

**Summary Statement of Jeffrey P. Kushan on Behalf of Genentech, Inc.**  
**PATENT QUALITY IMPROVEMENT: POST-GRANT OPPOSITION**  
**Subcommittee on Courts, the Internet and Intellectual Property**  
**House Judiciary Committee**  
**June 24, 2004**

Genentech strongly supports the creation of an effective, fair and expeditious post-grant administrative patent review procedure. An appropriately structured post-grant review system will enhance public confidence in the patent system, and provide a much needed alternative to patent litigation in Federal courts.

Genentech believes any post-grant review procedure administered by the Patent and Trademark Office (PTO) should incorporate the following main elements.

1. Scope: The system must permit review of questions of compliance with 35 U.S.C. §101 and §112, first paragraph (other than best mode), in addition to §§102 and 103. Compliance with the written description, enablement and utility requirements is often an important inquiry for biotechnology patents.
2. Estoppel. Participation in a post-grant review system must not create any barrier for participants to litigate patent validity on issues that were not actually addressed in the PTO proceeding. Congress should avoid creating special statutory estoppel provisions in post-grant review legislation.
3. Preliminary Showing to Initiate Procedure – Any party wishing to commence a proceeding should be required to establish a *prima facie* showing of invalidity of one or more claims. Genentech believes this “initial proof” requirement is an important part of any post-grant review procedure that, if omitted, could subject, patent owners to groundless challenges.
4. Time Limits to Initiate Proceeding. Post-grant review procedures should be commenced within one to two years from the issue date of the patent. Genentech remains open to additional, appropriately limited circumstances in which oppositions may be commenced.
5. Applicable to All Patents. The system should permit review of any patent that is capable of being enforced, including patents issuing from applications filed on or before the effective date of the American Inventors Protection Act.
6. Limited Additional Evidentiary Procedures. Certain evidentiary procedures (e.g., cross-examination of parties who offer testimony, an oral hearing, limited numbers of interrogatories and requests for admission upon an appropriate showing of need) should be available in a post-grant review procedure. Other measures – particularly discovery of documents or production of fact witnesses – should be prohibited.
7. No inequitable conduct challenges based on post-grant proceedings. Public post-grant review procedures that include the active participation of third parties eliminate the need for any enhanced disclosure obligations comparable those applied in original ex parte examination. Events during a post-grant proceeding should not be capable of rendering a patent unenforceable in subsequent litigation.
8. Authority to Delegate Certain Issues for Resolution. Congress should permit the PTO to delegate responsibility for resolve certain fact issue, but should require the PTO to make the ultimate determination of validity of the patent once a proceeding has been commenced.

**PATENT QUALITY IMPROVEMENT: POST-GRANT OPPOSITION**

**Testimony of**

**Jeffrey P. Kushan  
Partner, Sidley Austin Brown and Wood, LLP**

**on behalf of  
Genentech, Inc.**

**Before the  
Subcommittee on Courts, the Internet and Intellectual Property  
of the  
House Judiciary Committee**

**June 24, 2004**

Mr. Chairman and distinguished Members of the Subcommittee,

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

Today, I have the privilege of offering testimony on behalf of Genentech, Inc. Genentech is a world-leading biotechnology company, based in South San Francisco, California. Genentech is committed to developing new biotechnology products to meet unmet medical needs. Genentech actively procures patent protection for its technology, and depends on an effective and fair patent system. Genentech very much appreciates the opportunity to provide testimony to the Subcommittee on the issue of today's hearing. We commend you, Chairman Smith, along with your colleagues on the Subcommittee, particularly the Ranking Member, Mr. Berman, for taking up this important and timely issue.

Genentech strongly supports the creation of an effective, fair and expeditious post-grant administrative patent review procedure. Options that exist today – so-called *ex parte* and *inter partes* reexamination –do not present a viable alternative to litigation in the Federal courts, primarily because these procedures do not provide third parties with a fair and balanced degree of participation relative to patent owners. The absence of a fair and efficient administrative

procedure to review patent validity makes it possible for owners of invalid patents to use the often enormous expense of patent litigation to shield invalid patents from challenge. An improperly granted patent that cannot be reviewed in a cost-effective manner creates unjustified burdens and risks for American companies, including those in the biotechnology industry.

