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Implications of Recent Patent Law Changes on Biotechnology Research and the Biotechnology Industry

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I. Introduction

1. The purpose of the U.S. patent system is to promote work in the sciences and useful arts by providing a reward to inventors as an incentive to disclose information for the benefit of the public.[1] The reward is given in the form of a grant from the federal government of the right to exclude others from making, using, or selling an invention.[2] U.S. public policy regards patents as a means for creating new industries and jobs. The U.S. system is based on quid pro quo; strong protection is granted for a limited time in exchange for complete disclosure. By granting an exclusive right to the inventor to manufacture and sell an invention for a certain amount of time, the inventor will have a financial incentive to invest in the discovery of new innovation. This incentive will be particularly important in the pharmaceutical and biotechnology fields, where important discoveries often require extremely expensive and time consuming research and development.[3]

2. In the past, Congress has passed legislation with the purpose of promoting pharmaceutical and biotechnology research. For example, in 1980, Congress passed the Patent and Trademark Act amendments to encourage universities to patent inventions made in the course of government-sponsored research.[4] In 1984, Congress found that the effective life of patents for pharmaceuticals was shortening as a result of the significant amount of time often required for pre-market approval by the Food and Drug Administration (FDA). Congress also found that the decrease in patent life was causing a decline in the introduction of new research.[5] Furthermore, Congress found that pharmaceutical corporations, in particular, had demonstrated the need for financial incentives to commit to the high cost of research and development. Therefore, Congress passed the Drug Price Competition Act and Patent Restoration Act of 1984, which allowed a patent term for a drug to be extended if the drug was waiting for pre-market approval from the FDA.[6]

3. The biotechnology industry itself is a relatively new phenomenon. In just fifteen years, biotechnology has changed from a virtually non-existent business to an industry creating almost $8 billion in revenues and over 100,000 jobs.[7] In 1994 alone, the biotechnology industry spent $7 billion on research and development. In fact, the biotechnology industry is now responsible for creating more innovative food and medical treatments for cancer and heart patients than all other research industries combined.[8] Also during the last 15 years, significant changes have occurred in U.S. patent law, particularly those changes arising from the creation of the Court of Appeals for the Federal Circuit, as well as the General Agreement on Tariffs and Trade (GATT) Uruguay Round implementing legislation.[9] These recent changes in patent law, as well as upcoming legislation, are likely to have a significant impact on the future of the biotechnology industry.

4. In 1982, the United States Congress created the Federal Circuit, which now has exclusive jurisdiction over all appeals in patent cases. Before the creation of the Federal Circuit, patent cases went to any one of eleven different federal appellate courts. Many people, including Congress, believed that the widespread disparity in the application of patent law by the different courts had the effect of weakening patent protection. Therefore, the Federal Circuit was created to promote greater uniformity in the application of patent law and to reduce the availability of forum shopping by parties seeking favorable courts.

5. Since its creation in 1982, the Federal Circuit has decidedly been "pro-patent."[10] As a result, patent protection has increased and patent litigation has become increasingly worthwhile for many technical industries. Moreover, federal trial courts have followed suit by granting higher damage awards than ever before. In fact, high damage awards have driven some defendants to near bankruptcy.[11] For example, in 1990, Polaroid won over $870 million from Kodak after Kodak infringed the patented instant camera technology owned by Polaroid.[12] Therefore, as a result of the creation of the Federal Circuit and the large damage awards that have followed, patented innovations have been strongly protected in the United States in recent years. This increase in patent protection has given a vital incentive to many businesses to invest in the research and

development of biotechnology.

6. In the last few years, the GATT Uruguay Round implementing legislation, as well as other legislation, has also had a large impact on patent law and patent protection. Specifically, the length of patent terms, the creation of "provisional" patent applications, and changes concerning the "date of invention" in foreign countries are some of the new changes that will significantly affect the biotechnology industry. In addition, the possibility of publishing patent applications and the possibility of expanding third party participation in patent reexamination procedures have been heavily debated issues in recently proposed legislation.

