Robert B. Chess

Executive Chairman, Nektar Therapeutics

San Carlos, California

Testifying on Behalf of

The Biotechnology Industry Organization

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Committee on the Judiciary

Subcommittee on Courts, the Internet, and Intellectual Property

Hearing on: An Amendment in the Nature of a Substitute to H.R. 2795 the "Patent Reform Act of 2005"

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Chairman Smith and Members of the Subcommittee, I am pleased to testify before you today regarding the pending patent reform legislation, the Amendment in the Nature of a Substitute to H.R. 2795, the Patent Act of 2005. I would like to thank the subcommittee for its continued leadership on issues related to strengthening the foundation of American innovation: Intellectual Property. On behalf of BIO, I would also like to thank Chairman Smith and the other Members of this Subcommittee for working with us, as well as other stakeholders, in trying to fashion fair, effective patent reform legislation.

I am here today representing the Biotechnology Industry Organization (BIO). BIO's membership includes more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 U.S. states. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products.

I base my comments today on 14 years of experience as a top executive of a biotechnology company that is successful because of the strength and predictability of its patent portfolios. It is primarily through the strength of the patents covering our technologies that Nektar Therapeutics has been successful in obtaining the venture capital and public market financing necessary to develop its pipeline of innovative products.

In addition to my experience in the biotechnology sector, I have held management positions in the information technology sector with Intel Corporation and Metaphor Computer Systems, which is now owned by IBM.

Nektar Therapeutics is a leading drug delivery and pharmaceutical company providing a broad portfolio of drug delivery technologies. At Nektar, we develop high technology products that enable the development of new and innovative biotechnology products. Our patented technologies enable pharmaceutical and biotechnology companies to

increase the safety and efficacy of their drug products and to improve their ease of use --leading to greater compliance with drug therapies.

Our pipeline contains twenty programs that have concluded or are currently in human clinical testing. Among the products using our technologies that have been approved by the FDA and are in use by patients are leading and innovative therapies for hepatitis C, for age related macular degeneration, and for decreasing infections associated with chemotherapy. One product in development in collaboration with Pfizer is the first inhaleable insulin. I will talk more about this product later.

In addition, I am a member of the board of directors of several public and private entities including BIO, the Biotechnology Venture for Global Health, Pharsight Corporation and CoTherix. I have also served as a trustee for the Committee for Economic Development.

The Importance of Patents to the Biotechnology Sector

Mr. Chairman, perhaps no other industry is as dependent upon patents as is the biotechnology industry. It is safe to say that most, if not all, of the revolutionary medical advances developed by the biotechnology industry would not exist had the U.S. Supreme Court not ruled in 1980 that biotechnology inventions were entitled to patent protection. Because of the complexity of biotechnology, it can easily take one or two decades, or more, for a biotechnology company to discover and develop a profitable product that revolutionizes treatment of a disease that has resisted conventional pharmaceutical or other medical treatment. To illustrate, I point to my own company Nektar. Nektar has been in existence since 1991. Although we have raised $1.2 billion through 17 rounds of financing, and have several products currently on the market, we are still not yet profitable. Most of the money we have raised has, or will be, spent on research and development. Like many other U.S. biotechnology companies, we have spent hundreds of millions of dollars in R&D, and we diligently protect our intellectual property. Our

company business model is based almost entirely on partnering with large biotechnology and pharmaceutical companies. We combine Nektar's innovative technology with our partner's vaccines or pharmaceuticals to deliver a more efficacious and easier to use product. For example, Exubera ®, an inhaled human insulin powder was developed in collaboration with Pfizer. It is the first non-injectable form of insulin, and could be a major advance in therapy for the 18 million Americans who suffer from diabetes. This product was recommended by an FDA advisory committee for approval last week, but a key patent covering the product was granted in 2000. Upon word of the issuance of the patent covering inhaled insulin in dry powder form, Nektar's stock valuation increased by 20%. This market increase helped make it possible for us to attract the investment capital necessary to bring this innovative product this far along in the process. Our story is similar to the story of the hundreds of U.S. biotechnology companies in the United States.