Genentech believes that the availability of an appropriately structured post-grant review system will enhance public confidence in the patent system, and provide the public with a much needed administrative alternative for resolving questions of patent validity. We recognize that there is broad support within and outside the patent community for creating a viable post-grant patent validity review procedure. The challenge, however, will be for Congress to define certain critically important elements of such a procedure— in this case, the devil truly is in the details. Our testimony below identifies what we believe to be the most significant requirements of a viable post-grant review procedure. We thank the Subcommittee for giving us the opportunity to share our views on this important issue, and stand ready to work with the Congress to make a viable post-grant patent review procedure a reality.

## **Introduction**

The United States patent system is structured to deliver reliable results in a cost-effective and timely manner. Examination is conducted on an “*ex parte*” basis – meaning that the PTO and the patent applicant are the only participants in the examination process. The advent of publication of patent applications prior to grant from the 1999 American Inventors Protection Act (AIPA) has shed some light onto ongoing examinations, but, fundamentally, the patent examination process remains closed to substantive participation by parties other than the patent applicant.

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

intervention in the examination of pending U.S. applications would create immense practical problems, given the volume of applications now pending before the PTO, and the limited amount of examination resources that are available.

The logical alternative is a *post*-grant review procedure administered by the PTO. Congress, perhaps recognizing this, has always focused on procedures that envision an opportunity for the public to have the PTO review the validity of an issued patent. The first such system adopted by Congress was the “*ex parte*” reexamination system, enacted in 1982. In the *ex parte* reexamination system, any person, including the patent owner, may commence a reexamination of any issued patent on the basis of a patent or a printed publication that raises a substantial new question of patentability. See, 35 U.S.C. §302. The *ex parte* reexamination procedure, like original examination, is a closed procedure – only the patent owner and the PTO participate substantively in the proceeding. As a result, most third parties avoid use of this procedure for commercially significant patents, since it does not afford those third parties a meaningful opportunity to participate in the proceeding.

### **The 1999 *Inter Partes* Reexamination Effort**

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

The most significant deficiencies of the *inter partes* reexamination system can be summarized as follows.

- It is not possible to use the procedure to review patentability issues that are most commonly encountered in biotechnology patents and applications; namely,

compliance with 35 U.S.C. §§101, and 112, first paragraph. It has been our experience that issues of compliance with the written description and enablement provisions of 35 U.S.C. §112, first paragraph, and the utility requirement of §101, frequently are significant inquiries affecting the validity of many biotechnology patents and patent applications. Not permitting these grounds to be raised in a post-grant review procedure renders the system far inferior as an alternative to litigation in a Federal court.

- The law imposes two distinct “statutory estoppels” that in combination make the procedure unattractive as an alternative to litigation in a Federal court. The first, found in 35 U.S.C. §315(c), prohibits a requestor from raising in a Federal court *any* issues of validity that “could have been raised” at the time of the request for reexamination in view of art known to the requestor. This broad estoppel attaches by the mere filing of a *request* for *inter partes* reexamination. The second “estoppel” is found in an uncodified section of the AIPA (§4607 of the Intellectual Property and Communications Omnibus Reform Act of 1999, as enacted by §1000(a)(9) of Public Law 106–113), and is designed to prohibit a third party who participates in a reexamination proceeding from later contesting the legitimacy of any “facts” determined in the proceeding. These statutory estoppel provisions impose an unacceptable price on use of the *inter partes* reexamination procedure in almost all situations.
- The *inter partes* reexamination system does not permit third parties to use certain evidentiary procedures that would ensure that the procedure is sufficiently rigorous. For example, it is not possible to cross-examine expert witnesses used in the proceeding or direct questions to the opposing party.
- Finally, the system cannot be used to review issues of validity involving patents issued on applications filed before November 29, 1999. We note that this limitation, in particular, has rendered the system of marginal value to many companies in the biotechnology industry, in part because there still remains a

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

These limitations in the *inter partes* reexamination system –ostensibly established in 1999 to provide a more robust alternative to *ex parte* reexamination – have made the procedure of marginal value to the public. It is not an effective alternative to expensive, unpredictable and protracted litigation in the Federal courts. As such, the *inter partes* reexamination procedure has not met expectations.

