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Major Biotechnology Issues for the U.S. Patent and Trademark Office

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MAJOR BIOTECHNOLOGY ISSUES FOR THE U.S. PATENT AND TRADEMARK OFFICE

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* Bruce Lehman was nominated to be Assistant Secretary of Commerce and Commissioner of Patents and Trademarks by President Clinton on April 23, and was confirmed by the U.S. Senate on August 5, 1993. During his tenure, Mr. Lehman has streamlined the Patent and Trademark Office (PTO) to create an agency that is more responsive and customer focused. He has launched an ambitious reengineering effort to enhance efficiency and improve quality in patent and trademark examining operations. As part of an ongoing endeavor to establish quality services, public hearings have been held throughout the country to learn more about the concerns and needs of PTO customers. The results of these sessions include new guidelines for patents in the biotechnology field, and the establishment of partnerships with the City of Sunnyvale, California to provide better service closer to home for the California high tech industry and with the Detroit Public Library to bring PTO information and services to the Great Lakes and mid-west region.

Mr. Lehman has been a key player on intellectual property issues between the United States, Japan, and the European Union. He has also headed numerous delegations to consider intellectual property at the World Intellectual Property Organization and guided the development of legislation implementing the intellectual property provisions of the TRIPs agreement in the Uruguay Round. As a result of these efforts, American inventors can now more easily pursue commercialization of their inventions in the highly lucrative Japanese marketplace.

In addition to serving as Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Mr. Lehman chairs the Working Group on Intellectual Property Rights within the Information Policy Committee on the Information Infrastructure Task Force chaired by the Secretary of Commerce. The group released a Report on Intellectual Property and the National Information Infrastructure on September 5, 1995. The Report examines the role of copyright law in cyberspace and makes limited recommendations to change the Copyright Act to ensure sound protection of intellectual property in the networked environment.

Mr. Lehman's work and accomplishments have won international praise. In 1994, he was named lawyer of the year by the National Law Journal, the largest selling publication for lawyers in the United States. In recognizing Mr. Lehman, the Journal noted that "this has been the year of intellectual property–the second industrial revolution–and Bruce Lehman has personified intellectual setting the rules of the road for the information superhighway, conducting a public education program and providing a balance between owners of the content and public interests."

Mr. Lehman joined the Patent and Trademark Office from the law firm of Swidler & Berlin in Washington, D.C., where he worked for 10 years. Prior to joining Swindler & Berlin, Mr. Lehman served for nine years as Counsel to the Committee on the Judiciary of the U.S. House of Representatives, and Chief Counsel to the Subcommittee on Courts, Civil Liberties, and the Administration of Justice. Mr. Lehman served as the committee's principal legal advisory in the drafting of the 1976 Copyright Act, the 1980 Computer Software Amendments and 1982 amendments to the Patent Laws.

In more than nine years of private law practice, Mr. Lehman represented individuals, companies and trade associations in the area of intellectual property rights as it affects the motion picture, telecommunications, pharmaceutical, computer software, and broadcasting industries. While in private practice he served as a member of the Advisory Board of The Bureau of National Affair's Patent, Trademark and Copyright Journal, and as a member of the District of Columbia General Hospital Commission, the board of directors of Washington's largest public hospital.

Prior to his service with Congress, Mr. Lehman served as legal counsel to the Wisconsin State Legislature, as an attorney with the U.S. Department of Justice and as an officer in the U.S. Army. Mr. Lehman was born in Beloit, Wisconsin, on September 19, 1945, and graduated from the University of Wisconsin in 1967 and its law school in 1970. He is a member of the Bar of the District of Columbia.

INTRODUCTION

There are few subjects of greater importance to the development of biotechnology than the issuance of patents. Therefore, I was disturbed to hear Dr. Edward Penhoet's comments about the twenty-year patent term.[1] This is one of the things I am going to address in this discussion, which addresses the major issues in biotechnology facing the U.S. Patent and Trademark Office (PTO). Indeed, there are a number of major issues regarding biotechnology facing the Patent and Trademark Office, and I think that one could reverse that by saying that some of the principal issues facing the biotechnology industry have to do with not only the PTO, but the whole question of patenting in general.