II. Patent Terms

7. Although the benefit of social good and professional recognition can be a motivation, financial profit is often the critical incentive for inventors to conduct vital research.[13] By granting longer terms of patent protection, patentees will have an opportunity to receive royalties for a longer period of time. As more royalties are earned, more money can be invested in funds for future research and development. Therefore, decreasing patent terms could reduce incentives for researchers to continue valuable research and may decrease the availability of improved and affordable health care. Biotechnology innovations that have human diagnostics uses, such as drugs or medical procedures (*e.g.*, gene therapy), will often have very long development and clinical trial periods. By reducing the time of patent protection, many biotech industries may find that it is not financially worth the significant investment of expensive and time consuming research.

8. Up until now, patenting of biotechnology by small entities, such as startup biotech companies and academia (universities), has been very significant.[14] It is the small startup biotech companies, in particular, that are likely to be affected by changes in patent terms because these companies are often established upon the basis of innovative patents. It is probable that any shortening of patent terms will detrimentally affect the livelihood of many of these small entities. Conversely, foreign and multinational corporations will benefit if patent terms are shortened because they will be paying reduced royalties to U.S. inventors and investors.[15] Moreover, reducing patent terms will diminish royalties and, consequently, incentives for inventors to conduct biotechnology and biomedical research. This reduced benefit to inventors will be passed onto the public by way of reducing the availability of new and innovative medicine and increasing the cost of medical treatments. Therefore, it is in the best interest of the American people to have a strong patent system with patent terms lasting long enough to make biotechnology research and development a worthwhile investment.

9. Prior to the implementation of GATT, the term for a patent issued in the United States was 17 years from the date the patent was granted by the Patent and Trademark Office (PTO). The legislation implementing GATT, however, has amended 35 U.S.C. § 154 to provide that a patent granted after June 8, 1995 will have a patent term of twenty years from the earliest filing date of the patent application.[16] Therefore, although the new patent term is for a longer period (20 years

rather than 17 years), it begins at an earlier time. A patent term now begins at the moment an inventor applies for a patent, not from the time the patent has been granted. Under 35 U.S.C. § 154(b), however, the current patent law does allow for patent term extensions if there are delays in the application process due to interference procedures, secrecy orders, or successful appellate review.

10. One of the rationales for changing the patent term is that the current U.S. patent term is now more consistent with the rest of the world, particularly with Japan and Europe. Many still believe, however, that the 17-year patent term from date of issue in the best interest of promoting biotechnology research, as well as the U.S. economy in general. The advantages and disadvantages of the different patent terms are explored in the next several paragraphs.

A. Advantages of the 20-year From Date of Application Filing Patent Term

11. According to Bruce Lehman, the Commissioner of the PTO, the average pendency for a patent is 19 to 20 months.[17] If patents are granted within any time less than three years after the initial filing, an invention will have a longer patent protection time with the current 20-year term, as compared to the previous term of 17 years from patent issue. Since longer patent terms are beneficial to the biotechnology industry, the 20-year patent term could be favorable to biotechnology research. Commissioner Lehman has also asserted that as a result of the new patent term and the increase in number of patent applications over the years, the PTO now has an incentive to give speedier determinations of patent rights.[18] Therefore, the PTO is planning to re-engineer the patent system to produce a better patenting process. In particular, the PTO plans to reduce the PTO processing time, establish industry sectors within the patent cores, and receive and process applications and published patents electronically.[19]

12. One major advantage of the 20-year term over the previous 17-year term is that the 20-year term reduces the "submarine patent" problem. A patent application becomes a submarine patent when an inventor purposely refiles an application, or otherwise prolongs the application process, to prevent the patent from issuing. A patent might be submarined for the purpose of allowing a particular industry to use the invention before the patent is issued. Later, after businesses have been using the newly patented technology, those businesses will be surprised to discover that they owe automatic royalties to the patentee. Under the current 20-year term, however, inventors could lose protection altogether if they submarine their inventions in the PTO by filing continuing applications.