### **Recent Developments**

In the past year, the Federal Trade Commission (FTC) and the National Academies of Science (NAS), have both issued reports calling for the creation of a more robust and effective administrative post-grant patent review system. The motivation for these organizations is the same as that which led Congress to establish the *ex parte* and *inter partes* reexamination procedures. Specifically, each organization recognizes that the PTO has a special expertise in evaluating certain patentability issues, such as anticipation, nonobviousness, enablement, written description and utility. They also recognize that certain issues often addressed in litigation before a Federal court (e.g., infringement, inequitable conduct) are a major source of the high cost of patent litigation, yet are not pertinent to validity of the patent. Both organizations accurately recognize that an administrative patent validity review proceeding can be conducted more rapidly than litigation in a Federal court, and that the public would significantly benefit from the availability of a procedure that does not present the burden, duration and associated expenses of patent litigation. These organizations also appreciate that that any new system should not permit third parties to harass patent owners, or initiate groundless attacks on patents.

### **Recommendations for Reform**

Genentech believes it is possible to create a viable, cost-effective, and fairly balanced post-grant administrative patent review procedure. A variety of models have been proposed for such a system in the past few years, including those from the Patent and Trademark Office in its 21<sup>st</sup> Century Strategic Plan, the NAS, the FTC and the American Intellectual Property Law

Association (AIPLA). Many of these proposals have significant merit, and could serve as a suitable foundation for legislation. Moreover, these organizations have identified a number of important assumptions and conditions for a successful post-grant review procedure. We encourage the Congress to study these proposals carefully.

The excellent work done by these organizations also permits us to focus on a number of key issues that Genentech believes are of particular importance, regardless of the ultimate framework chosen for the system. We note that each of these organizations, for example, recognize that the PTO has resource constraints. They also recognize that the PTO has a special expertise in certain, but not all patentability issues. For example, the PTO rarely encounters issues associated with compliance with the “best mode” requirement of 35 U.S.C. §112, first paragraph. Similarly, the PTO does not often evaluate compliance with the duty of disclosure requirement of 37 CFR §1.56. Such topics in which the PTO has no special expertise or which cannot be fairly evaluated using objective inquiries should not be placed in the hands of the PTO to evaluate in a post-grant review procedure.

We also recognize that certain decisions will have to be taken as to how the new regime relates to the existing *ex parte* and *inter partes* reexamination procedures. For example, we believe there is value in retaining an efficient and simple documentary procedure for reviewing validity issues raised by a patent or a printed publication. It may be possible to design a flexible post-grant review procedure to permit parties to conduct the procedure in a way that preserves this “least complicated” approach. We also believe it is appropriate for the PTO to continue to have the authority to conduct Director-ordered reviews, but to expand this authority to evaluate compliance with issues under 35 U.S.C §101 or §112, first paragraph (other than best mode).

The Congress should also carefully evaluate how multiple proceedings initiated under the new system will be coordinated, both with respect to other opposition requests, and with interference proceedings. We note that it may be desirable to provide statutory guidance to the PTO and to parties as to how such proceedings may be merged, suspended or otherwise coordinated so as to reduce the potential burdens on patent owners involved in multiple proceedings, and to ensure that efficient disposition of validity issues associated with a patent.

