Testimony of

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Mr. Chairman, Senator Leahy and Members of the Subcommittee, Thank you for the opportunity to testify today. My name is David Beier and I am Senior Vice President for Global Government Affairs for Amgen, a health care biotechnology company. Amgen's mission is to serve patients. As the world's leading biotechnology company, we use scientific discovery and innovation to produce medicines that dramatically improve people's lives. For nearly 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 recently inducted into the SBA Hall of Fame.1 We are one of almost 1,500 biotechnology companies in the United States as of December, 2003.2 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, and other life-threatening and debilitating diseases such as psoriatic arthritis and ankylosing spondylitis3. The ability to invent, develop and market these medical breakthroughs was made possible by the promise of strong patent protection and an effective patent enforcement system.

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 position, sometimes creating a forward-stooped posture. Spondylitis Association of America website (accessed 7/22/05 at http://www.spondylitis.org/about/as.aspx)

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, ? 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 financial resources. Overall, the cost of drug development is approximately $800 million to $1.2 billion per successful drug.5 Biotech products take a very long time -12 to15 years - to move

4EuropaBio, "Comments on WHO Priority Medicines Project," September 15, 2004 (accessed 10/25/04 at http://www.europabio.org/positions/WHOPriorityMedicines.pdf) 5 Boston Consulting Group, "A Revolution in R&D - the impact of genomics," BCG Focus, June 2001.

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, and the size of the market. 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 ? 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. An effective patent system encourages innovation by providing economic incentives to innovate. To be effective in this regard, the patent system must have the public's confidence. A strong patent system that is transparent, reliable, predictable and enforced will foster public confidence and therefore investment. Biotech, more so than other high tech sectors, needs access to huge levels of venture capital. Those investors need some degree of certainty, and a vital ingredient is a predictable set of rules for obtaining patents, a measure of efficiency and certainty concerning enforcement, and the application of sound science both in the PTO and the courts. Amgen urges the committee to carefully consider the impact each proposed patent reform change would have on innovation before altering what is widely considered to be the most effective patent system in the world. Congress's first commitment must be to do no harm to industries that are effectively served by the current patent laws. Where the system is not broken, it should not be changed. We recognize that the software and financial services industries have identified legitimate problems with the way the system impacts business activities in those sectors. To those ends, we appreciate the tireless efforts made by Chairman Smith and his staff in the House to proceed cautiously and attempt to secure consensus before embracing wholesale change.

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)

Patent Reform that Will Deter Innovation Two aspects of patent reform embodied in a bill introduced in the House (HR 2795) - (e.g. the sections regarding injunctions and post grant opposition) - will undermine the value of patents and therefore hinder innovation in biotechnology and other resource-intensive industries. Perhaps most fundamental to patent rights, and therefore of grave concern to the biotechnology industry, is the proposal to limit a patent owner's ability to enforce a patent through an injunction. Equally troubling is the proposal to establish an additional administrative procedure through which patents can be challenged throughout the life of a patent. Amgen opposes these proposed reforms and urges the Congress to consult with innovative companies in a wide range of industries when considering these changes. Obtaining Injunctions The right to enforce a patent against infringement is fundamental to the value of patents. The critical remedy for patent infringement is the issuance of an injunction to prevent future infringing actions. The biotechnology industry and other resource intensive industries rely on the right to exclude others from using the patented information to recover the millions of dollars invested in research and development. However, other industries, lead by the software industry, argue that they are threatened with injunction as a means of unjustly harassing them or extorting fees from them. A number of proposals have been put forth to address this