13. In addition to patent term changes already implemented, recent legislation which was voted on by Congress this year could have provided an even longer patent term under certain situations. Last year, Representative Moorhead introduced H.R. 1733, a bill supported by the PTO, the American Bar Association, the American Intellectual Property Law Association, and Intellectual Property Owners, as well as the Clinton administration.[20] This Moorhead bill would extend the current 20-year patent term to allow a patent owner to receive an extension where issuance of a patent was

delayed due to "unusual administrative delays" by the PTO.[21] It would also enable an extension of up to ten years (as compared to five years under current law) for pre-issuance delays. H.R. 1733 was unanimously approved by the Subcommittee on Courts and Intellectual Property of the House Judiciary Committee.[22] Furthermore, on June 11, the House Judiciary Committee approved H.R. 3460, otherwise known as Moorhead's Omnibus Patent Reform Bill, which is a new bill proposed last May that combines former bills H.R. 1733, 1732, and 1659.[23] The 104th Congress, however, did not pass H.R. 3460 before adjourning in early October.[24]

14. Likewise, there were bills proposed by Representative Rohrabacher and Senator Dole (H.R. 359/S. 284, the Rohrabacher/Dole bills) that would change the current 20-year term to a term lasting either 20 years from filing or 17 years from issue, whichever is longer. Since the problems of submarine patents could still exist under the alternative term, however, H.R. 359/S. 284 were rejected by the Judiciary subcommittee by a vote of 12 to 2. Nonetheless, the Rohrabacher/Dole bills were sent up to the full Judiciary Committee.[25]

B. Advantages of the 17-year From Date of Issue Patent Term

15. Just prior to June 8, 1995 (the date that the 20-year patent term provision came into effect), there was a flood of patent applications to the patent office.[26] This huge increase in filing indicates that many inventors and patent attorneys believed that the 17-year term would provide more favorable protection than the 20-year term. Critics of the 20-year term have cited multiple reasons as to why the current 20-year term will result in shorter patent terms for inventors.

16. As mentioned previously, one justification for creating the 20-years-from-filing patent term is that the United States will now be consistent with patent terms worldwide, particularly with Japan and Europe. However, the European Patent Office and the Japanese Patent Office do not process patents at nearly the volume processed in the United States. For example, last year, 13,500 biotechnology patent applications were filed in the United States, compared to 1000 in Japan and 3500 in all of Europe.[27] Considering the magnitude of biotechnology patent applications filed in the United States and the fact that the number of biotech patent applications is clearly rising, it may not be in the best interest of the U.S. biotechnology industry to force the PTO to function under a system that might only be adequate for a smaller workload.

17. The PTO has stated that the average pendency for a patent is only 19 to 20 months.[28] John Doll, the Group Director of Group 1800 (Biotechnology), has stated that the average total pendency for Group 1800 was 21.4 months last year.[29] The pendency statistics from the PTO, however, may have determined by averaging the complex patents, which required relatively long examination processes, with the other ninety percent of patents that were relatively simple to process.[30] Therefore, an inventor who files a revolutionary and complicated patent is put in the same category as one who files a relatively straightforward application with little new technology. In addition, the 19 to 20 month average pendency statistics released by the PTO may be misleading

since the statistics are based on the most recent continuation date, and not the original or ancestral filing date.[31] Thus, a patent that required prosecution through four continuation-in-part applications over ten years would be counted as five applications with a pendency of two years, rather than one application with a pendency of ten years.

18. Biotechnology patent applications, in particular, will often involve the most pioneering and innovative research. In addition, biotechnology research can be extremely complex and unfamiliar to PTO examiners. Consequently, it will often be those patent applications involving newly developing biotechnology that require longer patent examination times. According to a recent journal article, by using the pendency figures of thirty patents from a recent 1994 Patent Gazette, the average pendency period is actually seven years.[32] Recent Congressional testimony of Diane Gardner of Molecular Biosystems, Inc., a small biotech company, has suggested that some biotech patent applications may take up to ten years or more to issue.[33]

19. Under the current system, the patent term could be determined by a number of factors that are outside of the control of the inventor. Any patent prosecution process by the PTO that takes longer than three years will cause the patent term to be less than 17 years. Therefore, the inventors will be at the mercy of the speed at which the PTO can perform. Specifically, inventors could be adversely affected by the significant increase in patent filing that has occurred in the last decade, especially during a time when the federal government is attempting to downsize.

