2008-1352

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

TRIANTAFYLLOS TAFAS,
Plaintiff-Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline), SMITHKLINE BEECHAM PLC, and GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),
Plaintiffs-Appellees,

v.

JON DUDAS, Undersecretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendants-Appellants.

Appeal from the United States District Court for the Eastern District of Virginia in consolidated case nos. 1:07-CV-846 and 1:07-CV-1008, Senior Judge James C. Cacheris

---

BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF APPELLEES AND IN SUPPORT OF AFFIRMANCE

Ronald A. Schechter
ARNOLD & PORTER LLP
555 Twelfth Street, N.W.
Washington, DC 20004
Tel: (202) 942-5160
Fax: (202) 942-5999
Attorney for *Amicus Curiae*
Biotechnology Industry Organization

David R. Marsh
Matthew M. Shultz
Kristan L. Lansbery
ARNOLD & PORTER LLP
555 Twelfth Street, N.W.
Washington, DC 20004
Tel: (202) 942-5000
Fax: (202) 942-5999
Of Counsel for *Amicus Curiae*
Biotechnology Industry Organization

October 3, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Tafas v. Dudas

No. 2008-1352

CERTIFICATE OF INTEREST

Counsel for the ~~(petitioner) (appellant) (respondent) (appellee)~~ (amicus) ~~(name of party)~~ Biotechnology Industry Organization certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Biotechnology Industry Organization

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None

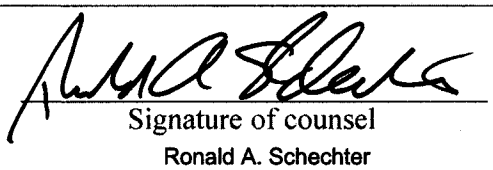
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Ronald A. Schechter, David R. Marsh, Matthew M. Shultz and Kristan L. Lansbery
all of Arnold & Porter LLP, 555 Twelfth Street, NW, Washington, DC 20004

October 3, 2008
Date


Signature of counsel

Ronald A. Schechter
Printed name of counsel

Please Note: All questions must be answered

cc: _____

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES AND REGULATIONS

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*

The Biotechnology Industry Organization ("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. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related enterprises across the United States and in more than thirty other nations. Although BIO members' concerns with the final rules published by the Patent and Trademark Office ("PTO") on August 21, 2007, 72 Fed. Reg. 46,716 (Aug. 21, 2007) ["Final Rules"], overlap with the Appellees', 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 the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, renewable sources of energy, enhanced agriculture, and a cleaner and safer environment.

GlaxoSmithKline is a member of BIO. No representatives from GlaxoSmithKline participated in the preparation of this brief. BIO has no stake in the parties to this appeal, or the result of this case other than its interest in voiding

the *ultra vires* changes to the patent laws and rules that will irreparably damage the biotechnology industry, BIO members, and the public.

SUMMARY OF ARGUMENT

The District Court clearly was correct in concluding that the PTO lacked the statutory authority to promulgate the Final Rules. This Court recently confirmed that the PTO does not have the power to issue substantive rules—those that "effect[] a change in existing law or policy which affect[s] individual rights and obligations." *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008) (internal quotation marks omitted) ("*Cooper Technologies*"). For the biotechnology industry, the Final Rules' de facto limitations on continuations and claims practice will seriously affect the scope of the substantive patent rights that biotechnology companies depend on to foster the expensive and time-consuming development of new drugs and other important products.

In addition, the Final Rules encroach upon the role that Congress and the federal courts play in the patent system. Congress left to itself the role of making substantive changes to the patent law. It also provided the federal courts with a more significant role in implementing patent law than in other administrative contexts. Under the patent statutes, the courts not only review agency action, they also have jurisdiction to grant patents and determine patent rights. The Final Rules

upset this balance by asserting authority for the PTO that Congress has failed to provide.

ARGUMENT

I. Introduction

Biotechnology is a highly capital- and research-intensive industry. 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 or vaccinate against the most vexing of human diseases, such as various forms of cancer, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS, and arthritis. 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 companies that develop such products have yet to achieve profitability and may be years from bringing their technologies to market. To such development-stage 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. For this and other reasons, start-up biotechnology companies must apply for patents early in the innovation cycle. For such companies, patent prosecution strategy and product development strategy are but two sides of the same coin. Decisions made during the arduous process of translating inventions into viable commercial products directly affect how applicants prosecute patent applications. Conversely, the options available to applicants during the patent prosecution process, including continuations and claims practice, directly affect product development and investment decisions.

The Final Rules' limitations on continuations practice and the number of permissible claims will weaken the substantive patent rights available to such biotechnology companies, and thus will undermine their ability to obtain financing and other support, such as cross-licenses, to continue research on products that often take more than a decade to reach the market. Because of the length of time involved in bringing complex biotechnology products to market, continuations practice is more critical, and therefore more common, with respect to biotechnology patents than patents in other technology areas that operate under a shorter development cycle, such as electronic and mechanical patents. Biotechnology applications and the associated patentability issues are also often more complex than in the predictable arts, which results in a longer and more

involved examination process requiring more continuing applications, more requests for continued examination ("RCEs"), and more claims. By one measure, the percentage of first Office Actions on the merits that are sent in response to continuing applications[1] 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. Thus, the Final Rules would have a significantly greater impact on the life sciences industry compared to other sectors of the United States economy.