Obviously, patenting is a very important part of commercializing biotechnology. The biotechnology industry requires considerable capital expenditure, not only for the initial research and development, but also to go through the regulatory approval process necessary to get a product—particularly a pharmaceutical product—on to the market.[2] That capital is essential and the ability to get that capital is very much dependent upon the capacity to get patent protection for a prospective product.

The first thing that must be understood, but which is unfortunately often forgotten, is that patent protection in the United States is patent protection, yes, but we are in a global economy. This means that products with patent protection in the United States will not necessarily receive patent protection on a global basis. Effective and timely patent protection in the United States may give a U.S. based innovator the capital necessary to continue without his research and develop a marketable invention. However, from a larger national policy perspective, it is no good to make American consumers pay by respecting the patent monopoly for the research and development costs of a particular product, only to give it away to the rest of the world for free. This is very important to remember, and I think American consumers have limited tolerance for this practice. Indeed, we often see that limit when particular fruits of biotechnology or other types of medical and pharmaceuti-

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1. Edward Penhoet, Ph.D., *Science & Technology Policy: A CEO's View*, 33 CAL. W. L. REV. 15, 23-29 (1996) (this volume). Prior to June 8, 1995, the term for a patent issued in the United States was seventeen years from the date of the patent grant. The implementing legislation under the General Agreement on Trade and Tarrifs (GATT) amended 35 U.S.C. § 154(a)(2) to change that term to one of twenty years from the date of filing the original application.

This change takes into account the prosecution process of the patent; if the process takes less than three years, the patent holder will receive a longer patent term under the new twenty-year term than he otherwise would have under the old seventeen-year term. On average, only 5% of the patent applications take more than three years, though biotechnology patents are among the slower applications. Kenneth J. Burchfiel, *U.S. GATT Legislation Changes Patent Term*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 222-224 (1995).

2. It takes an average of $359 million and about 10 to 12 years to bring one new pharmaceutical to market. James B. Silberman, *The North American Free Trade Agreement Effects on Pharmaceutical Patents: A Bitter Pill to Swallow*, 12 J. CONTEMP. HEALTH L. & POL'Y 607 (1996).

cal research become very expensive. Therefore, we see a lot of pressure for early generic products to come on the market and for public policies that permit that to happen.[3] This trend, which is counterproductive to our industry, is likely to continue in the absence of a system that provides the same degree of protection globally for biotechnology products as we have here in the United States. This is at the core of the twenty-year patent term issue. Before I get into that subject more thoroughly, however, I want to highlight some of the other issues this Article addresses.

The question of an effective patent term is clearly a very important issue in the biotechnology area, but there are many other issues that also affect our handling of biotechnology products in the PTO. The first time I ever went to the University of California at San Diego, we held hearings on our utility guidelines for examining biotechnology patents in the Patent and Trademark Office. One of the criteria for gaining a patent in the United States is that an invention must be novel,[4] non-obvious,[5] and useful.[6] As a result, one must outline in his application what the utility, or usefulness, of the product is going to be. This has raised many problems in the area of biotechnology in recent years,[7] but I think we have effectively moved to resolve those problems. Still, the utility issue remains a very important issue.

In addition to utility, it seems like once we resolve one issue, another comes down the pike. For example, we are now starting to receive a sizable number of applications seeking patent protection for the genome sequencing emerging from the large genome sequencing projects.[8] These applications raise practical questions, as well as difficult policy issues. We had hearings related to some of those practical issues just three weeks ago at the University of California, at San Diego.[9]

Furthermore, there is a much larger policy question that hangs over the whole future of the biotechnology industry. This is the question of the extent

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3. *See* Michelle S. Marks, *The Impact of the Patent Term Provisions of the 1994 Uruguay Round Agreements Act on the Drug Price Competition Patent Term and Restoration Act,* 51 FOOD & DRUG L.J. 445, 449 (1996) (explaining that the Hatch-Waxman Act promotes the availability of generic drugs by allowing studies to be conducted before the expiration of the patent term. This promotes the public policy of reducing the costs of drugs for consumers.).

4. 35 U.S.C. § 102 (1984).

5. 35 U.S.C. § 103 (1984).

6. 35 U.S.C. § 101 (1984).

7. Notice of Public Hearing and Request on Patent Protection for Biotechnological Inventions, 59 Fed. Reg. 45267 (1994). The PTO was seeking public input to help insure it was properly construing and applying statutory requirement of patentability, particularly those that depend upon evaluation of skill levels in field of biotechnology. Also, the PTO asked for input regarding sufficient legal standard that are clear and appropriate for biotechnology inventors.

