IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

TRIANTAFYLLOS TAFAS, Plaintiff, v. JON W. DUDAS, et al., Defendants.	)	Case No. 1:07cv846 (JCC/TRJ)

CONSOLIDATED WITH

SMITHKLINE BEECHAM CORPORATION, et al., Plaintiffs, v. JON W. DUDAS, et al., Defendants.	)	Case No. 1:07cv1008 (JCC/TRJ)

BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

I. Introduction

The Biotechnology Industry Organization ("BIO") respectfully submits this brief in support of the plaintiffs' motions for summary judgment in the above-captioned consolidated cases. The final rules published by the Patent and Trademark Office ("PTO") on August 21, 2007, significantly alter patent applicants' ability to claim and protect their inventions. Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug.

21, 2007) ["Final Rules"] (to be codified at 37 C.F.R. pt. 1). The adverse effects of the Final Rules will nowhere be felt more strongly than in the biotechnology industry. This industry relies heavily on patent law and the current, established PTO rules of practice to obtain adequate protection for its inventions and to attract financing for products that often take more than a decade to reach the market. BIO is deeply concerned about the irreversible loss of patent rights and the disincentives to innovation that the Final Rules will cause.

Like the plaintiffs, BIO believes that the Final Rules violate the patent laws and the Administrative Procedure Act. 5 U.S.C. § 706. Instead of repeating the arguments the plaintiffs have ably made on these points, BIO's brief will address the significant harm that the provisions of the Final Rules that place severe limitations on continuations and on the number of patent claims an applicant can make will cause to the biotechnology industry and the public at large if those Rules are allowed to go into effect.

II. Background

BIO is the largest trade association representing the biotechnology industry. BIO was founded in 1993 to represent biotechnology companies at the local, state, federal, and international levels. As of December 2006, BIO's membership consisted of more than 1,100 biotechnology companies, academic centers, state and local associations, and related enterprises. Although BIO members' concerns with the Final Rules overlap with the plaintiffs', BIO represents a diverse array of biotechnology organizations working in a variety of different fields that will be uniquely affected by the Final Rules. BIO's members range from large Fortune 500 companies to the smallest start-ups and university spin-offs. They are involved in researching and developing biotechnology products across a wide array of technology areas, including food and agriculture, healthcare, industrial, and environmental.

Biotechnology is a highly capital- and research-intensive industry. For example, in 2005, the U.S. biotechnology industry raised over $20 billion in financing and spent $19.8 billion on research and development of more than 400 investigational drug products and vaccines. BIO, GUIDE TO BIOTECHNOLOGY 2007, at 2, *available at* http://www.bio.org/speeches/pubs/er/BiotechGuide.pdf. Many of the medicines that companies in this industry developed are now being used to treat the most vexing of human diseases, such as various forms of cancer. Modern crop science applies biotechnology to enhance productivity in corn, cotton, and soybean farming, and to reduce their environmental impact. Bioethanol made from crop wastes using enzymes developed by the biotechnology industry could meet a quarter of U.S. energy needs by 2025. *Id.*

The vast majority of BIO's corporate members are development-stage companies that have yet to achieve profitability and that may be years from bringing their technologies to market. To such companies, patents are vital. The ability to obtain clear and comprehensive patent protection attracts the capital and corporate partners necessary for the costly and lengthy development, approval, and marketing process for biotechnology inventions. Sustaining the necessary level of financing and partnering depends on a biotechnology company's ability to develop comprehensive patent protection for investigational products. For this, and other, reasons, start-up biotechnology companies must apply for patents early and often.[1]

The Final Rules' limitations on continuations practice and the number of permissible claims will weaken the patent protection available to biotechnology companies for investigational products, and will undermine their efforts to obtain financing and other support to

[1] Forgoing patent protection and relying on trade secrets protection is generally not a realistic option for early-stage biotechnology companies. Several factors may drive the early disclosure of new discoveries, including (1) the need to publish in scientific journals, (2) regulatory review processes that require disclosure, (3) securities regulations that may compel disclosure, and (4) the need to attract investors or development partners during the early stages of development, which are typically the most difficult to fund.

continue research. This in turn will harm the public, which may never receive the benefits of products the development of which may be abandoned for lack of funds.