The vast majority of biotech companies spend more than 50 percent of their operating expenses on research and development. This is due to the huge investments required to bring a product through the discovery and lead optimization phase, preclinical testing, and then clinical trials required to gain market approval. The total amount of spending to bring a successful product through commercialization is typically several hundred million dollars. It is the early stages of drug development that are most vulnerable to perturbations in the capital markets. It is also precisely at these early stages that a patented idea can generate the interest of investors, entrepreneurs, and corporate partners. Without the certainty that comes from knowing that an invention discovered 10-15 years prior to coming to market can be protected, there would be little incentive for investors to fund high risk biotechnology products.

Bolstered by an effective patent system, the nascent biotechnology industry has produced more than 370 drug products and vaccines that target more than 200 diseases. Biotechnology applications have led to cleaner processes that produce less waste and conserve energy and water. Consumers are already enjoying biotech food products. The

biotechnology industry is one of the most innovative industries in the U.S. economy: In fiscal year 2003 alone, the biotech sector filed over 40,000 new biotechnology patent applications and this trend is expected to continue.

Mr. Chairman, we have barely scratched the surface of the promise of biotechnology. It has been through strong, predictable and global patent protection that society has been able to reap the benefits of biotechnological innovation. As such we commend this Subcommittee for its strong support of intellectual property rights.

With these thoughts in mind, BIO offers the following ideas pertaining to patent system reform. First and foremost, we believe that Congress should take steps to fully fund the Patent and Trademark Office and to end diversion of PTO funds. Many of the reforms before Congress require implementation of new procedures within the PTO that, in turn, require significant additional funding. In its review of the Patent Office processes, Congress should take into consideration measures that would streamline PTO processes. For example, in its five-year strategic plan, the PTO recognized the need to reform "restriction practice." "Restriction practice", or the PTO's current discretionary practice of dividing a single discovery into multiple applications, is especially deleterious for biotechnology companies and reforms should be considered by this subcommittee. This is because prosecution of multiple applications is extremely costly, and also results in delayed issuance of patents that would provide the full coverage expected from the initial application filing. Further, for a resource limited biotechnology company, maintaining multiple issued patents is also expensive. At Nektar, for example, we spend over $3 million per year to maintain our portfolio of over 952 patents of which 141 were granted in the United States.

Also, in considering patent reform, we urge Congress to take great care to ensure that the reforms enacted serve all sectors of society and do not disproportionately benefit or harm one segment of the users of the PTO.

Mr. Chairman, BIO members believe that, in the biotechnology arena, the patent system has done exactly as it was intended to do: stimulate innovation and R&D. By and large, biotechnology patents are of high quality. That is not to say that there is no room for improvement, but rather to urge that changes be considered carefully and not tip the balance of quid pro quo too heavily in favor of one segment.

Amendment in the Nature of a Substitute to H.R. 2795

With respect to the Amendment in the Nature of a Substitute (Substitute bill or Substitute H.R. 2795), we are pleased to note that this bill is a substantial improvement over its previous versions. We congratulate you, Chairman Smith, for listening to the concerns expressed by the biotechnology industry and responding to these concerns with many constructive revisions to H.R. 2795. We note that provisions that would have severely weakened the ability of innovators to obtain and enforce patent protection have been eliminated. Specifically, we note that the current version of the draft does not contain provisions that would alter the standard for obtaining a permanent injunction, limit the ability of patent applicants to file continuation applications to obtain appropriate patent protection, and subject a patent holder to multiple challenges after a patent has been issued.

It was critical to BIO that these provisions be deleted from the bill, as they seriously threatened our ability to continue bringing life-saving therapies to the market. In regards to the permanent injunction reform present in the previous iteration of the bill, we were concerned that lowering the present standard would create uncertainty and confusion in the law, hampering our ability to attract the VC financing vital to our ability to develop innovative products. As you know, except in rare instances, under current law, once a patent is judged valid and infringed, the patent owner has the right to exclude others from using the invention. This is as it should be. If you allowed courts to weigh equities and

balance hardships, our patents would be weakened, and research and development would suffer.

