opposition process is effective or efficient, thus excessively burdening the PTO without any evidence that the quality of the patent system will be improved.

Rather than implementing a new post-grant opposition system, it would be preferable to eliminate the current inequities in the *inter partes* reexamination system. In the PTO's report to Congress there are specific recommendations on how the existing *inter partes* reexamination system can be made more effective.[14]

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14 United States Patent And Trademark Office Report To Congress on *Inter Partes* Reexamination Report available through the USPTO web-site at: http://www.uspto.gov/web/offices/dcom/olia/reports/reexam_report.htm

Any new post-grant opposition system should have a single 9-month window and be accompanied by fundamental reform of the inequitable conduct defense and elimination of the best mode requirement. Although both are based on sound principles, they have spawned excessive litigation and other unintended consequences for the patent system and its participants. As detailed in the recommendations below, best mode is an outdated requirement that does not accommodate the rapid pace of innovation today. Similarly, the doctrine of inequitable conduct has done more damage to the patent system than good.

In the event that Congress chooses to adopt a post-grant opposition procedure, it is essential that the threshold for invalidating a patent in court – clear and convincing evidence – be applied in the PTO proceeding as well. It is impractical to apply two different standards ("preponderance of the evidence" in post-grant, "clear and convincing evidence" in court) to the same question of patent validity; such an arrangement would almost certainly raise more questions than it answers and result in absurd outcomes.

It is appropriate to require a challenger in post-grant opposition to demonstrate by a standard of clear and convincing evidence that a patent is invalid. Other administrative procedures within the PTO that apply the preponderance of the evidence standard are effectively an extension of the examination process and allow extensive revision of claims. A post-grant opposition proceeding as proposed in HR 1908 and S 1145 would be an adversarial adjudication process with only a single opportunity to amend a claim guaranteed. A clear and convincing standard would prevent abuse of the opposition process and allow the significant property right of a patent to be invalidated only when the facts clearly establish that it was issued in error. Applying the appropriate evidentiary standard will also reduce the expense of such a new and untested program.

Other safeguards would be necessary for ensuring that the patent system continues to foster innovation. Most important, the number of post-grant procedures should be limited, and challengers who pursue an opposition should be prohibited from later disputing the patent's validity in court, in order to prevent harassment of patent holders by bringing redundant claims of invalidity. The real party in interest must be identified in order for the patent holder to effectively defend the patent. Oppositions should only be permitted by the PTO when the challenger has established a substantial question of patentability. The patent owner must be allowed to amend the challenged claims. An opposition must not be a barrier to enforcing a patent; the law should explicitly state that a post-grant proceeding does not prevent a patent owner from obtaining a preliminary injunction (so a court may <u>not</u> stay infringement litigation pending the outcome of a post-grant challenge).

<u>Damages for Infringement</u>

Under current law, a patent infringer must compensate the patent holder for the infringement by putting them in the position they would have been in, but for the infringement. Depending on the circumstances, the patent owner can seek to recover lost profits or a reasonable royalty, which is the minimum amount of damages allowed under current law. Presently, the law provides for consideration of a number of factors, some of which may be more or less important based on the facts of the case, and judges or juries have some flexibility in determining what constitutes a reasonable royalty (when lost profits cannot be shown). Most courts rely on the *Georgia Pacific* case, which sets forth 15 factors to be considered in determining a reasonable

royalty.[15] In the vast majority of cases, these legal principles lead to an appropriate damage award.

If enacted, the proposed legislation would make it harder for patent owners to be properly compensated for patent infringement and would cause greater uncertainty in litigation. The proposal is intended to apply a reasonable royalty "only to that economic value properly attributable to the patentee's specific improvement over the prior art" in an attempt to apportion the value of the infringing article between the patented features, the prior art and "other features." However, the language is quite confusing, and courts (and juries) will struggle with how to apply the proposed language to first determine and then subtract out the economic value of the prior art and the other features, and to come to a fair damage award. The proposed language goes even further, and disallows a royalty to be applied to the entire market value of the infringing product unless the patent owner proves that the "patent's specific improvement … is the predominant basis for market demand" for the product. We believe that the net effect of these provisions is to make it cheaper and easier to infringe a patent. In short, it discourages innovation and encourages copying.

We believe that the concerns of some from the software industry and other sectors can be addressed with discrete changes. For example, requiring allegations of infringement to be stated with specificity will prevent the blanketing of an industry with infringement letters, a legitimate concern expressed by the information technology industry. Congress could also permit a court to find a patent unenforceable if the owner is found to have alleged infringement without merit more than a specified number of times. This will encourage patent holders to more carefully evaluate possible infringement claims prior to making allegations.