Furthermore, because of the length of time involved in bringing complex biotechnology products to market, continuations practice is more prominent with respect to biotechnology patents than those in other areas of technology, such as electronic and mechanical patents. By one measure, the percentage of first Office actions on the merits taken from continuing applications is highest with respect to patents in the life sciences and biotechnology area by a wide margin (approximately 42%, compared to about 24% to 28% in all other technologies). *See* James Toupin, General Counsel, PTO, Presentation at the Los Angeles Intellectual Property Law Association "Washington and the West" Conference: The State of the Patent System 8 (Jan. 25, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/laiplabackground.ppt. The Final Rules will affect biotechnology more than other technology areas because biotechnology applications and the associated patentability issues are often more complex, which results in a longer and more involved examination process requiring more continuing applications and requests for continued examination ("RCEs").

Thus, the Final Rules are likely to have a disparate impact on BIO's members. These effects have important implications for the public's access to the benefits of advances in biotechnology. In particular, the Final Rules may prevent biotechnology companies from developing the next generation of agricultural products, industrial processes, environmental solutions, or drugs, treatments, and therapies.

III. If Implemented, the Final Rules Will Harm the Biotechnology Industry and the Public Interest

Because of the diversity of BIO's membership and the wide-ranging scope of the technologies its members work with, it would not be possible to touch on all of the ways the

Final Rules will adversely affect the biotechnology industry. Rather, in the sections that follow, BIO focuses on several effects of the Final Rules, including some examples.

The first section discusses what are perhaps two of the most critical aspects in the lives of biotechnology companies: (a) the decision as to which products to invest often limited resources; and (b) the ability to secure financing for research and development of these products. The second section discusses how biotechnology inventions benefit both from fully-developed claims sets, which would be limited by the Final Rules to five independent and twenty-five total claims, and from the ability to file multiple continuations and RCEs beyond the Final Rules' de facto limit of two continuations and one RCE. The final section highlights how these adverse effects will harm the public good by suppressing the number of new biotechnology advancements that reach the market and the number of biotechnology inventions publicly disclosed.

A. Protecting All Aspects of Inventions Through Continuations and Comprehensive Claims Sets Is Essential to Biotechnology Companies in Making Investment Decisions, Obtaining Financing, and Negotiating Technology Transfers

Biotechnology companies often must choose to pursue a limited number of new products or technologies from among several viable ideas. In some instances, these decisions have to be made early in the development process because of the high up-front costs and capital requirements involved in proceeding with development of a technology. Significant factors in this decision-making process are the ultimate scope and robustness of patent protection. Absent well-developed and robust patent protection, a biotechnology company is less likely to invest in promising new technologies and will find it more difficult to obtain the financing necessary to see the technologies through their long developments.

For example, biotechnology companies developing large molecule biologics[2] often have to make large investment decisions early in the development process. Biologics are produced using cell culture facilities that, on average, take three to five years to construct, cost between $250 million and $450 million, and must often be constructed during clinical testing. *See* Henry Grabowski et al., *The Market for Follow-On Biologics: How Will it Evolve?*, 25 HEALTH AFFAIRS 1291, 1294 (2006). To make such investments, the company must have a clear prospect of adequately protecting all aspects of the invention, including those aspects that become important during the development process and are amenable to protection through continuation or continuation-in-part ("CIP") applications. Because the limitations in the Final Rules related to continuations, CIPs, and claims sets will lead to more limited patent protection, biotechnology companies are less likely to make these significant investments, thereby depriving the public of the important resulting benefits.