20. Commissioner Lehman has stated that "we're no longer in the era of big government. We're no longer in the area of massive public expenditures . . . and we're going to be depending on the private sector to keep America strong technologically. And the very essence of private sector investment in technology is the patent system."[34] In other words, high technology areas such as biotechnology will be increasingly dependent on private funding, and thus, on the patent system to help provide those funds. However, the PTO (along with the rest of the federal government) is trying to reduce the size of the government, while at the same time the burden of work for the PTO is increasing.

21. For the last decade, the PTO has had an increase in the average annual work load between four and six percent.[35] Furthermore, in the last three years, the work load has shown an increase of over six percent.[36] And last year, the increase was thirteen percent.[37] In other words, the PTO now has thirteen percent more patent applications to deal with, while at the same time is under orders to not increase its work force.[38] The PTO claims it is in the process of designing a better procedure to process patents more quickly. Whether the PTO can succeed in providing a satisfactory way to deal with the increased workload without the benefit of an increase in personnel remains to be seen.

22. Group 1800 Director Doll has stated that the average primary examiner has 18.5 hours to completely examine a biotechnology application.[39] It is not clear, however, that 18.5 hours is sufficiently long enough to examine a complex biotechnology patent properly. For example, one

of most challenging areas in biotechnology for the PTO is the search and examination of DNA sequences. Faster and less expensive methods for identifying DNA sequences are continuously being created, and consequently, the number of patent applications involving DNA sequences has increased dramatically.[40] Furthermore, the PTO must send recombinant DNA sequences to be analyzed by a supercomputer in Los Alamos.[41] Moreover, it takes a enormous amount of an examiner's time to read an output from the computer.[42]

23. Above and beyond the time it takes to get a patent examined by the primary examiner, many biotechnology patents also undergo continuations-in-part, which can significantly increase the patent processing time. In fiscal year 1994, about 55 percent of biotech patent cases at the PTO were continuing applications, and the rate of filing continuing applications has remained very high compared to other areas at the PTO.[43] Biotechnology research and development in both the academic and industrial settings are continuing to move forward at an incredible rate. Often, inventors want patent applications to reflect new discoveries that are directly relevant to the invention at hand. Because of the nature of the field, the practice of continuing to perfect an invention after filing will be especially predominant in the biotechnology area.

24. As mentioned previously, another potential advantage of the 20-year from filing term is the elimination of submarine patents. However, it could be possible to prevent the problem of submarine patents by other means. For example, the PTO could prevent the abuse by refusing to accept continuing applications after a certain amount of time has passed after filing. Moreover, as discussed ahead, publication of patent applications could be another mechanism to eliminate the effects of submarine patents. In addition, although the possible abuse and damage resulting from submarine patents is potentially severe, submarine patents and the subsequent misuse of the patent system have not been a prevalent problem. In fact, most will contend that submarine patents have occurred only rarely in the past. Commissioner Lehman has stated that from 1971 to 1993 there were 627 cases out of approximately 2.3 million patents issued (0.027 percent) where the patent pendency exceeded 20 years.[44] Examination of these allegedly "submarine" patents cases by Donald Banner, former Commissioner of Patents under President Carter, has indicated that 257 of these are owned by the U.S. government and their issuance was probably delayed because of secrecy orders.[45] The remaining 370 may have also been held up by non-intentional delays, such as interferences and secrecy orders. Therefore, there is evidence to indicate that "submarine" patent abuses may be very minor.