Patent Reform Recommendations

Amgen supports patent reforms that will foster a stronger and more certain patent system. We support a number of measures within the Berman-Smith-Leahy-Hatch bill, as well as other proposals.

HR 1908 / S 1145 Proposals Amgen Supports

1. ***Permit assignee filing of patents.***
   The process of filing a patent application can and should be simplified and streamlined by permitting an assignee to file. Currently, inventors are required to file a declaration of assignment with the patent office before the assignee – typically the employer of the inventor – may sign the declaration in a patent application. Allowing the assignee to sign the application without requiring the inventor to submit additional paperwork will simplify the filing of patent applications by assignee companies. The assignee would be required to identify the actual inventor and certify that the assignee believes the inventor to be the true and original inventor. Other countries have adopted this practice and it has worked well.

[15] Georgia-Pacific Corp v US Plywood Corp, 318 F Supp. 1116 (SDNY 1970)

2. ***Eliminate the exception to the requirement that all patent applications be published within 18 months of filing.***
Publication of patent applications is an important means of facilitating the dissemination of information and should be applied uniformly to all patent applications. Patent applications submitted around the world are made public 18 months after filing. However, in the United States there is an exception to this publication requirement if a patent applicant certifies that the applicant does not intend to file the application in any other country and has not already filed in another country. This exception defeats one of the important objectives of the patent system -- increasing information in the public domain -- without providing any significant public benefit. Elimination of this exception will more effectively achieve the objectives of the patent system and help to harmonize patent laws around the world. Further, adoption of 18-month publication of *all* applications will eliminate any remaining potential for submarine patents (the practice of keeping the existence of a pending patent secret until after the technology develops in the market).

3. ***Adopt the "first inventor to file" standard***.
In every country except the United States, patents are awarded to the first to file a patent application. In the United States, under current law, a patent may be awarded only to the first to invent the product or process or use covered by the patent. Relying on invention date creates a significant level of uncertainty for the patent holder because it is only after litigation and discovery that the patent holder can be certain the references used to determine the invention date are reliable and that the patent holder is therefore the first inventor under the law. In contrast, a first to file system allows for a greater level of certainty because the filing date is easily established. The international community has long urged the United States to adopt the international standard for purposes of regulatory harmonization. The concerns of small inventors that their patent rights will be lost, for instance by the person who hurries to the patent office after stealing the inventor's work, would be addressed by specifying that it is the first "inventor" to file, not just the first to file, that will be granted the patent.

<u>Proposals Recommended by Amgen but Not Addressed in or Different from HR 1908 / S 1145</u>

4. ***End patent fee diversion.***
Adequate funding for the USPTO must be the foundation for any other patent reform efforts. It is widely recognized that the USPTO lacks sufficient funds to hire, train and retain skilled examiners who can consistently make high-quality determinations as to whether patent applications deserve to be granted. The USPTO has been funded exclusively by user fees for over ten years. A significant portion of the user fees collected by the USPTO is diverted to other government uses. In the past decade, $650 million dollars -- approximately ten percent of all the user fees paid to the USPTO -- have been diverted. Ending fee diversion is an important step in securing adequate funding for the USPTO.

5. ***Change the willful infringement doctrine to permit punitive damages only for egregious offenses, including theft and deliberate copying.***
Making, using, selling, or offering to sell patented material without the permission of the patent owner is considered patent infringement. If the infringement is found to be "willful," the court may sanction the offender by awarding up to three

times the amount of damages.[16] This doctrine was intended to deter patent infringers, but in most cases all that infringers have to do is have an opinion of counsel that the patent is either invalid or not infringed, in order to avoid a finding of willfulness. Since this does not deter infringers, the doctrine has seemingly ceased to serve its purpose. The law on willful infringement has forced companies to take one of two approaches: either 1) seek opinions of outside attorneys on every third party patent that poses a threat, even if you believe that you do not infringe, or 2) avoid reading competitors' patents, even for the purpose of determining what patents the applicant might be infringing, in order to avoid being found "willful." [17] The first approach imposes significant financial burdens on companies, and the second approach is contrary to the purpose of the patent system, which is to disseminate information on new technology and thereby foster innovation.[18]

The law on willful infringement should be changed to allow punitive damages only in the most egregious cases, such as where there has been deliberate copying or continued infringing activity after a judicial determination of infringement and validity.