For small, development-stage biotechnology companies, a key concern is financing their research and development efforts. Unlike large biotechnology companies that may be able to rely on their established portfolio of corporate assets and revenue streams to produce capital and to attract investment, development-stage companies must solicit investments in the capital markets based on the commercial attractiveness of their inventions. Patents play a unique role in the business models of such companies, for whom business risks are unusually high. For example, of all compounds entering clinical testing, approximately 70% fail to reach Food and Drug Administration ("FDA") review. *See* Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 470,

[2] Large molecule biologics include proteins, such as antibodies, growth factors, and hormones, as opposed to small molecular entities derived from chemical synthesis.

472 (2007). Biotechnology businesses must raise large amounts of capital in the face of such failure rates. A recent study estimates the total capitalized cost of developing a biotechnology drug at $1.2 billion—money that, in large part, must be raised by convincing investors. *Id.* at 475. If such high failure rates were not enough of a disincentive to investing such large amounts of money, investors must also consider the time they have to wait before, if ever, getting a return. It takes, on average, over eight years to advance a biotechnology drug through the required clinical testing and the FDA approval process—time during which those investment dollars could bring a safer, and quicker, return if invested elsewhere. *Id.* at 473.

Strong patent protection mitigates the impact of these many disincentives to biotechnology investment, and therefore is critical to the biotechnology industry. Patents ensure a limited period of exclusivity during which a profitable biotechnology product, developed against all odds, can provide investors a reasonable return and at the same time allow the public to benefit from use of the product.[3] Comprehensive patent protection, including that afforded by continuations and fully-developed claims sets, mitigates business risk in the biotechnology industry. The imposition of a de facto limit on the number of continuations and claims, however, raises the likelihood that not all commercially important aspects of an invention can be protected. This will lead to higher perceived business risk, reduced levels of investment, and hence a lower

[3] It is for this reason that capital markets are extremely sensitive to the impact of patent law changes on the biotechnology industry. For example, on March 14, 2000, when President Clinton and Prime Minister Blair made a joint statement raising doubts about patent protection for newly decoded human gene sequences (a statement that was subsequently clarified), biotechnology stocks went into a tailspin. In a single day, the NASDAQ biotechnology index dropped by about 13%, Alex Berenson & Nicholas Wade, *A Call for Sharing of Research Causes Gene Stocks to Plunge*, N.Y. TIMES, Mar. 15, 2000, at A1, with some companies losing as much as 20% of their market value within a few hours, Eliot Marshall, *How a Bland Statement Sent Stocks Sprawling*, 287 SCI. 2127, 2127 (2000).

likelihood that research is begun, continued, or brought to fruition in the form of new products or technologies that benefit the public.

These adverse consequences of the Final Rules also will affect university-based research. Unlike many other industries, much of the biotechnology industry's pipeline of products is developed initially in a university setting. Basic research discoveries initially made by universities and research institutions often lead to multi-faceted inventions, which are frequently patented and licensed to start-up biotechnology companies for further development and commercialization. This process of patenting and licensing promotes the interests of research institutions in seeing their discoveries translated into real-world products that benefit patients and consumers, and funnels billions of dollars from the commercial marketplace back into basic research and higher education.[4] But, because the limitations on continuations, CIPs, and claims sets in the Final Rules will limit the patent protection for these discoveries, the flow of funds to universities for basic research will be reduced, because private industry will not risk making substantial investments without adequate protection for their intellectual property.