With these initial observations in mind, we believe there are a number of important parameters that must be included in any post-grant review procedure. These can be summarized as follows:

1. Scope: The system must permit review of questions of compliance with 35 U.S.C. §101 and §112, first paragraph (other than best mode), in addition to §§102 and 103. As noted earlier, compliance with the written description and enablement requirements of 35 U.S.C. §112, first paragraph, and with the utility requirement of §101, is often an important inquiry for a biotechnology patent. These issues also tend to be among the more significant issues addressed during original examination, rather than prior art issues. A system that omits the possibility of raising these non-prior art issues would significantly reduce the value of a post-grant review procedure to most biotechnology companies.
2. Estoppel. Participation in a post-grant review system must not create any barrier for the participants to litigate patent validity on issues that were not actually raised and addressed in the post-grant review proceeding before the PTO. Genentech believes Congress should avoid including estoppel provisions in any post grant review legislation, and should specifically avoid including provisions that are comparable to the codified and uncodified estoppel provisions applicable to *inter partes* reexamination proceedings.
3. Preliminary Showing to Initiate Procedure – Any party wishing to commence a proceeding should be required to set forth, supported by substantial evidence, a *prima facie* showing of invalidity of one or more claims. If such an initial showing is not made, the Office should not commence the proceeding. Genentech believes this “initial proof” requirement is an important part of any post-grant review procedure that could result in invalidation of one or more claims of a patent. Without this initial determination, patent owners could be subjected to groundless challenges to their patents.

4. Time Limits to Initiate Proceeding. Any third party should be allowed to initiate a post-grant review proceeding provided it has made an appropriate preliminary showing within a fixed period following issuance of the patent. In our view, that period of time could range from one to two years after grant of the patent. Genentech also believes it may be appropriate to allow post-grant review proceedings to be commenced after this fixed period has expired, but only in strictly limited circumstances. One example would be where the patent owner consents to having the proceeding commenced before the PTO. Genentech remains open to consideration of additional, appropriately limited circumstances in which oppositions may be commenced after a fixed period from patent grant.
5. Applicable to All Patents. The system should permit review of any patent that is capable of being enforced, subject to the threshold showings and limitations noted above. Thus, the system should permit review of patents issuing on applications filed on or before the effective date of the American Inventors Protection Act.
6. Limited Additional Evidentiary Procedures. Genentech believes a viable post-grant review procedure should permit use of evidentiary procedures that will provide a more rigorous review of issues pertinent to the validity of a patent than are permitted under the current *inter partes* reexamination authority. At the same time, we recognize that if all the evidentiary procedures available in litigation before a Federal Court were allowed to be used in a post-grant review procedure before the PTO, no benefits would be realized from using the PTO-based procedure. As a result, Genentech believes it would be appropriate to make available only certain limited additional procedures in a post-grant review procedure. Such additional procedures should include the right to cross-examine a witness who offers testimony in the proceeding. Additionally, if the presiding authority (e.g., an administrative patent judge) finds it appropriate, certain additional procedures could be made available including: (i) limited requests for admissions, (ii) a limited number of interrogatories, and (iii) the opportunity for an oral hearing. Other measures, however, should be prohibited. In particular,

parties to a post-grant proceeding should not be subject to document production, or forced to produce fact witnesses for depositions. Such restrictions are appropriate and will not undermine the effectiveness of the procedure, in part because they are unnecessary. We note in this regard that the PTO, unlike a court, can use officials with technical expertise in the particular field of a patented invention to conduct and manage proceedings. This provides the PTO with a capacity to independently assess assertions made by the parties to the proceeding. We believe these limitations on the types of evidentiary measures made available in a post-grant proceeding will help to ensure that the PTO procedure does not replicate the functions of full-scale litigation in a Federal court.

7. Prohibit inequitable conduct challenges based on actions of parties during post-grant proceedings. The inequitable conduct doctrine operates to ensure that patent applicants during *ex parte* examination of their applications are held to a higher standard of dealing with the PTO. See, 37 CFR §1.56. A party that does not meet his or her duty of disclosure to the Office can cause that party's patent to be held unenforceable. The reason for this enhanced duty of disclosure is that the *ex parte* examination procedure is closed and the public cannot participate. Unlike *ex parte* examination, however, post-grant review procedures under consideration would be public and would include the active participation of one or more parties opposed to the patent owner. These factors eliminate the need for any enhanced disclosure standards comparable those imposed during original examination. Moreover, there is no comparable sanction that can be imposed on third parties in such a proceeding (i.e., those parties will be free to litigate infringement, enforcement and invalidity in the future largely unfettered by their participation in the proceeding). In view of this, Genentech does not believe it would be appropriate to impose an enhanced duty of disclosure on participants in a post-grant proceeding that could result in the patent being held unenforceable. Certainly, regulations designed to ensure proper conduct of parties in such proceedings are appropriate, and should be enforced by the PTO. If the PTO finds that one party has made a misrepresentation, it should have the authority to