Further, the Amendment in the Nature of a Substitute deletes the provision from H.R. 2795 which would have provided the PTO unlimited authority to regulate continuation practice. Flexibility in the patent application process is essential for complex inventions. Proposals that limit flexibility will ultimately undermine the quality of patent applications and deny inventors the ability to obtain the appropriate scope of protection. We are very concerned that unfettered authority in the hands of the PTO will be used primarily by PTO to decrease the patent application backlog by imposing arbitrary limitations on the number of, or timing for, continuation applications and reduce the coverage that patent owners are entitled to obtain. BIO urges Congress and the PTO not to seek to limit continuation applications.

BIO members have many legitimate needs for filing continuations. Continuation practice allows biotechnology inventors to obtain adequate protection for the full scope of their inventions. The practice is common in our industry because it can take 12-15 years to bring a product to market, and during this period the inventor's understanding of his or her basic invention increases over time. Take as an example the initial discovery of a gene whose presence is predictive of a class of related disorders. During the patent examination process, the inventor is likely to obtain a patent only on one aspect of his discovery (i.e. a detection assay for one disorder in the class of disorders). This initial patent will allow the inventor to seek investment capital to further the product development process, while he files patent applications commensurate in scope with the full scope of his discovery. The inventor, however, is entitled to protection for the totality of his discovery which the PTO is reluctant to abide by at the initial filing.

The flexibility to file continuation applications is even more important in light of recent cases decided by the Federal Court of Appeals for the Federal Circuit and the U.S.

Supreme Court (for example the Supreme Court decision in Festo[1]) where the law encourages the filing of continuing applications of successively broader claims to ensure that an inventor obtains the rights to which he is entitled.

Additionally, we are very pleased to note that the "second window" in the new post-grant opposition procedure was not included in the Substitute bill. This provision drastically would have decreased patent certainty by opening a new time period wherein patents could be challenged, up to the point of patent expiry. Any new administrative challenge process should have one, and only one, window to challenge a patent. It should not allow for multiple challenges. If this is the case, patent certainty would never be fully settled. With no certainty, venture capital would leave our industry, again threatening our ability to bring new cutting-edge products to the market.

BIO members have in the past supported efforts that would harmonize U.S. laws with those of our trading partners. Our members also believe that reforms that would streamline PTO practices will help to eliminate redundancies, which in turn will make obtaining patent protections more efficient and cost-effective. Moreover, BIO is on record for supporting the elimination of the subjective elements of litigation which are a financial burden to many in our industry. To the extent that the Substitute bill addresses these issues, BIO is supportive of these efforts. For example, BIO supports the provisions in the Substitute bill that would: move the U.S. toward a first inventor to file system; allow the assignee in an invention to file for a patent; eliminate the best mode requirement which is unique in U.S. patent law; limit inequitable conduct defense to patent infringement; provide for pre-grant submissions of prior art; simplify the definition of prior art; require publication of all applications at 18 months from filing; and reform the willfulness standards.

[1] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U. S. 722 (2002).* Under Festo, an inventor gives up his rights to protect the aspects of his invention under the doctrine of equivalents that he has given up throughout prosecution. This holding has made it good practice to claim narrowly initially and seek broader protection through continuations.

BIO Members, however, have expressed considerable concern and opposition to the new venue reform provision contained in the Substitute Amendment. Our members are concerned that this provision significantly shifts the advantage in patent litigation in favor of the defendant. Under current law a patent holder may bring suit anywhere that he/she can establish personal jurisdiction over the infringer. The Substitute H.R. 2795 would only allow a law suit to commence in the district where the defendant resides or the district where the defendant has committed acts of infringement and has a regular established place of business. The implications of such a provision for the biotechnology industry are considerable. As owners of patents, our members are concerned that this provision would severely weaken or possibly abrogate their patent enforcement capabilities. In particular, resource limited biotechnology companies may be forced to file law suits far outside of their normal jurisdiction since, the location where the act of infringement is committed or the place where the defendant resides are not likely to be in close proximity to the patent holder's jurisdiction. A small biotechnology company may find it difficult if not impossible to assert its patent rights against a more powerful competitor outside of its jurisdiction. We urge you to eliminate this provision from the legislation. BIO members are not opposed to working with Members of this Subcommittee and other interested stakeholders to find ways to limit abusive venue practices, but we believe it is critically important that no provision in the bill operates to constrain the ability of biotechnology companies to obtain and effectively enforce their patent rights.