Many of BIO's member companies are small companies that demonstrate the relationship between university-based research and the private marketplace. The initial technology for these companies often is developed at major research universities. These biotechnology companies often seek their initial round of investment from venture capital firms. It was important to these venture capital firms that the patents protecting the biotechnology companies' technology have

[4] For 2006 alone, U.S. academic institutions organized in the Association of University Technology Managers ("AUTM") reported receiving research funding from industry licensees under more than 12,600 active licenses. *See* AUTM U.S. LICENSING ACTIVITY SURVEY: FY 2006, SURVEY SUMMARY 5 (2007), *available at* http://www.autm.org/events/file/AUTM_06_US%20LSS_FNL.pdf. At approximately $3.18 billion, industry-provided research funding constituted the second-largest source of research funding for U.S. universities, hospitals, and research institutions during that year. *See id.* at 20. Of almost 5,000 new licenses granted under university patents, two-thirds went to small companies and start-ups. *See id.* at 31.

enough longevity to support the research and development cycle necessary to make the technology commercially mature and be sufficiently robust to withstand competition. These biotechnology companies can be successful in securing initial and on-going investments if they are able to develop a patent strategy using a series of continuations and fully-developed claims sets—an approach that would be foreclosed by the Final Rules.

Without the flexibility to protect all aspects of any one of their inventions through continuations and full claims sets, universities, through spin-off companies, may not be able to attract the investments necessary to bring the inventions to commercial fruition—all due to the new rigidity of the Final Rules.

B. Biotechnology Inventions, and the Public, Benefit from Current Continuations Practice and Fully-Developed Claims Sets

The PTO justifies the new restrictions on continuations practice, in part, on what it views as unfocused and abusive practices. *See* 72 Fed. Reg. at 46,719-46,720. The PTO also claims that the new limits on the number of claims and the examination support document ("ESD") requirement will assist patent examiners in their examination and evaluation of patent applications. *See id.* at 46,721. But the PTO already has the authority to regulate and punish those rare instances of actual abuse of the patent process. *See* 37 C.F.R. § 10.18; Manual of Pat. Examination Proc. § 410.[5]

[5] Prior to June 8, 1995, the term of protection of a U.S. patent, including a patent issued on a continuation application, was seventeen years measured from the *grant* of the patent. Since June 8, 1995, however, the term of protection begins on the date of grant and ends twenty years from the *filing* date of the application for the patent. If priority of an earlier application or applications is claimed under sections 120, 121, or 365(c) of Title 35, the twenty-year period is measured from the filing date of the earliest of such earlier applications. The patent term provisions of Section 154, applicable to virtually all currently pending patent applications, thus provide a significant disincentive to dilatory prosecution tactics since successive continuation filings "eat up" patent term of any patent issued on such applications. Applicants' incentive therefore is to obtain allowance as quickly as possible to have the greatest amount of term remaining after the patent issues.

More importantly, the PTO ignores that current practices regarding continuations and claims sets, on the whole, have a beneficial effect on patent quality and validity. Biotechnology inventions tend to be more complex than those in many other areas. They also frequently arise in a competitive, rapidly developing research environment characterized by high rates of scientific publications, vibrant scholarly discourse in public forums, and substantial amounts of prior art that must be discovered over time and carefully analyzed. Existing continuations and RCE practice affords applicants the several rounds of prosecution that may be necessary to fully prosecute a complex biotechnology invention, gives examiners the opportunity to fully consider the case, and permits both examiners and applicants to develop the prosecution history to a point where it is in an appropriate—rather than premature—posture for allowance or appeal. In this respect, the Final Rules cause greater harm to inventions from biotechnology and other highly complex technologies that may legitimately require multiple rounds of prosecution, because they force applicants to "use up" their available continuations rather than settle for premature appeals or insufficient protection.

Moreover, at the time of filing of an original patent application, a biotechnology company often does not yet know which of several disclosed alternative embodiments of the invention will ultimately be developed commercially. The company must fear that important embodiments of their inventions—those whose commercial importance becomes clear only during the product development phase—will not receive adequate patent protection because all available continuations have been "used up" during earlier rounds of prosecution. The competition for investment dollars drives biotechnology companies to file patent applications early in the development of the invention to generate interest or to satisfy milestones required by

their investors. As a result, these companies properly file applications long before the technology has advanced to clinical trials, manufacturing, or commercialization.