8. Dr. Craig Venter led one of the more prominent of these projects. On May 24, 1995, he and another scientist announced that for the first time, a complete DNA sequence of a free-living organism had been decoded. The sequence is the entire genetic code of the bacterium Hemophilus influenzae. Nicholas Wade, *Bacterium's Full Genetic Makeup is Decoded,* N.Y TIMES, May 26, 1995, at A1.

9. *E.g.,* Notice of Hearings and Request for Comments on Issues Relating to Patent Protection for Nucleic Acid Sequences, 61 Fed. Reg. 9980 (1996).

to which we are going to continue to patent life forms.[10] It is unclear what role we in the PTO will play in answering this question. I am not certain that such a role is something that I have any control over directly, one way or another, because it is ultimately in the control of Congress. This is certainly a large international issue, and I must say, it gets my blood boiling to hear Eileen McMahon's remarks[11] that a major trading partner, Canada, with whom we are supposed to have reasonable relationships, has already embarked on seeing that all the fruits of U.S. research in this area will be in the public domain.[12]

This leads me into the final issue, which is the international system that overlays all these other issues. The international system is related to each and every one of the previous issues, but it is also a issue standing on its own. We are very much in the biotechnology era, an era in which we have made much progress toward common international standards for the protection of intellectual property[13]; however, there are still many questions lingering around other places in the world as to whether those new standards are even going to apply. It is even unclear as to whether the standards developed in the Uruguay Round Implementing Act,[14] such as the TRIPS agreement,[15] are even going to apply on an international level.

PATENT PROTECTION IN A GLOBAL ECONOMY: THE TWENTY-YEAR PATENT TERM ISSUE

The twenty-year patent term issue has two sides. First, there is the question of the twenty-year term from filing and its implications for the biotechnology industry. The United States, as part of the Uruguay Round Implementing Act enacted over a year ago last December, went from a patent term of seventeen years from the date of the issuance of the patent to a term

10. *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980) (holding that a live, human-made organism may be patented under 35 U.S.C. § 101).

11. *See* Eileen McMahon, *NAFTA and the Biotechnology Industry*, 33 CAL. W. L. REV. 31, 33-36 (1996) (this volume). *See also* Eileen McMahon, *Nucleic Acid Sequences and Other Naturally Occurring Products: Are the Patented in Canada*, 10 CAN. INTELL. PROP. REV. 11 (1993) [hereinafter McMahon, *Nucleic Acid Sequences*].

12. McMahon, *Nucleic Acid Sequences*, *supra* note 11, at 11.

13. General Agreement on Tarrifs and Trade Multilateral Trade Negotiations (The Uruguay Round): Agreement Establishing the Multilateral Trade Organization (World Trade Organization), Dec. 15, 1994, 33 I.L.M. 13; Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Apr. 15, 1994, 33 I.L.M. 1197; Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiators, Apr. 15, 1994, 33 I.L.M. 1125.

14. Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125.

15. The Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *opened for signature*, Apr. 15, 1994, 33 I.L.M. 1197. TRIPS established minimum international standards and rule for intellectual property protection as well as minimal procedural norms for enforcement.

of twenty years from the filing of a patent application.[16] This change is what many people identify as the key issue when they discuss patent terms.

The second issue regarding the patent term is a subspecies of the change in term, which is also somewhat controversial. Although it concerns fewer people, the people it does concern are very concerned about it. This issue is how we in the U.S. PTO and the FDA are interpreting the transition period from the seventeen-year issuance system to a twenty-year from filing system; and particularly, how that relates to the administration of the so-called Hatch-Waxman Act[17] and the Patent Term and Drug Price Competition Act of 1984.[18] I suppose that raises the question of whether the Patent Term and Drug Price Competition Act should even be revisited.

The reasons why we in the United States have chosen to adopt a term of twenty years from filing are extremely sound. First, we were virtually the only country in the world that did not measure the patent term twenty years from filing. When I first became involved in this subject matter many years ago, I asked the question, "What's the difference between the twenty-year term that everybody else has and our seventeen-year term?" The answer I received was, "Not much, because it takes you three years to get through the PTO here." A few months or a year or two may be the practical difference, but the practical effect is the same. In Germany, you have three years to get through the patent office and then you have seventeen years of patent protection. In the United States, you have three years to get through the PTO, and then you have seventeen years of patent protection. In either case, the protection comes out to twenty years.