25. If the patent terms begins at the date of filing, inventors may have to weigh the consequences of filing as quickly as possible against the repercussions of filing at a later time. Filing early has the obvious advantage of granting protection as soon as possible to the one who is the first to invent. Filing too early, however, can significantly reduce the time that an invention will be protected, particularly if the invention is still evolving and will involve continuations-in-part. Conversely, waiting to file an application could give the advantage of a longer patent term. Filing too late, however, could potentially cost the inventor significant patent rights. For inventors, the dilemma of whether to file earlier or later may become a prohibitively expensive gamble.

III. Provisional Patent Applications

26. In conjunction with changes in patent terms, recent patent law changes have established the "provisional" patent application.[46] In response to the previously mentioned concerns, provisional patent applications were specifically created with the interest of small entities (such as small businesses, independent inventors, and academia) in mind. A provisional patent application is similar to a non-provisional patent application in that it must state a detailed description of the invention and the best mode for practicing the invention. However, a provisional application can be filed for a reduced fee and does not require a claim, oath or declaration, nor does it mature into a patent. Therefore, provisional patent applications have the advantage of establishing an early filing date at a low cost and with very few legal and formal requirements. In addition, provisional applications are never published and remain confidential.

27. If an inventor files a provisional patent application, the inventor has up to a year to further develop the invention, acquire investors and capital, determine marketability, and seek licensing and manufacturing for the invention. In other words, a provisional application can "buy" a year of time for the inventor to determine whether the invention is worthy of further research, time and financial input. The invention will be protected for up to one year while the inventor decides whether to invest in a non-provisional patent application. Furthermore, the one year term of the provisional patent does not count toward the 20-year term.

IV. Date Of Invention In a Foreign Country: Section 104

28. Another important change in U.S. patent law that has occurred in response to GATT, as well as the North American Free Trade Agreement (NAFTA), is the "date of invention" in foreign country. Prior to the ratification of NAFTA and GATT, 35 U.S.C. § 104 stated that a patent application could not establish a date of invention in the U.S. by reference to knowledge, use, or other activity in a foreign country. Following the ratification of NAFTA and GATT, however, § 104 has been amended to allow evidence of inventive activities in NAFTA countries, as well World Trade Organization (WTO) member countries.[47] This change is significant since the WTO now has over 100 member countries and encompasses nearly all of the industrialized world.

29. References to inventive activity in NAFTA or WTO member countries are now to be treated the same as inventive activity in the United States. In other words, if an invention is made in a NAFTA or a WTO member country, the inventor is entitled to the same rights of priority in establishing a date of invention in the U.S. as one who actually invents within the U.S. Therefore, foreign inventive activity will not have any advantage or disadvantage relative to domestic inventive activity for the purposes of establishing a date of invention in the United States.

V. Publication Of Patent Applications: New Legislation On the Horizon

30. In addition to extending the 20-year patent term, recent legislation is also addressing the idea of publishing patent applications. Currently, all applications for U.S. patents are kept confidential until a patent is granted.[48] By not publishing the information until after the patent is issued, the inventor is protected from competitors, particularly large corporations that can afford expensive law suits. In addition to extending the 20-year patent term under certain situations, the Moorhead bill (H.R 1733) would have required automatic publication of patent applications eighteen months after the earliest effective filing date.[49] Under this bill, publication would occur after eighteen months, regardless of whether the patent is granted or not. Provisional patent applications and design patent applications would not be published, however.[50] In addition to the Moorhead bill, another patent reform bill proposed by Senator Hatch (S. 1961) also sought to require that patent applications be published 18 months after filing.[51] Furthermore, the Rohrabacher/Dole bills also had a provision requiring the publication of patent applications, but only if a continuing application is filed on an application that has been filed more than 60 months previously.[52] Although these bills did not pass before Congress adjourned, it is likely that the issue of publishing patent applications will arise again in future patent reform bills.[53]

31. There could be advantages to publishing patent applications following a designated amount of time after filing. First of all, publication of new technology can stimulate constructive informational exchange, which is vital in biotechnology research. In fact, publication of scientific discoveries is critical to the progress of research in general. Prompt publication can help avoid repetitive experiments and can help promote more effective research. Publications of current information also can indicate active areas of investigation and signal when certain areas have led to dead ends.