Frequently, an initial biotechnology patent application will describe several products, and several uses for these products, based on the inventor's laboratory experiments. For example, a scientist may find a way to halt the abnormal growth of a number of different cancer cell lines in cell culture, and corroborates this finding with a mouse study using experimental tumors from several of these cancer cell lines. The patent application teaches that the invention is useful in the diagnosis and treatment of solid tumors generally, and discloses specific methods for treating a number of cancers. During prosecution of the patent application, however, the patent examiner may allow only some of the specific cancer treatment claims—for example, those that are supported by both mouse and cell culture data—and may finally reject claims related to treating solid tumors generally, or treating specific types of cancer for which the applicant presented only cell culture data.

This common conundrum presents the patent applicant with a difficult choice: the applicant does not yet know for which of the several disclosed embodiments—in this example the medical indication—the invention will eventually be commercially developed, if at all. Should the applicant accept a patent with narrow claims, and run the risk that subsequent clinical research confirms the medical and commercial value of the invention in another indication that was disclosed in the application but not among the allowed claims? In biotechnology, the development of the commercial product requires significant further testing in animals, and FDA approval is needed to conduct the series of clinical trials necessary for final approval. As noted above, because the lengthy animal and human clinical trials are extremely resource-intensive,

applicants may pursue different products serially over time, using continuations and robust claims sets to cover the various embodiments.

For example, an antibody product initially pursued for one type of cancer was later developed for other types of cancer—indications that were disclosed in the original patent application. Some of these additional indications are covered by continuation applications. Similarly, other antibodies, initially claimed and developed through clinical trials for rheumatoid arthritis, were subsequently pursued for other originally disclosed diseases such as Crohn's disease, psoriasis, and sarcoidosis, which have been the subject of continuation applications. However, the Final Rules may not permit the biotechnology company to file continuations with claims to capture such additional, medically valuable uses.

Development-stage companies need patent protection for such commercial embodiments whose importance only becomes clear after investing in additional research—not only for the initial embodiment whose prosecution may already have used up the available continuations. As such, the vastly restricted continuations and claims practice under the Final Rules robs such companies of much of the flexibility needed to protect their investigational products and bring their technology to fruition.

The small BIO member companies described above, which often develop technologies first generated at a university, are able to implement a patent strategy that involves a series of continuations with disclosures that are both broad and deep. The ability to plan for multiple continuations allows these companies initially to make broad disclosures safely with limited funding. This strategy plays an important role in a company's ability to secure initial and on-going investments, which are necessary for continued research and development. The ability to satisfactorily capture all of the benefits of a broadly enabling technology also is important in

convincing investors to help biotechnology companies commercially develop their new technology.

As mentioned above, claims practice under the Final Rules will allow only five independent and twenty-five total claims to be examined per application before an ESD is required (the "5/25 Rule"). The 5/25 Rule will also extend across all copending, commonly owned applications containing at least one patentably indistinct claim. If the sum of all the claims in each commonly owned application containing at least one patentably indistinct claim is greater than the limits of the 5/25 Rule, the applicant either must file an ESD before the first Office action on the merits or must cancel claims in excess of the limit.

The PTO has included this provision ostensibly "to preclude an applicant from submitting multiple applications with claims that are patentably indistinct . . . for the purposes of avoiding the requirement to submit an examination support document." 72 Fed. Reg. at 46,722. However, the 5/25 Rule also effectively prevents applicants from prosecuting *parallel* CIPs or continuations with any patentably indistinct claim for the purpose of capturing improvements or other aspects of the invention. *See id.* at 46,725 Applicants and investors do not know whether a continuation application contains a "patentably indistinct" claim until the PTO makes that determination, making it necessary to delay filing of continuation applications until the parent application is prosecuted to allowance. Such a result, however, will have a significant negative impact on even well-meaning applicants who, far from engaging in "unfocused"' or "abusive" prosecution tactics, wish to prosecute a continuation application to allowance as quickly as possible. A patent issued on such a serially filed continuation application is certain to lose part of its effective protection, because much of its effective patent term (which is measured from the

filing date of the earliest prior application) is consumed by the time it takes to sequentially prosecute its one or more parent applications.