Industry reliance on these time frames is so strong that there was a major negative reaction when patent processing times started to creep up to an average of about 36 months in the 1980s, causing many patents to take longer than 36 months from the time they were filed to issue. In response to this problem, we began restructuring the PTO so as to decrease pendency and so that, as a practical matter, no patents would take longer than 36 months to issue. Indeed, that project was extremely successful. Today, in the U.S. PTO, the average pendency for a patent is 19.1 months. Although there was no incentive to process an application in less than 36 months prior to the enactment of the Uruguay Round, other than just doing our job quickly, there was no effective loss of patent term if it did take longer than 36 months to

16. 35 U.S.C. § 154(a)(2) (1996).

17. 35 U.S.C. § 156 (1996) (requiring that restoration extension of a patent term for delay caused by the Food and Drug Administration (FDA) approval process not preclude application of restoration extension to patent term changed from seventeen years after issuance to twenty years, pursuant to the Uruguay Round Agreements Act); Merck & Co., Inc. v. Kessler, 80 F.3d 1543 (1996) (confirming that a patent with a term of twenty years from filing pursuant to URAH, could also be extended through the restoration expansion provided by the Hatch-Waxman Act due to delays in the FDA approval process).

18. Patent Term and Drug Price Competition Act of 1984, Pub. L. No. 98-417, 98 Stat. 1598 (codified as amended at 35 U.S.C. § 156) (1984).

issue a patent.[19] Therefore, if a person wanted to drag out the process, and some people did, they could do so.[20] Even so, the statistics show that at the time we shifted to the new system, less than 5% of U.S. patents were issued in a time period greater than 36 months after filing. Thus, only a very small group of patents cannot be processed in 36 months.

There are some who criticize the twenty-year term. Some fear that they will lose patent protection because we will not be able to issue a patent within 36 months. Therefore, they will have less patent time than the traditional seventeen years. Our response to this fear is that 5% is a fairly manageable number.[21] We are in the process of re-engineering our systems in the PTO so that we can virtually guarantee that no patent will take longer than 36 months to process.[22] Thus, everyone will have at least seventeen years of protection.[23] As a practical matter, most patent applicants will have more

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19. G. Lloyd Knight, *An (UN)Intended Transitional Provision in the GATT Act–20 Years from When?*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 717 (1995). Before implementation of twenty year inclusive term, the seventeen year term started from the date the patent was issued. Therefore, if it took longer than thirty-six months to enact a patent, there was no loss of the seventeen year patent term.

20. The strategy behind dragging out the process is that the term does not begin to toll until the clinical trials are complete.

21. I understand the position of those who have a particular patent pending, which they have put their hearts and souls into, as well as all their money and all their friends' money. For them, nothing is more important than that patent. But the real issue here is the relationship between the patent examining process and the regulatory approval process in the FDA. It is simply a fact that in these cases where there are particular approval problems, such as financing or the wherewithal to engage in the testing, a very convenient tool to drag out the issuance of the patent and therefore extend your patent term without having to deal with Hatch-Waxman, was to file continuances in the PTO. Every single major user group of the PTO from the National Association of Manufacturers to the Electronics Industry Association, the Software Publishers Association, the American Intellectual Property Association, the American Bar Association, intellectual property law section and on and on and on, has asked us and the Congress to go to a twenty-year term because their interest, uniformly, is in having a common international standard so that patents cannot expire at different times in the United States than when they expire abroad. No electronics company wants to be in a position where a competitor's patent, many times a foreign competitor's patent, expires three years earlier in Japan or Germany than it does in the United States. Then, they are prohibited from using that as public domain material, which their foreign competitors can do, and they have their hands tied behind their back. We have to look at what the majority of American industry is saying.

22. In the event that the PTO does not diligently prosecute a patent application, the bills currently pending on Capitol Hill provide for an extension of the patent. This technique is more effective because it is not simply a one-size-fits-all system that prejudices 90% of the other high-tech industries in America, putting them at a competitive international disadvantage. H.R. 3460, 104th Cong., 2d Sess. (1996); H.R. 1733, 104th Cong., 2d Sess. (1995).