take actions to sanction that party during the proceeding. Where such misrepresentations are discovered after the patent emerges from the proceeding, courts may give due consideration to the actions of the party, but should not be allowed to hold the patent unenforceable.

8. Authority to Delegate Certain Issues for Resolution. The PTO faces annual challenges and uncertainty in its funding. In view of this, it would be desirable for Congress to allow the PTO to delegate responsibility to private parties to resolve certain fact issues. For example, as is the case with the existing interference authority, the PTO may allow parties to arbitrate certain issues. In a similar fashion, the PTO could allow a third party to adjudicate certain conflicts, and then to rely on those findings in making its patentability determinations. This authority may be useful to have to ensure that funding problems do not adversely affect the progress of cases that have been commenced. Genentech believes, however, that the ultimate determination of validity of the patent within the context of these proceedings – once a proceeding has been commenced – must remain the exclusive jurisdiction of the PTO. In other words, while we support the use of appropriate cost-saving measures, the PTO must continue to make its final, independent determination of whether a patent meets the statutory requirements of validity.

## **Conclusions**

Genentech relies extensively on the patent system to protect its innovations. Our experiences teach us that invalid patents cause the greatest business disruptions –both when Genentech owns the patent and when Genentech is facing the patent. A cost-effective procedure that allows for robust participation by third parties, yet is appropriately limited to avoid prejudice and the problems of litigation before a Federal court, would provide immense value for patent owners and the public alike.

As Congress begins its deliberations on this important issue, it should keep certain fundamental principles in mind. First, there is no right of a member of the public to retain and

enforce an invalid patent. It also is not appropriate to permit entities to use the high cost and complexity of patent litigation to prevent discovery of invalidity of a patent. Invalid patents impose an immense and unjustified cost on American businesses, including companies in the biotechnology industry.

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

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

Genentech thanks the subcommittee for the opportunity to present its views, and encourages the Congress to act promptly to enact this much-needed legislation.

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## **GENENTECH**

Genentech's mission is to be the leading biotechnology company, using human genetic information to discover, develop, manufacture and commercialize biotherapeutics that address significant unmet medical needs. We commit ourselves to high standards of integrity in contributing to the best interests of patients, the medical profession, our employees and our communities, and to seeking significant returns to our stockholders, based on the continual pursuit of scientific and operational excellence. The company has headquarters in South San Francisco and is traded on the New York Stock Exchange under the symbol DNA.

Eighteen of the currently approved products in biotechnology originated from or are based on Genentech science. Genentech manufactures and commercializes 12 products in the United States:

- Herceptin® (Trastuzumab) for first line therapy in combination with paclitaxel and as a single agent in second and third line therapy for patients with metastatic breast cancer who have tumors that overexpress the HER2 (human epidermal growth factor receptor2) protein;
- Rituxan® (Rituximab) for the treatment of patients with relapsed or refractory low-grade or follicular, CD20 positive, B-cell non-Hodgkin's lymphoma;
- Avastin™ (bevacizumab) for use in combination with 5-Fluorouracil-based chemotherapy in the treatment of first-line metastatic cancer of the colon or rectum;
- Xolair® (Omalizumab) for Subcutaneous Use for the treatment of moderate-to-severe persistent asthma in adults and adolescents;
- RAPTIVA™ (efalizumab) for the treatment of chronic moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy;
- TNKase™ (Tenecteplase), a single-dose clot-busting agent for the treatment of acute myocardial infarction (heart attack);
- Activase® (Alteplase, recombinant), a tissue-plasminogen activator to dissolve blood clots, for treating patients with acute myocardial infarction, patients with acute massive pulmonary embolism (blood clots in the lungs), and for treating patients with acute ischemic stroke (brain attack) within the first three hours of symptom onset;