concern through changes to injunction practice - all of which would undermine the exclusivity of patent rights as guaranteed by the Constitution and should therefore be opposed by Congress. HR 2795 would alter the standards governing permanent injunctive relief where the patent has been found to be both valid and infringed by allowing infringers to continue infringing during the pendency of an appeal. An appeal could take more than four years. Any change in injunction practice would disrupt the well-settled law governing the rights of patent owners to promptly enforce a patent and would lead to greater uncertainty and confusion in the law. Investment in high-cost ventures such as biotechnology will be unacceptably risky if patent owners cannot reliably enforce a patent in a timely manner. If enacted, this legislation would undermine one of the essential functions of a patent - the capacity to prevent the unauthorized use of the patented invention. As C. Boyden Gray, former White House Counsel from 1989 to 1993, noted in his recent article on injunction practice, It is ironic that at a time when intellectual property is assuming a critical role in generating growth and value-added jobs for the U.S. economy and the world, Congress is considering patent law changes that would, if adopted, ultimately destroy one of the crown jewels of our economy. The problem that the proposed legislation seeks to address is real, but not nearly so serious as to justify undermining the patent system, which is one of the very few building blocks of the market economy that are specifically set out in the U.S. Constitution. "Patent Reform Bill: A Troubling Proposal for the U.S. Patent Law System," BNA's Patent, Trademark, and Copyright Journal Volume 70 Number 1723 Friday, June 3, 2005 page 122. Although we appreciate the challenge faced by the software industry, it is counterproductive to hinder the ability of legitimate patent holders to enforce their patent rights. For that reason, we urge Congress to decline the proposed changes to injunction practices and work with the many interested parties to find solutions in other areas around which consensus can be built. 4
Post Grant Opposition Proposals to establish a "post-grant opposition" procedure available throughout the life of a patent would decrease the efficiency of the patent system, increase the cost of patent prosecution and validity challenges, and add uncertainty to the patent system that will deter investment in innovation. Post grant opposition is proposed as an additional administrative procedure for reviewing patent validity without court involvement. Under the House proposal, the validity of a patent could be challenged in the U.S. Patent and Trademark Office (USPTO) through post grant opposition within nine months after the patent was issued, within six months after a party received a notice of alleged infringement, or any time at the consent of the patent holder. Other proposals allow for an even wider window of opportunity to challenge a patent using post grant opposition. While we acknowledge and are sympathetic with the concerns of the NAS, FTC, commentators, and some trade groups about patent quality, 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. Experience in Europe and Japan with similar systems counsels that a post grant system is not a panacea. A variety of patent correction mechanisms are already provided by statute to permit anyone to administratively challenge the validity of a patent in the United States after it has been issued. Many U.S. patent owners have extensive experience in post-grant opposition proceedings in Europe and other jurisdictions and have found that such a procedure is less than satisfactory in both defending their own patents and in challenging third party patents. In addition to ensuring that the procedures are fair and efficient, our concerns on post-grant opposition center on the following: 1) The quasi-judicial nature, limited discovery and relatively short time frames for the USPTO's opposition panel to consider the arguments presented would make it difficult in many oppositions for the panel to understand and discern the truth. Patents in biotechnology are

valuable property rights that should not be easily tossed out. Although costly, litigation usually provides a more fulsome review of the facts and more conviction that the right result was achieved. 2) Imposing an opposition proceeding at the beginning of a patent term erects an additional hurdle to patent enforcement and could serve to shorten the effective term of a patent. Although the proposed legislation attempts to address this concern, the practicality is that a patent owner would have to convince a court to proceed with infringement litigation in the face of an opposition to the patent in the USPTO. By the time that appeals from the opposition are resolved, the patent term could be effectively shortened by four or more years. We believe that this could greatly harm biotech patent owners who may only have 5-8 years of effective patent life after FDA approval to market the drug.. 3) Establishing an opposition proceeding places an additional burden on the USPTO, which is already facing a 510,000-application backlog, and may have the actual effect of reducing overall patent quality instead of increasing it as intended. For these reasons, we recommend that Congress proceed cautiously with regard to an initial opportunity to challenge patent validity in a post grant opposition. However, we

strongly oppose adopting a so called "second window" for challenging patents in a post grant opposition system. The "second window" in post grant would be inefficient and would undermine innovation in biotechnology and other resource-intensive sectors. Proposals to create a "second window" in which patent validity can be challenged in the USPTO upon notice of infringement enable a challenger to force a patent holder into the USPTO process, in addition to court, for determinations of patent validity. This would inefficiently split into two separate forums the determination of validity and the determination of infringement. Because these determinations are largely based on the same set of detailed and technical facts, this split would require two different bodies to examine the same facts, significantly increasing the resources both patent holder and alleged infringer must invest as a result of presenting the case twice to two different forums. The second window also negates the possible merit that post grant opposition enables patent holders, challengers, and investors to learn at the beginning of the patent term the scope and validity of the patent. Challengers would have incentive to wait until threatened with a notice of infringement before bringing an opposition to the USPTO, thus making the first window less effective in enhancing patent quality and certainty. Furthermore, allowing post grant opposition challenges throughout the life of the patent would delay a patent owner's ability to enforce a patent because the infringement suit could be postponed until the opposition is completed. This would significantly increase uncertainty for patent holders and investors, and therefore discourage investment in industries that rely on strong patent protection. Finally, the second window would increase dramatically the number of oppositions likely to be presented to the USPTO for consideration, before it is clear the opposition process is effective or efficient, excessively burdening the USPTO. 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 USPTO's report to Congress there are specific recommendations on how the existing inter partes reexamination system can be made more effective.9 Fixing the current inter partes reexamination system would be more efficient than adding another administrative process. Rather than reducing bad faith challenges to good patents, implementing a post grant opposition procedure would create yet another forum in which patent holders can be harassed. This additional burden will weigh heaviest on small patent holders with limited resources. 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 USPTO proceeding as well. It is impractical to apply two different standards to the same question of patent validity; such an arrangement would almost certainly raise more questions than it answers and result in absurd outcomes. For example, it appears that under the proposal where there is a stay of the opposition pending the outcome of the enforcement litigation in HR 2795 an infringer could lose in court on the clear and convincing standard but later win in the USPTO and invalidate a patent on the preponderance of the evidence standard. 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 USPTO that apply the preponderance of the evidence standard are effectively an extension of
9 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