23. Some of the new measures are as follows:

> Under this legislation, the total duration of all extensions shall not exceed 10 years. To the extent that periods of delay overlap, the period of any extension granted shall not exceed the actual number of days the issuance of the patent was delayed;
>
> No Patent shall be extended that has been issued before the expiration of 3 years after the filing date of the application leading to the patent or the commencement of the national stage, whichever is later, not taking into account the benefit of any earlier filing applications of this title;
>
> The period of extension of the term of a patent under this subsection shall be reduced by a period equal to the time during the processing leading to the patent in which the applicant failed to engage in reasonable efforts to conclude processing or

protection.[24] For the vast majority of U.S. patent applicants, the Uruguay Round Implementing Act amendments extended their patent terms.[25] We will have longer patent terms than we had before. Therefore, if we were to try to reverse the Uruguay Round Implementing Act amendments and return to the old system, a lot of people would object. In fact, it probably would have become a subject of former-Senator Dole's takings legislation[26] that he was going to send to the Senate floor, claiming that we would be taking away people's property rights. People certainly would not like such a reversion at all. Indeed, nothing illustrates this more than the fact that one of the most controversial sub-issues in this larger patent term issue is the question of the impact of the transition rules in the Uruguay Round Implementing Act on certain patent applicants. There were more than twenty pharmaceutical companies whose patents were issued prior to 36 months originally and, therefore, received longer initial patent terms under the new system. When the extensions provided under the Hatch-Waxman Act[27] were added to the patent term, they gained even longer protection.[28] When we in the PTO decided to run the Hatch-Waxman extensions from the seventeen-year term,

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examination of the examination.

H.R. 1733, 104th Cong. 2d Sess. (1995).

> The total duration of any extensions shall not exceed 10 years. To the extent that periods of delay overlap, the period of any extension granted shall not exceed the actual number of days the issuance of the patent was delayed;
>
> The period of extension of the term of a patent shall be reduced by a period equal to the time in which an applicant failed to engage in reasonable efforts to conclude prosecution of the application;
>
> No patent the term of which has been disclaimed beyond a specific date may be extended under this section beyond the expiration date specified in this disclaimer.

H.R. 3460, 104th Cong., 2d Sess. (1996).

24. H.R. 1733 would weaken the patent system by mandating that a patent term will be measured by the filing date agreed to in the GATT agreement. "It scraps the 17-year patent protection in favor of a 20-year term extending from the day an application is filed. Under this arrangement, a patent that takes 15 years to grant–and many technical patents requires an extensive review process–would be entitled to only 5 years of protection." 142 CONG. REC. 7137-01 (1996) (statement of Rep. Forbes).

25. *Id.*

26. S. 22, 104th Cong., 1st Sess. (1995).

27. To qualify for an extension under the Hatch-Waxman Act, a patentee much provide the PTO with evidence of the actual amount of the patent term consumed during the premarket approval process. The act established a 5-year limit on the extension, which applies irrespective of the actual loss of the patent term. For patented human pharmaceuticals and food or color additives, which had entered the regulatory approval process prior to the date of the enactment of the Act, the maximum extension was set at 2 years. In any case, however, the overall patent term cannot exceed 14 years from the time of FDA approval. S. REP. NO. 414, 102d Cong., 2d Sess. (1992).

28. In 1836, the Patent Act was rewritten and the new law authorized a 7-year patent extension upon a showing by the holder that, without fault or negligence on his part, the patentee had failed to obtain reasonable remuneration for his time, ingenuity, and expense. Extensions were generally granted when the federal government was the cause of, or contributed to, the failure to be able to take advantage of the patent. Therefore, the Hatch-Waxman Act stretched out the overall patent term to 14 years. S. REP. NO. 414, 102d Cong., 2d Sess. (1992).

and not from the twenty year term, we were sued by those companies—and we recently lost in that litigation.[29] At least, we lost initially in the district court and the Court of Appeals for the Federal Circuit. There is still an open question as to whether we will appeal that decision to an *en banc* reconsideration in the Court of Appeals for the Federal Circuit, or even possibly file a petition for certiorari in the U.S. Supreme Court. Nevertheless, this proves that there are at least twenty large pharmaceutical companies out there that do better under the twenty-year term than they would have done under the old seventeen-year term.