- Cathflo™ Activase® (Alteplase), athrombolytic agent for the restoration of function to central venous access devices as assessed by the ability to withdraw blood;
- Nutropin AQ® [somatropin (rDNA origin) injection], a liquid formulation of Nutropin for the same indications as Nutropin®;
  - Nutropin AQ Pen™ for use with Nutropin AQ Pen™ Cartridge, a delivery device for Nutropin AQ® [somatropin (rDNA origin) injection] that provides simplicity, convenience, and safety features;
- Nutropin® [somatropin (rDNA origin) for injection] human growth hormone for treating GHD, for treating growth failure due to chronic renal insufficiency prior to kidney transplantation, and for treating short stature associated with Turner syndrome;
- Protropin® (somatrem for injection) growth hormone also for the treatment of GHD in children;
- Pulmozyme® (dornase alfa, recombinant) Inhalation Solution, the first new therapeutic approach for cystic fibrosis in more than 30 years.

## **Medicine Development at Genentech**

Genentech has the biotechnology industry's most extensive track record in all phases of bringing new disease treatments to patients – from discovery research through development, commercialization and product operations. With 12 protein-based products on the market for serious or life-threatening medical conditions, Genentech has experience taking a drug from A to Z, transforming the seed of an idea in a lab into a novel therapy for a patient in need. Such a fully integrated approach differentiates Genentech from other biotechnology companies.

### Discovery Research

Research is the wellspring of potential products, and Genentech's research organization is among the world's finest. Genentech scientists are the most prolific in the biotechnology industry, publishing at a rate of 200+ scientific papers a year, and are among the top researchers in the world in terms of total citations. In addition, Genentech's scientists have secured more than 4,600 patents worldwide and have another 5,000 pending.

Discovery research at Genentech focuses primarily on three areas of medicine where there is a strong need for safer, more efficacious therapies: oncology, immunological disease, and disorders of tissue growth and repair, with a major focus on angiogenic disorders. In addition, Genentech remains open to other projects where the company has significant opportunities to fill a therapeutic void in important areas of medicine.

To ensure continued scientific excellence, Genentech opened the Founders Research Center, a 275,000 square-foot, \$85 million research facility devoted solely to biotechnology, in October 1992. It was dedicated to Bob Swanson and Dr. Herbert Boyer in honor of their pursuit

of the promise of biotechnology when they established Genentech 25 years ago in 1976. In April 2001, the company celebrated its 25th anniversary by breaking ground on the 280,000 square foot expansion of the Founders Research Center. Completed in 2003, the complex – comprising the existing facility and the new expansion – houses specialized laboratories and state-of-the-science equipment in several interconnected buildings.

### Development

Genentech uses a rigorous set of criteria, including scientific factors, medical need and market potential, to determine which projects to move from discovery research into development. The scientists and medical professionals in Laboratory and Clinical Development then play the essential role of translating basic science into patient benefit. They help Genentech determine which potential new drugs are tested against specific diseases in the clinic and guide chosen drug candidates through the many phases of clinical testing. Therapeutic proteins must be delivered into the body safely, and their effectiveness must be measured and documented in order to secure marketing approval. Genentech's development pipeline has both breadth and depth, with projects targeting a range of disease areas across all phases of clinical development.

### Manufacturing

Genentech was the first biotechnology company to scale up protein manufacturing successfully from the small quantities used for research to the much larger quantities needed for clinical trials and marketing. With approximately 30 percent of the world's total licensed capacity for the production of biologics, Genentech is the world leader in biologics manufacturing. Over the last two decades, Genentech has built world-class production facilities, developed expertise in commercially viable manufacturing processes and also attracted and retained key personnel with experience in all aspects of large-scale biologics manufacturing. Genentech's manufacturing expertise and capacity (more than 275,000 liters of installed fermentation capacity) provide important competitive advantages in the maturing biotechnology industry and position the company well to meet the demands of its promising product pipeline. Genentech presently has two manufacturing facilities in California (South San Francisco and Vacaville) and one nearing completion in Porriño, Spain.