While our members agree on many of the provisions in the Substitute bill, there are areas where our members are divided. One disagreement concerns the standard of proof required to invalidate a patent in the proposed post-grant opposition procedure. As you know, the current substitute requires that a patent challenger show by a "preponderance of evidence" that a patent is invalid. Within BIO's diverse membership, there are those companies who prefer the "preponderance of evidence" standard for post grant

opposition set forth in the Substitute Amendment, while others argue that the standard should be changed to a "clear and convincing" evidence standard. Those in favor of a "preponderance of evidence" standard argue that it is appropriate for a PTO-conducted proceeding, whereas those who favor a "clear and convincing standard" argue that examined patents deserve a higher standard of validity because of the rigorous review of patent applications at the PTO. They argue that the lower burden of proof will result in frivolous oppositions, wherein competitors or undisclosed third parties take a chance at invalidating a patent, even if they have little likelihood for success.

Other areas where certain of our members believe further improvements should be made (or at least further considered) include the provision in the post grant opposition procedure to keep the identity of the opposer secret; provisions that expand prior user rights; provisions that reform re-examination; provisions directed to the apportionment of damages and additional protections included in the post grant opposition procedure; e.g. the ability of a patent owner to move the challenge to district court.

To the extent that there is disagreement, individual members are free to address their views to you and other members of the Committee. While BIO has yet to forge consensus on all of these provisions, we will continue to work diligently with our members and Congressional staff on patent reform.

Coalition for Patent Reform Proposal

We recently became aware of a Coalition Patent Reform which includes some in the pharmaceutical, electronics and information technology communities. We have been apprised that this Coalition has developed a new patent reform proposal for consideration built upon your Substitute Amendment. The proposal differs from your Amendment in that it includes a new transfer of venue provision, repeals section 271(f), revises the previous provision on apportionment of damages and clarifies the conditions for

patentability taking into consideration the CREATE Act. Like the Substitute Amendment, we view this proposal as a substantial improvement over H.R. 2795 in that the proposal does not contain permanent injunction reform, continuation practice reform, and a “second window” in post-grant.

With respect to apportionment of damages, BIO has not been able to achieve a consensus as to whether such a change to the patent laws is necessary. The provision in the Coalition draft as in the Substitute Amendment would codify one specific factor among a dozen or so factors used by the court to determine apportionment of damages. This factor directs the court to award damages based on the proportionate value of the invention in question to the whole product in the market. Some of our members believe that it is bad precedent to codify and potentially overemphasize one of these factors to the exclusion of the others. Others disagree and believe that this provision does no more than codify an aspect of existing law.

Our companies are also concerned about the new transfer of venue provision in the Coalition draft. We note that this draft removes the onerous venue provision from the Substitute Amendment and replaces it with a transfer of venue provision. However, the primary objection to this particular approach within our membership is the belief that transfer of venue motions will delay and divert patent infringement actions. The interpretation of "substantial" in the mandatory setting of the language will encourage transfer of motions by the alleged infringers. Nevertheless, our companies are open to considering language that would change the venue statute.

Conclusion

In conclusion, BIO supports and applauds the continuing efforts of this subcommittee to improve the patent system. As noted, intellectual property protection is a critical element

of biotechnology product development, and while BIO supports efforts to strengthen this system, we urge caution that the delicate balance of the system be maintained.

Given the significant technological breakthroughs that have been achieved in the medical and health fields, BIO believes that the patent system has served the health and welfare of the nation and the world.

Thank you again for your support of biotechnology's efforts to contribute to continued innovation in the United States. I would be pleased to respond to questions from the subcommittee.