When we begin talking about months and twenty-year terms, the Hatch-Waxman Act, the Uruguay Round Implementing Act, and everything else, it becomes quite complicated. But the real issue here is the issue of under what circumstances should delay, either in the issuance of a patent or in the effective ability to utilize the patent, be recognized in the context of patent term restoration?[30] This is the real issue. Presumably, if Hatch-Waxman and the 1984 Patent Term Restoration and Drug Price Competition Act were working, at least in the manner that many biotechnology innovators would like them to work, there would be no concern at all. If the FDA took a long period of time to approve a product, they would have relief in the form of an extension of their patent. So, when people criticize the twenty-year term, they are really criticizing their inability to take advantage of a "loophole" in the law that was provided earlier. This loophole allowed them to stall in the PTO, so that in getting a patent issued, quite apart from the congressional policies specifically mandating patent term extensions in certain cases where there is a very long FDA approval period, they would get an extra extension that we would create because they were "futzing" around in the PTO and delaying the process. That is the behavior we are talking about here and I think we have to be very clear about that.

If that is the issue, then my response is that it is inappropriate to prejudice 99% of the users of the PTO, as well as all of the other users of the intellectual property system who want a very secure twenty-year term from filing, simply to provide this extra advantage to the biotechnology industry. If there is a case to be made for longer patent terms for the biotechnology industry and the 1984 legislation is inadequate, then we should focus on that and amend that legislation to resolve the problem.

That pretty much describes the patent term issue and I think it is wishful thinking to believe that it will change. There is legislation pending on Capitol Hill to modify the 1994 legislation, the Uruguay Round Implementing

29. Merck & Co., Inc. v. Comm'r of Food and Drugs, 80 F.3d 1543 (Fed. Cir. 1996).

30. *Id.* Patent term restoration is the term used when a patent, which has expired because of delays in obtaining FDA approval, is restored. With respect to any restoration period granted after June 8, 1995, this fourteen-year limitation will be part of the calculation of the permissible number of days of the restoration extension. *Id.* at 1551. A patent in force on June 8, 1995, is entitled to have restoration extension, whenever granted, added to the term of either seventeen years from issuance or twenty years from filing. *Id.* at 1553.

Act, but I would not count on its passing. I do not believe that legislation will pass; it has not passed yet. I think the twenty-year term from filing is here to stay. Therefore, we should focus on what the real issues are and not go back to the old system.

REINVENTING GOVERNMENT: UTILITY GUIDELINES

The next set of issues, which is perhaps a little less cosmic but very important, is the question of utility guidelines. I think this is a good example of our doing good government, reinventing government. I believe these reinventing efforts will continue, but it was very clear when I came into the PTO three years ago, that there was still a very large residue of old thinking in the PTO. This thinking was that the role of a patent examiner is to create hurdles that a patent applicant had to cross and that if you were really clever and developed some nice hurdles and the applicant was able to jump over them, then he deserved a patent. It was a very adversarial proceeding. In fact, I remember at one point in my career many years ago, someone referred to the prosecution of patent applications at the PTO as *ex parte* litigation. That is certainly not the way in which we in the Clinton administration are proposing to do business.

There are legal standards for the patentability of virtually every invention that is proposed to the PTO.[31] The only issue for us is to determine whether the applicant has met those standards. If he has not, then we help him try to meet those standards where we clearly can, and then get him out of the PTO as quickly as possible and into the marketplace where he can get venture capital and strengthen our economy by making his invention into new products that are going to make us globally competitive and put people to work. That is our function.

Ironically, in the biotechnology area, we have found reforms that we had made which were initially thought to be positive, turned out to exacerbate the old thinking. That is, if you projected yourself back ten years ago when the biotechnology industry was really growing, we did not have an adequate examining staff in the PTO to handle these very high-technology applications. We had a lot of people with B.S. degrees in chemical engineering, who were trying to examine patents in this very complicated recombinant DNA-based technology. We moved to fix that. We are very proud of the fact that we now have approximately 150 Ph.D.s examining biotechnology applications, many with post-doctoral work. In this sense, our office is unique in comparison with the rest of the world.