## Commercialization

Commercial translates research and development innovations into changes in medical practice that enhance and extend patients' lives. The Commercial team introduces multiple products into new and different markets, directs pre-launch commercial development activities, and utilizes cutting-edge sales approaches. The Commercial organization is also involved with development activities that bring forward products in the pipeline in the most efficient way to meet the demands of the market and the healthcare community – directing market research, sponsoring medical education efforts, and developing a leading patient reimbursement program. The Commercial team's unique consultative education, sales, marketing, and distribution models have resulted in 13 successfully marketed products to date and have made Genentech a valuable and sought-after partner.

## **Product Pipeline**

With close to \$3 billion in cash and investments and 2003 revenues of more than \$3.3 billion, Genentech reinvested approximately 22 percent of its revenues into research and development (R&D) in 2003 — significantly more than the pharmaceutical industry average. To balance resource use with the strongest likelihood of success, Genentech moves only the most promising of its products into clinical development.

Genentech's development pipeline continues to grow, now numbering over 30 projects in three therapeutic focus areas – oncology, immunological disease, and vascular medicine – with an additional category for projects outside of these focus areas, specialty therapeutics. The pipeline is also balanced between breakthrough innovations and new indications for existing, well-understood products that may fight more than one disease or more than one form of a disease.

## Oncology

Genentech is taking part in the fight against cancer by continuously studying and developing therapies for a variety of cancers, including four of the most common – lung, breast, prostate, and colon. At present, we are investigating Avastin and Omnitarg™ (Pertuzumab) in multiple tumor types; Tarceva™ (erlotinib HCl) in non-small cell lung cancer, pancreatic cancer, and brain cancer; and our marketed products Herceptin and Rituxan in several new oncology indications.

## Immunology

Immune disorders such as asthma, psoriasis and rheumatoid arthritis affect over 20% of the population of the United States. Immunology is a growing area of expertise and emphasis for Genentech, and we are developing several potential therapies for immune-related diseases. Our two most recently approved products, RAPTIVA for moderate-to-severe chronic plaque psoriasis and Xolair for moderate-to-severe persistent asthma, are aimed at immunological conditions.

## Vascular Medicine

An example of our investigational work in vascular medicine is our anti-angiogenesis drug, Lucentis™ (ranibizumab), formerly rhuFab V2, which is being studied for the potential treatment of age-related macular degeneration.

## Specialty Therapeutics

Genentech also develops medicines outside of these three focus areas, provided they address unmet medical needs and utilize the company's areas of expertise. Our medicine for cystic fibrosis, Pulmozyme® (dornase alfa), and our growth hormone products are in this category.

## **Employees**

Genentech's success is predicated on its ability to recruit and retain highly qualified and motivated people in all areas of the company. Of the more than 6,200 Genentech employees, more than 80 percent have college degrees and more than 20 percent hold advanced degrees, including Ph.D.s and M.D.s. Genentech demands the best from its employees and rewards them accordingly with a benefits plan that includes healthcare benefits that are among the best in the industry, an employee stock purchase plan, a paid sabbatical program and a large corporate-sponsored child care center.

## **Access to Care Foundation**

Although Genentech's products are covered by most government and private insurance, Genentech has established the Genentech® Access to Care Foundation to make its marketed products available to qualified uninsured or underinsured patients in the United States. In 2003, more than 4,200 patients participated in the program and Genentech provided more than \$40

million worth of drugs to patients in need, keeping the company's promise that no one will go without a Genentech product based on financial reasons alone.

### **Corporate Growth Strategy**

Genentech aims to continuously create growth in different areas of the company. With this in mind, Genentech developed the "5X5 goals" in 1999, five goals it plans to meet by year-end 2005. These goals help the company stay focused on its top priorities and make Genentech's plans transparent to investors and others:

- 25% average annual increase in EPS
- 25% net income as % of revenues
- 5 new products/indications approved
- 5 significant products in late stage clinical trials
- \$500 million in new revenues from strategic alliances or acquisitions.