the examination process and allow extensive revision of claims. In contrast, a post grant opposition proceeding as proposed in HR 2795 is an adversarial adjudication process and guarantees only a single opportunity to amend a claim. A clear and convincing standard would provide some limitation on the number of oppositions filed, prevent abuse of the opposition process and allow the significant property right of a patent to be invalidated only when the facts clearly so establish. Patent Reform to Enhance Innovation The following are changes to the patent system that Amgen believes enhance innovation in all sectors. 1. 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 that 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. 2. Prohibit the pleading of inequitable conduct unless one or more patent claims is declared invalid by court; establish "but for" as the threshold for the court holding a patent invalid. The legal standard for inequitable conduct 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 law currently allows patents to be granted only for inventions that are novel and not obvious, as determined by a review of "prior art." In the United States, there is a duty to disclose to the USPTO any prior art of which the applicant is aware and that is material to the patentability of the invention.10 Failure to comply with this obligation - for instance, by disclosing too little information that is "material" - can result in a determination that the applicant engaged in "inequitable conduct", thereby rendering unenforceable any patent that might issue on the application even if the patent is still adjudged to be valid. 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 plead as a defense only after one or more patent claims has been held invalid by a Court. The standard for inequitable conduct should be a "but-for" test: that is, but for the conduct, the PTO would not have issued the patent. 3. 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
10 Quoted from Arnold B. Silverman, "Disclosing Prior Art to the U.S. Patent and Trademark Office," JOM 49 (7) (1997), p. 74 (accessed at http://www.tms.org/pubs/journals/JOM/matters/matters-9707.html)
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found to be "willful," the court may sanction the offender by awarding up to three times the amount of damages.11 The doctrine was intended to deter patent infringers, but in most cases all that infringers have to do is to have an opinion of counsel that the patent is either invalid or not infringed 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: 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." 12 The first approach imposes significant financial burdens on companies while the second approach is contrary to the purpose of the patent system to disseminate information on new technology and thereby foster innovation.13 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. 4. Eliminate the "best mode" requirement. Best mode is a subjective requirement of the patent law that requires disclosure of the "best way" known to an inventor of practicing the claimed invention. 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. It is noted that in current patent harmonization discussions serious consideration is being given to non-inclusion of the best mode requirement as the best alternative for the world. For these reasons, the best mode requirement should be eliminated. 5. 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 with the patent office a declaration of assignment before the assignee - typically the employer of the inventor - may sign a declaration in a patent application. Allowing the assignee to sign the application without the inventor submitting 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. Moreover, other countries have adopted this practice and it has worked well. 11 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. 12 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. 13 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.
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6. 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 to all patent applications uniformly. 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, that is, 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 submarine patents. It also provides inventors the benefit of provisional rights for published application claims that are identical or substantially similar to those contained in the granted patent. 7. End restriction practice and implement a "unity of invention" standard instead For decades, the USPTO has used "restriction practice" - that is, the policy of dividing related types of claims into separate patent applications - to increase fees and narrow the scope of examination of an application. Not only does this process increase the cost of securing a patent because of increased application fees, it also results in delays in the issuance of the patents, effectively shortening the effective patent life of a drug. Most of the rest of the patent world uses a "unity of invention" standard to determine whether a single application may contain claims to multiple inventions. In practice, unity of invention allows multiple related inventions having a common inventive contribution in one patent to a much greater extent than restriction practice. The United States should move to a unity of invention standard for all patent applications. 8. 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, a patent may be awarded only to the first inventor of a product. 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 therefore the patent holder is the first inventor under the law. By 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 concern 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, have been addressed by specifying that it is the first "inventor" to file, not just the first to file, that will be granted the patent. Adopting the new universal standard will increase patent predictability and therefore reduce the risk to those who rely on patent rights. Conclusion In summary, to preserve the integrity of the U.S. patent system and maintain the market incentive for R&D, any patent law reform must be aimed at encouraging innovation. Amgen supports patent law reform that supports innovation and enhances the U.S. patent system to address the economic needs of the country for the 21st Century. The USPTO 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 patent pendency will be substantially reduced. Injunctions should be readily obtainable by patent owners when their valid patents have been infringed. The plague of inequitable conduct defenses as they are now being played out in the courts should be eradicated. Enhanced damages should be awarded only where there is reprehensible conduct found. The system should be streamlined and improved by eliminating antiquated relics of the current system such as the best mode requirement, limitations

on assignee filing, exceptions to 18 month publication, restriction practice, and interferences to determine who among competing parties was the first inventor. To the extent that it is adopted, post grant opposition should apply the clear and convincing evidence standard used in court to invalidate a patent and include only one nine-month window of opportunity to initiate an opposition immediately after the patent has been granted.