Unfortunately, when we hired all of these great Ph.D.s, we were so busy that we put them right to work without telling them much about the patent system. As a result, we began to see that the PTO procedures looked more like oral examinations for Ph.D.s in biotechnology and that we were engaging

31. *See* 35 U.S.C. §§ 101-103 (1984).

in peer review rather than patent examination. So, we moved to correct that problem. We held hearings in California and in Washington and heard from people in the biotechnology industry. And we wrote a new set of guidelines[32] to guide examiners and then trained them on how to apply the law. As a result, we have seen a very substantial reduction in the number of rejections. In fact, our data shows that before the guidelines were issued, utility rejections under section 101 of the United States Code[33] were made in about 5.9% of the applications. After we issued our final guidelines, such rejections dropped to a mere 1.9% of the applications, one-third the previous number. Obviously, that is good news to a lot of people. Not only is it good news to the people who are now getting through the system who were not before, it is also good news for everybody else because those examining resources will be put where they are needed and not engage in needless activity.

The essence of the utility guidelines was that we were getting ourselves into a problem that is actually somewhat related to the FDA. That is to say, if you take a strict constructionist view, you do not know whether a pharmaceutical or biotechnology invention is really going to be useful until you have gone all the way through the human testing process. The essence of our work was to avoid that. That would obviously be a completely unworkable situation. For example, if you published your results, but did not subsequently file a patent application in the United States within twelve months, you would never be able to patent your work. Instead, it would go into the public domain. In the rest of the world, work goes into public domain if you publish without having first filed an application. You would be placed in a terrible position if you had to make your work available and go through the testing, all of which would be available to the public; neither would you able to file the patent application until maybe five or six years later.[34] If this were the case, then nothing could be patented. This was obviously not the intention of the law.

To avoid the paradox just described, we now look at the affidavits filed with the applications and give consideration to the expert opinions assuring some reasonable expectation that the technology proposed will be useful. This is simply a question of applying common sense to our procedures and utility guidelines. Let me say, though, there are those who would like to suggest that almost any representation made to the PTO should be accepted at face value and that we should issue a patent on everything. This clearly is not the case. There are always going to be people who will be disappointed. We hear that some people feel that section 112 rejections, enablement

32. Utility Examination Guidelines, 60 Fed. Reg. 36,263 (1995).

33. "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (1996).

34. The delay would occur because it would take this long for the applicant to accumulate enough data to satisfy the utility requirements for a patent.

rejections,[35] are being substituted by some examiners for the utility rejections[36] that they used to make.[37] Indeed, we found this to be the case in some situations and we have moved to correct that, but enablement, being able to describe how you enabled use of the invention, is a very important aspect of patent law and we cannot give that up completely.

Maybe that is a good way to lead into the next issue, genome sequencing, particularly the human genome sequencing[38] applications.

GENOME SEQUENCING APPLICATIONS

This is an issue that might have ripened earlier, had not the National Institutes of Health (NIH) in the person of Harold Varmis, the director of the NIH, made a decision very early in his tenure to withdraw the applications that the NIH had presented before the PTO. That decision, I think, was really made on policy grounds and there is a serious policy question hanging over this area. Obviously, the role of the patent system is to encourage innovation.[39] It is not to create a tollgate to innovation. There is a question in many people's minds, certainly those in the scientific community, as to whether the patent applications which are being filed for this particular technology do not operate as tollgate type patents for further research, as opposed to incentives for innovation.[40] This is something we will be examining more closely in the future.

This also raises the especially practical problem that these applications are enormously difficult to process. Simply running the genome sequences

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35. Section 112 requires that a specification shall contain a written description of the invention as well as the manner and process of making and using it. The specification must be in such full, clear, concise, and exact terms as to enable anyone skilled in the art to which it pertains to make and use the invention. 35 U.S.C. § 112 (1996).

36. U.S. CONST. art. I, § 8, cl. 8; 35 U.S.C. § 101 (1996).

37. Rejections which assert that an invention is inoperative, and therefore lacking utility under 35 U.S.C. § 101, are often accompanied by rejections which assert that the specification is not "enabling" under 35 U.S.C. § 112. The problem with Section 112 is the requirement that the inventor's disclosure enable any person "skilled in the art" to make and use the claimed invention. There is some controversy as to the meaning of "skilled in the art" for the purposes of analyzing utility and enablement. The lack of precision concerning the meaning of "skilled in the art" has led to criticism of inconsistent standards. Nada Jain, *To Patent or Not to Patent: Gene Therapy in the European Union and the United States*, 4 CARDOZO J. INT'L & COMP. L. 103, 129 (1996).