32. In addition to the potential advantage to biotechnology research itself, publication of patent applications also has a number of other possible positive effects. First of all, publication of patent applications would give the patent applications "prior art" status.[54] This would give inventors a greater opportunity to submit relevant prior art. Secondly, publication of applications would force the disclosure of potential submarine patents. A patentee would not be given the opportunity to "surprise" anyone by demanding automatic royalties years after the technology has been used in the industry. Finally, publishing applications eighteen months after filing (under the Moorhead bill) would give U.S. inventors equal access to technology disclosed in patent applications that are also filed abroad. Currently, disclosure of U.S. origin applications is available in foreign countries eighteen months after filing in the U.S., if those applications are also filed under the Patent Cooperation Treaty or in a foreign country requiring publication.[55]

33. There are some serious disadvantages to publishing patent applications, however. It is important to note that publication of a patent application would occur at a specific time after filing, *regardless of when or whether that patent is granted*. Publication of a patent before it is granted could prematurely put an inventor's ideas out to the public for the taking. If a patent is rejected more than 18 months after the filing date has passed, competitors could simply use the information of the invention without giving any benefit or future incentive to the inventor. Therefore, the inventor

would lose out on the possibility of developing the invention further under patent protection or keeping the invention as a trade secret under state law.

34. If an invention can be published without giving any corresponding benefit to the inventor, an inventor will be more likely to choose to maintain trade secrets or delay the filing of a patent application. Unlike patents, which require the disclosure of patented technology, trade secrets actually require nondisclosure.[56] Therefore, disclosure of valuable knowledge underlying biotechnological inventions could be seriously compromised. Nondisclosure of important and innovative biotechnological information goes against the objective behind the patent process. In addition, early publication could also give larger corporations, both domestic and foreign, an incentive to take advantage of smaller inventors who have smaller resources. Punishing inventors for disclosing information in patent applications, as well as discriminating against small inventors, runs contrary to public policy and the fundamental purpose of the patent system

VI. Third Party Role In Patent Reexamination: More New Legislation

35. In an attempt to create a low-cost alternative to patent litigation, Congress created a reexamination system to review the validity of issued patents.[57] During the reexamination process, a patent owner is allowed to file amendments, conduct interviews and make appeals. Current law allows the PTO to reexamine patents based on additional prior art (consisting of prior patents and printed publications) not previously considered by the PTO.[58] After reexamination, the PTO has the ability ex parte to cancel claims, confirm claims, or incorporate amendments or new claims. Section 302 states that "[a]ny person at any time may file a request for reexamination." However, third-party participation (by one who is not the patent owner) is limited to filing an initial request for reexamination and responding to the patentee's statement. Furthermore, if a patent owner amends the claims during the reexamination process, a third party cannot comment on the significance of those changes. As mentioned previously, the H.R. 3460 was a new bill that combined former bills H.R. 1733, 1732, and 1659.[59] H.R. 1732 was a bill proposed by Representative Moorhead that would have allowed reexamination on a basis other than prior art.[60] Specifically, § 302 would have expanded the basis for reexamination to include compliance with all aspects of § 112 disclosure, with the exception of the best mode requirement. In addition, H.R. 1732 also proposed to increase third party participation in the reexamination process.

36. The amendments proposed in the Moorhead bill would have also increased third party participation in several ways.[61] First, § 305 would have been amended to give third parties the opportunity to provide written comment on issues covered by a PTO office action or a patentee's response. Second, § 306 would have been modified to allow third parties to request an appeal of any decision favoring the patentability of claims. Third, § 134 would have been expanded to allow third parties, in addition to the patentee, to appeal a final PTO reexamination decision to the Board of Patent Appeals and Interferences. Similarly, § 141 would also have been expanded to give third parties the option to appeal a Board decision to the Federal Circuit. The bill also included,

however, precautionary measures to prevent third parties from harassing patent owners.[62] For example, there would have been limitations on when a request for an examination can be filed. Furthermore, § 308 would have been amended to clarify that neither the patentee nor the third party may file a subsequent request for reexamination once a final decision has been rendered by the PTO.