The 5/25 Rule will also prevent a biotechnology applicant from using so-called "genus" and "species" claims to describe their inventions. Broad genus claims cover a wide breadth of subject matter, often with few limitations. However, such claims are more vulnerable to invalidity challenges on the basis of unidentified prior art or lack of enablement. Narrow species claims describe different embodiments of the invention that fit within the scope of a genus claim. Species claims are generally less vulnerable to invalidity challenges, but may allow a competitor to successfully design around the claim limitations. Thus, during patent enforcement, it is important to have both genus and species claims because the combination of these claims allows the inventor to protect the full scope of the invention.

The Final Rules effectively eliminate the ability of patent applicants to develop such strategies of using multiple applications that are filed as research progresses. In addition to the changes in claims and continuations practice, the PTO is requiring that applications containing overlapping genus and species claims be prosecuted serially, rather than in parallel as is currently allowed, and is requiring that a genus claim application be fully prosecuted before species claims applications are even filed in an application with only patent distinct claims, called a "divisional." 72 Fed. Reg. at 46,727-46,728. As a practical matter, the second application would not issue until about six years after filing under the best-case scenario, depriving applicants of the full patent term to which they are entitled. In reality, the prosecution would likely require significantly longer time and reduce the patent term accordingly.

Under current practice, genus and species claims could issue at the same time, typically about three years after filing. By forcing applicants to prosecute continuations or divisionals

serially, the PTO will reduce the effective period of exclusivity for the scope of the invention. By reducing available patent term, the value of the patent, and thus the incentive to make the investment necessary to develop the patentable technology, is eroded significantly.

Genus and species claims also are important for a discovery that can be licensed in more than one market, an approach often used by universities and other research institutions. For example, a basic genetic invention made in a research laboratory may eventually be of interest to companies that develop very different products, such as laboratory reagents, veterinary medicines, diagnostic services, forensic tests, fermentation or biological manufacturing, or medicines for human use. Each of the various parties has its own specific patent-related needs: a diagnostic company may have a need for claims specifically directed to test kits and diagnostic methods; a drug company may need specific pharmaceutical composition claims; and a manufacturing company may need specific biological process claims. With flexible use of claims and continuations, specific aspects of the invention all can be protected separately, allowing a research institution to license several small start-ups with different, specific commercial applications, thereby promoting the dissemination and wider adaptation of new technology in the marketplace. Under the Final Rules, however, both claims and continuations become a precious commodity, confronting such licensors with hard choices between the competing needs and interests of its licensees and, ultimately, quenching incentives for further innovation.

This competition will occur, in part because the order in which subject matter is claimed and examined can have significant effects. As explained above, the 5/25 Rule effectively reduces the amount of time that a second or third patent is enforceable. Although the PTO argues that the Final Rules will permit applicants a maximum of fifteen independent claims and

seventy-five total claims through the use of two continuations or CIPs, those continuing applications must be pursued serially to avoid exceeding the 5/25 limit across co-pending applications. 72 Fed. Reg. at 46,725. Thus, should these subsequent claims issue in patents, the applicant would have less enforceable patent term for second and third patents than afforded the first patent. This necessarily harms applicants and particularly, applicants in biotechnology and other high technology areas that require more claims to adequately cover the scope of the invention.

Experience has shown that, in the case of complicated, evolving technologies such as those in the biotechnology field, fully-developed claims sets and unrestricted continuations practice actually improve patent quality and validity.[6] For example, more claims encompassing specific embodiments of the invention will often allow patent examiners to better understand the subject matter. While several continuations are pending, the patent examiner becomes intimately familiar with the technology through prior art searches and the back-and-forth with the applicant explaining the invention. During this period, applicants may also provide additional prior art, possibly as a result of additional research or testing. Because of such extensive examination, the quality of the examination and the quality of the claims are improved, and a much stronger patent of appropriate scope issues.