38. The aim of human genome sequencing is to discover and document the entire genetic make-up of the human body. Sequencing of genomes is best described as the unraveling of information, that is the genetic code, contained within each human gene. Charles DeLisi, *The Human Genome Project*, 76 AM. SCIENTIST 488 (1988).

39. The United States Constitution grants Congress the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to use their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8.

40. Dr. Varmis' decision to withdraw the NIH applications from the PTO is telling. Perhaps it was feared that the filing of these patents would infringe on subsequent research due to the complexity of this field and the difficulty of drawing distinct boundaries at this early stage of research. Without more precision and clear definition of the boundaries, these early patents may have preempted subsequent filings and had a chilling effect on future research.

through the computer takes months of computer processing time. It will literally tie up our mainframe computers at the PTO and we will not be able to do any other patent applications. There are also questions of cost. We had hearings about this and received many recommendations as to how we can deal with this practical problem. We are still sorting through those recommendations, but we are going to have to come to terms with them.

U.S. REGULATORY AFFAIRS IN THE INTERNATIONAL CONTEXT

Finally, I would like to revisit the larger question, the international context for all of this. I am, as a public official, responsible for seeing that the United States has a regulatory and legal framework that assures the greatest possible economic growth and puts our society in the most competitive global position possible. This is extremely important in a period in history where the two most significant factors affecting our society are technology and the globalization of the economy. We cannot look at any problem in the United States, particularly if it concerns technology, without considering its global implications.

We have made a great deal of progress in getting basic recognition for intellectual property rights in countries around the world, as well as basic recognition for intellectual property rights, particularly in pharmaceutical technology. Nevertheless, the nature of the world is such that we always seem to be trying to catch up; history moves ahead faster than we can follow. That is very true in this area. I see us already headed toward yet another trade crisis within a few years if our foreign colleagues decide to diverge from us and decide that they will not patent life forms. If they decide to treat biotechnology differently than the United States does, we are going to have a major trade problem. That is simply unacceptable to the United States. We cannot have our people subsidize biotechnological research for the rest of the world and, at the same time, diminish the value of this investment as an asset in international trade. People cannot expect us to import automobiles and timber from Canada or textiles from China and then allow these countries simply to expropriate the fruits of our biotechnological research.

CONCLUSION

One of the many things we must do is to move in the direction of other countries—this is one reason why we adopted the twenty-year patent term; but we must expect them to come halfway as well. One of the issues that will clearly be on the table, an issue we have already started to discuss,[41] is the terms and conditions under which we will patent biotechnological research around the world. Our professional colleagues in Europe are very much on

41. In fact, in May 1996, I discussed this issue with officials from New Zealand and Australia, as well as with Artpad Bosch, the Director General of the World Intellectual Property Organization.

the same wavelength as we are, both in the European Patent Office and in the European Commission. Although the European Parliament rejected a draft directive by the European Commission[42] to deal precisely with this problem of biotechnology, they are considering a new directive. Those rejections stem largely from a total misconception of what the patent system is all about. We are not proposing to make slaves of a particular group of people whose genetic material may have been used in research. All we are proposing is to do what we have always done: provide for a novel, non-obvious, and useful innovation which has never before existed in the history of the world. We want to give a very limited period of commercial exclusivity to a fruit of the human mind, something that an individual has come up with so that his investment in that effort can be recouped. If this is not provided, the consequence will be that such useful innovations will be stifled.

In the short term, such stifling may be good for the United States. We will see more research conducted in the United States and the world's biotechnology industry increasingly concentrate here. However, this is not acceptable in the long-term because though it is wonderful to have all these new inventions in the United States, we cannot (and will not) subsidize the creation of biotechnology for the rest of the world.

42. Council Regulation 2641/84 of 17 September 1984 on the Strengthening of the Common Commercial Policy, 1984 O.J. (L 252) 1. Council Regulation 2641/84 was enacted to defend the legitimate interests of the European Union and to ensure that the Community acts with as much speed and efficiency as it trading partners. In both the United States and the European Union, there appears to be a general consensus that the development of biotechnology is dependent on the co-evolution of biotechnology and patent law. *See* Jain, *supra* note 37, at 129, 130.