37. According to Commissioner Lehman, the proposed changes to the reexamination proceedings under the Moorhead bill could give both patent owners and third parties a fast, inexpensive, and reliable way to resolve patent validity questions.[63] Small entities with limited resources, in particular, are likely to benefit from having an alternative to expensive and time consuming litigation. The option of a speedy and inexpensive process may help put startup biotech companies and independent inventors on a more equal footing with large corporations when addressing questions of patent validity.[64] As with the issue of publishing patent applications, it is very likely that proposals to increase third party participation in the reexamination process will be seen again in future patent reform bills.

VII. Conclusion

38. Recent legislation implementing GATT, as well as other upcoming legislation, has had and will continue to have a enormous impact on patent law and the corresponding industries that are dependent on strong patent protection. The biotechnology industry, in particular, is likely to be significantly impacted by changes in patent terms, the creation of "provisional" patent applications, and changes concerning the "date of invention" in foreign countries. In addition, the possibility of patent application publication, as well as the expansion of third-party roles in the patent reexamination proceedings, will also have significant repercussions. All of these controversial issues will need to be examined carefully to ensure that research and development of biotechnology, particularly by small entities, is not compromised in an effort to streamline the U.S. patent process.

Footnotes

[*] Jacqueline D. Wright is a second-year student at the University of Virginia School of Law, Charlottesville, VA. This paper was prepared while working as a summer associate at Banner & Witcoff, Ltd. (formerly known as Banner & Allegretti, Ltd., 10 South Wacker Dr., Chicago, IL 60606), under the guidance of John McDonnell, Ph.D., J.D., who is currently a partner at McDonnell Boehnen Hulbert & Berghoff, Ltd., 300 South Wacker Dr., Chicago, IL 60606.

[1] The U.S. 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 Rights to their respective Writings

and Discoveries." U.S. CONST. art. I, § 8, cl. 8.

[2] 35 U.S.C. § 154(a)(1).

[3] For example, a 1987 study by the Pharmaceutical Manufacturers Association determined the average cost of developing a new drug to be $150 million per drug. Budiansky, *The Cost of New Drugs Raises the Roof*, U.S. NEWS & WORLD REP., Apr. 6, 1987, at 47.

[4] 35 U.S.C. § 202(a), (c); Evan Ackiron, *The Human Genome Initiative and the Impact of Genetic Testing and Screening Technologies: Note and Comment: Patents for Critical Pharmaceuticals: The AZT Case*, 17 AM. J. L. & MED. 145, 156 (1991).

[5] H.R. Rep. No. 857, 98th Cong. 2d Sess. 14, 15-18, reprinted in 1984 U.S. CODE CONG. & ADMIN. NEWS 2647, 2648-51.

[6] 35 U.S.C. § 156.

[7] Daniel Freeman & John Carson, *The Legal Community/Intellectual Property/Status Report on Patent, Trademark and Copyright Legislation*, Metropolitan News-Enterprise; Capitol News Service, June 18, 1996, at 9.

[8] *Id.*.

[9] Pub. L. No. 103-465.

[10] John McDonnell & Thomas Fairhall, *U.S. Patent Law: A Strategic Overview*, 2 DIG. INT'L L. 1 (1995).

[11] Nancy J. Perry, *The Surprising New Power of Patents*, FORTUNE, June 23, 1986, at 57.

[12] Polaroid Corp. v. Eastman Kodak Co., 16 U.S.P.Q.2d 1481 (D. Mass. 1990), *as corrected*, 17 U.S.P.Q.2d 1711 (D. Mass. 1991).

[13] Helen Bergman, *Rationing Health Care: Social, Political and Legal Perspectives: Note and Comment: Case Comment: Moore v. Regents of the University of California*, 18 AM. J. L. & MED. 127, 139 (1992).