Genentech's performance against these ambitious goals remains strong.

Genentech has also turned its attention to the period beyond 2005 and developed a long-term company strategy, Horizon 2010, that builds on the success of our 5X5 goals and covers the period from 2006 to 2010. Because research and development can take many years, we are investing now to achieve the kind of revenue and earnings growth needed to remain a leading company past 2005. Horizon 2010 includes the following elements:

#### Our Vision

Utilize the science of biotechnology to become the world leader in revolutionizing the treatment of patients with cancer, immunological diseases and angiogenic disorders.

#### Our Goals

- Strive to become number one in U.S. oncology sales by 2010.
- Position ourselves for continued leadership in oncology by bringing five new oncology products/ indications into clinical development and into the market.
- Build a leading immunology franchise by expanding the fundamental understanding of immune disorders, by bringing at least five new immunology products/indications into clinical development, and by obtaining approval of at least five new indications or products by 2010.
- Increase our leadership in developing biotherapeutics for disorders of tissue growth and repair, with a major focus on angiogenic disorders, and move at least three new projects into late-stage research or developmental research and three or more new projects into clinical development by 2010.

- Achieve average annual earnings per share (EPS) growth rates sufficient to be considered a growth company.

### Our Strategy

- Manage the business with a primary intent of building sustainable, long-term growth in stockholder value
- Be recognized leaders in:
  - B-cell mediated diseases
  - Disorders of tissue growth and repair, particularly angiogenic disorders
  - Targeted therapies and their enabling diagnostics
- Excel in:
  - Making and shaping markets
  - Influencing the practice of medicine
  - Maximizing distinctive consultative selling approach
  - Manufacturing protein pharmaceuticals in a safe, high-quality, reliable, and cost-effective manner
- Scale our unique culture to remain a great place to work by:
  - Constantly emphasizing improving the lives of patients
  - Being the place for talented people to make a difference
  - Living our values
  - Sharing the financial success of the company with employees

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# SIDLEY AUSTIN BROWN AND WOOD, LLP

## JEFFREY P. KUSHAN

PARTNER

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JEFFREY P. KUSHAN counsels and represents clients on a diverse range of intellectual property matters, including patent procurement, licensing, policy and litigation. He specializes in Hatch-Waxman patent litigation, patent appeals, and complex patent administrative proceedings. In 2003, he was named one of the top 45 lawyers in the United States under the age of 45 by *American Lawyer* magazine.

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Before private practice, Mr. Kushan worked for the United States Government for over a decade. He served for two years with the Office of the U.S. Trade Representative in Geneva, Switzerland, where he represented the United States on intellectual property matters before the World Trade Organization and the World Intellectual Property Organization. While at USTR, he participated in WTO dispute settlement proceedings in the WTO concerning intellectual property matters, and served as chief U.S. negotiator in the WIPO "Internet" treaties. At the Patent and Trademark Office, he served as an attorney advisor in the Office of Legislative and International Affairs, where he helped develop and implement examination standards for biotechnology and software inventions, and worked on a variety of legislative and regulatory matters, including the implementation of the TRIPS Agreement. He also participated in international activities on behalf of the United States, including negotiations of the Convention on Biological Diversity and bilateral trade agreements. Initially, Mr. Kushan was a biotechnology patent examiner with responsibility for evaluating pharmaceutical and diagnostic protein-based inventions.

Mr. Kushan is a frequent lecturer on domestic and international intellectual property policy issues, particularly those relating to patents in the pharmaceutical and biotechnology industries. He is a member of the adjunct faculty and the Intellectual Property Advisory Board of the George Washington University. He serves on the executive committee of AIPPI-US, is Chair of the Patent Legislation Committee (Committee 101) of the ABA Section on Intellectual Property Law, and is active in American Intellectual Property Law Association.

Mr. Kushan received a B.S. in Chemistry from the College of William & Mary, a M.A. in bio-organic chemistry from the University of North Carolina at Chapel Hill, and a J.D. from the National Law Center of the George Washington University.