[6] Conversely, there is no empirical evidence that continuation practice has resulted in higher numbers of invalid patents. The finding of Lemley and Moore that continuations are more likely to be litigated can be seen as an indicator of the commercial importance of continuations, highlighting that continuation patents often are among a patent owner's most valuable assets. (In Lemley and Moore's sample, continuations constituted 23% of all issued patents, but 52% of all litigated patents. Mark A. Lemley & Kimberley A. Moore, *Ending Abuse of Patent Continuations* 13 n.40 (Geo. Mason Univ. Sch. of Law, Law & Econ. Working Paper Series, Paper No. 03-52, 2003; Univ. of Cal., Berkeley Sch. of Law, Pub. Law & Legal Theory Research Paper Series, Paper No. 140, 2003), *available at* http://ssrn.com/abstract=462404.)

In sum, without the ability to protect all aspects of the inventions through continuations and fully-developed claim sets, refinements made during the developmental testing process may never be disclosed or brought to commercial fruition. Details of a complex, commercially viable biotechnology invention are likely to unfold in a piecemeal fashion with continued research. As the research identifies new improvements and aspects of the invention that are commercially important, the biotechnology company properly will seek to patent them. If research is redirected, under current practice, an applicant is unlikely to withdraw a previously filed application if it covers a workable product, since the biotechnology company will want to maintain exclusivity around their invention. Without that patent protection, the disclosed material is in the public domain and may be used by a competitor that has not invested in the improvements. *See Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). Thus, without patent protection, the biotechnology company is unlikely to continue to invest in that improvement or aspect of the invention, and its importance or potential may be lost. Moreover, because the effect of the Final Rules would have applicants file and prosecute applications serially, a company may choose instead to pursue the aspects of the invention that were claimed first, rather than those that provide the best result, creating an additional disincentive to further innovation.

C. Resulting Harm to the Public Interest

As a result of the adverse effects discussed above, the public interest will be harmed in two related ways if the Final Rules are allowed to go into effect. First, fewer new products and technologies may be brought to market. Second, fewer products and technologies will be disclosed to the public, contrary to the express purpose of patents to disseminate information in order "to promote the Progress of Science and useful Arts." U.S. CONST. art. I, § 8.

As noted above, without the security of robust patent protections, development-stage biotechnology companies will be less likely to attract investors to finance the development of new products and technologies. Without these investments, these companies simply do not have the resources to bring their new ideas to the market. Larger companies will also be unwilling to invest substantial resources in developing new products and technologies without strong patents that will protect their inventions from being copied once they are brought to market. In either situation, the result is less investment in research and development and, ultimately, fewer new products and technologies.

Alternatively, biotechnology companies may turn to trade secrets to protect their intellectual property. As noted above, trade secrets protection is of less value to development-stage biotechnology companies, because of their need to raise funds in the capital markets. But any reliance on trade secrets protection will result in no public disclosure of these new technologies, stifling innovation. This stifling effect will ultimately result in fewer new products and technologies being developed. A similar effect may flow from patents filed and issued under the Final Rules. Given the restrictions on claims and continuations, biotechnology companies will have to limit what is claimed in a patent application. Accordingly, applicants will limit the scope of the disclosure in their applications to avoid dedicating to the public potential commercial embodiments. The effect, again, will be to stifle innovation because of the lack of public disclosure.

IV. Conclusion

In view of the foregoing harms to the biotechnology industry and the public that will be caused by the PTO's unlawful and unreasonable restrictions on patent practice, BIO, on behalf of its members, respectfully requests that this Court grant the plaintiffs motions for summary judgment and permanently enjoin the Final Rules in full.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of December 2007, I caused a copy of the foregoing Brief of *Amicus Curiae* Biotechnology Industry Organization in Support of Plaintiffs' Motions for Summary Judgment to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing to the following:

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