6. Eliminate the doctrine of inequitable conduct, or at least reform it by prohibiting the pleading of inequitable conduct unless one or more patent claims is declared invalid by court, and adopt a "but for" nexus between the invalidity of a claim and the alleged wrongful conduct.

As discussed above, we believe that the doctrine of inequitable conduct has ceased to serve a useful purpose in our patent system and should be eliminated. Originally, the doctrine was intended to ensure that patent applicants complied with their duty of disclosure to the PTO, because examination of patent applications was conducted in secret. Today, however, patent applications are no longer secret as the applications are published, the examination record and status can be viewed online, and interested parties can submit information to the PTO. When a patent is litigated, the most innocent statements, or failures to disclose the smallest thing, can become the bases for charges of inequitable conduct. In one recent case, for example, a patent was held to be unenforceable because several experts who submitted declarations in support of the patent application did not disclose that they had performed prior work for the patent owner, and as a result, their declarations could have been viewed as not impartial. Inequitable conduct is the defense of choice for patent infringers who scour the prosecution record of the patent and the patentee's files to find any hint of inconsistency. The threat of inequitable conduct has stymied open communication with the PTO.

The PTO can manage those who practice before it, as does a court, to ensure compliance with the duty of disclosure. At a minimum, the legal standard for inequitable conduct

[16] 35 U.S.C. § 284; Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, A Report by the Federal Trade Commission," October 2003 at Summary page 16, Chapter 5 page 28-29.
[17] Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, A Report by the Federal Trade Commission," October 2003 at Chapter 5 page 29.
[18] Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, A Report by the Federal Trade Commission," October 2003 Chapter 5 page 29.

should be modified to more effectively target egregious behavior and reduce the threat of snaring well-intentioned disclosures in a confusing standard that carries with it the patent equivalent of the death penalty. The allegation of inequitable conduct is raised as a defense in nearly every patent litigation and has become a "cancer" on the practice of patent law. To address this, the law should be changed to allow inequitable conduct to be pled as a defense only after one or more patent claims have been determined by a court to be invalid. The standard for inequitable conduct should entail a "but-for" test: that is, but for the conduct, the PTO would not have issued the patent. The House and Senate bills fail to address this important issue, which is critical to facilitate effective communication with the PTO.

7. ***Eliminate the "best mode" requirement.***
Best mode is a subjective requirement in patent law that requires disclosure of the "best way" known to an inventor of practicing the claimed invention. Best mode is an outdated requirement that does not accommodate today's rapid pace of innovation. The inventor's opinion about the best way of making the invention may be different from the challenger's, and it may evolve over time. Whether or not the patent applicant submitted the best mode is widely litigated and requires extensive – and expensive – discovery. Because attacks on best mode are more of a threat to patents than an aid to promote disclosure, the best mode requirement should be eliminated. In ongoing patent harmonization discussions, serious consideration is being given to non-inclusion of the best mode requirement as the best approach to take worldwide. For these reasons, the best mode requirement should be eliminated in the U.S. Both the House and Senate bills fail to eliminate this requirement of patentability.

Conclusion

To preserve the integrity of the US patent system and to maintain the market incentive for R&D, any patent law reform must be aimed at encouraging innovation. Amgen supports patent law reform that encourages innovation and enhances the US patent system, in order to address the economic needs of the country in the 21st century. The PTO should be adequately funded and be given access to all the fees it collects, with the expectation that quality of examination will improve, valid patents will issue on original examination, and the length of patent application pendency will be substantially reduced.

Set forth below are the elements of a patent reform bill that could address the needs of innovators from multiple industry sectors, and which would not unnecessarily disadvantage any one particular sector:

(1) The plague of inequitable conduct defenses in patent litigation --- as they are now being used offensively in the courts ---should be fundamentally reformed.
(2) Enhanced damages for willful infringement should be awarded only where reprehensible conduct is found.
(3) The system should be streamlined and improved by eliminating antiquated relics such as (A) the best mode requirement, (B) limitations on assignee filing, (C) exceptions to 18-month publication, (D) restriction practice, and (E) interferences to determine who among competing parties was the first inventor.
(4) In the event that the Congress chooses to adopt a post-grant opposition system, we respectfully request Congress: (A) consider a sector-specific pilot program to test the program before applying it on a wider basis; (B) require the clear and convincing evidence standard to be applied in post-grant to invalidate a patent, and (C) encourage

rapid challenges to patents by providing *only one* nine-month window of opportunity to initiate an opposition immediately after the patent has been granted.