[14] Twenty nine percent of patent application filed in 1995 were by small entities. Bruce Lehman, *Prepared Statement of Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Before the House Committee on Science Subcommittee on Energy and Environment on*

Changes in U.S. Patent Law, The Implications For Energy and Environmental Research and Development, FEDERAL NEWS SERVICE, May 2, 1996, at In the News.

[15] Dana Rohrabacher & Paul Crilly, *Congressional Commentary: The Case For a Strong Patent System*, 8 HARV. J. L. & TECH. 263, 264 (1995).

[16] 35 U.S.C. § 154.

[17] Lehman, *supra* note 14.

[18] *Id.*

[19] Bruce Lehman, *Hearing of the Technology Subcommittee of the House Science Committee; Subject: Patents and Modern Technology*, FEDERAL NEWS SERVICE, June 6, 1996, at In the News.

[20] Freeman & Carson, *supra* note 7.

[21] Lehman, *supra* note 14.

[22] Reginald Rhein, *Bill To Extend Life of Patents Approved by Judiciary*, BIOTECH. NEWSWATCH, May 20, 1996, at 1.

[23] *Patents, Pending Patent Reforms Approved by Judiciary Committee*, DAILY REPORT FOR EXECUTIVES, June 12, 1996, at A113.

[24] AIPLA WASHINGTON LETTER EXPRESS, October 1996 at 1.

[25] Rhein, *supra* note 22.

[26] Diane L. Gardner, *Testimony May 02, 1996, Diane L. Gardner, Molecular Biosystems, Inc., House Science Energy and Environment U.S. Patent Law and Research Implications*, Federal Document Clearing House Congressional Testimony, May 2, 1996, at Capitol Hill Hearing Testimony.

[27] Lehman, *supra* note 19.

[28] Lehman, *supra* note 14.

[29] John Doll & Teresa Stanek Rea, *Status of Group 1800: Presentation by John Doll*, AIPLA BULLETIN, Jan.-Feb. 1996, at 277.

[30] Rohrabacher & Crilly, *supra* note 15, at 265.

[31] *Id.*

[32] Rohrabacher & Crilly, *supra* note 15, at 266.

[33] Gardner, *supra* note 26.

[34] Lehman, *supra* note 19.

[35] *Id.*

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] Doll & Stanek Rea, *supra* note 29, at 278.

[40] Mary Lee & Teresa Stanek Rea, *Further Information on Group 1800: Presentation by Mary Lee*, AIPLA BULLETIN, Jan.-Feb. 1996, at 278.

[41] Lehman, *supra* note 14.

[42] Lehman, *supra* note 19.

[43] Doll & Stanek Rea, *supra* note 29, at 278.

[44] Rohrabacher & Crilly, *supra* note 15, at 268.

[45] *Id.*

[46] 35 U.S.C. § 111(b).

[47] 35 U.S.C. § 104.

[48] 35 U.S.C. § 122.

[49] Lehman, *supra* note 14.

[50] *Id.*

[51]*Congress Resists Last-Minute Effort to Weaken Patent Laws*, PR NEWSWIRE, October 4, 1996, at Domestic News.

[52] Lehman, *supra* note 14.

[53] AIPLA WASHINGTON LETTER EXPRESS, *supra* note 24.

[54] Lehman, *supra* note 14.

[55] *Id.*

[56] MCCARTHY'S DESK ENCYCLOPEDIA OF INTELLECTUAL PROPERTY 450 (2d ed. 1995).

[57] 35 U.S.C. §§ 301-307 (enacted in 1980).

[58] 35 U.S.C. §§ 301-307; MCCARTHY'S, *supra* note 56, at 367.

[59] *Patents, Pending Patent Reforms Approved by Judiciary Committee*, *supra* note 23.

[60] Lehman, *supra* note 14; *News & Comment, Legislation: Bill Would Expand Third Party Role in Patent Reexaminations*, 50 BNA's PAT., TRADEMARK & COPYRIGHT J. 115 (1995).

[61] *Id.*

[62] *Id.*

[63] Lehman, *supra* note 14.

[64] *Id.*