The Government's simplistic picture of current continuations and claims practice fails to account for this disparate impact, and displays a clear lack of appreciation for the complexities and business realities that intertwine research, development, and patent prosecution in the life sciences industry today. In this industry, where patent prosecution often takes place in parallel with expensive, risky, and exceptionally time-consuming research and development, multiple

[1] Defined for this purpose as "Continuing (CONs and CIPs), RCE, CPA or 129(a) applications (excludes Divisionals)."

continuation applications and properly presented claim sets perform a necessary, legitimate, and innovation-enhancing role that would be eliminated by the authority that the PTO has tried to assert, but does not possess.

II. The Final Rules Are Substantive Rules and Therefore Are Beyond the PTO's Rulemaking Authority

The District Court correctly held that the Final Rules are beyond the PTO's limited rulemaking authority because the Final Rules are substantive in nature and the PTO does not have the authority to promulgate substantive rules. *Tafas v. Dudas*, 541 F. Supp. 2d 805, 817 (E.D. Va. 2008). Indeed, this Court recently confirmed that "35 U.S.C. § 2(b)(2) does not authorize the Patent Office to issue 'substantive' rules." *Cooper Technologies*, 536 F.3d at 1336. The Court described a substantive rule as one that "effects a change in existing law or policy which affect[s] individual rights and obligations." *Id.* (alteration in original) (internal quotation marks omitted). Thus, the PTO's rulemaking authority is limited to those rules that "merely clarif[y] or explain[] existing law or regulations. . . ." *Id.* (quoting *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991)).

The Government acknowledges, as it must, that the PTO does not have broad, general rulemaking authority. *See* Appellants' Br. 14. In the Government's view, the PTO has the statutory authority to issue procedural-type regulations even if they have incidental effects on applicants' substantive rights, as long as the regulations do not interpret or alter the substantive criteria by which patentability is

evaluated. *See id.* at 31-32 (discussing *In re Van Ornum*, 686 F.2d 937 (CCPA 1982)); *id.* at 25 ("The Rules [78 and 114] regulate the timing and availability of procedural mechanisms, not the substantive criteria that will be applied in the proceedings."); *id.* at 27-28 ("The Rules [75 and 265] do not address or alter the substantive statutory criteria by which the application will be evaluated to determine whether a patent should issue."). Such a definition of the PTO's rulemaking authority is far too broad.

The "substantive rulemaking" in which the PTO is prohibited from engaging encompasses more than rules interpreting or altering the substantive criteria by which patentability is evaluated—as this Court noted in *Cooper Technologies*, a rule is substantive if it changes "existing law or policy" that affects "individual rights and obligations." *Cooper Technologies*, 536 F.3d at 1336 (internal quotation marks omitted). Furthermore, the Government is wrong in characterizing the effects of the Final Rules on applicants' rights as merely incidental. As described below, the scope and effects of the Final Rules go directly to an applicant's ability to "claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. These Rules represent a sweeping change in existing law and policy regarding continuations and claims practice, and they would have a significant impact on the substantive rights of patent applicants.

The distinction between substantive and procedural rules made in connection with determining the required rulemaking procedures under the Administrative Procedure Act, 5 U.S.C. § 553, provides helpful analytical guideposts here. The characteristics of a substantive rule include whether it has a substantial effect on private parties' rights, whether it manifests the agency's approval or disapproval of a type of action, and whether it represents the agency's normative judgment. *See Chamber of Commerce v. United States Dep't of Labor*, 174 F.3d 206, 211 (D.C. Cir. 1999). Furthermore, a rule imposes more than incidental burdens on a party's rights, and is therefore substantive, if it requires more than compliance with current law. *See id.* at 211-12.

At their core, the Final Rules, as the Government's brief explains, reflect disapproval of the continuations and claims practices that the patent law permits. For example, the Government condemns the practice of using continuation applications to add claims to cover products in the marketplace that fall within the disclosed subject matter. Appellants' Br. 6, 26. Through the Final Rules, the PTO will codify regulations based on its judgment that this practice should be eliminated despite contrary case law from this Court. *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988) ("[T]here is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the

market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application."). This Court has recognized numerous other legitimate reasons for filing continuation applications, which the PTO has decided to curtail as "abusive." *See, e.g., Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005). However, under this Court's precedent, only Congress can make substantive changes to the patent law; the Patent Office lacks the statutory authority to make such changes through rulemaking.

Because of the diversity of BIO's membership and the wide-ranging scope of the technologies with which its members work, it would not be possible to touch on all of the ways the Final Rules will adversely affect the biotechnology industry. Rather, in the following sections, BIO discusses several ways in which the Final Rules represent a significant change in the substantive protection provided by the patent law.

A. The Final Rules Alter Substantive Patent Rights by Severely Limiting Established Continuations and RCE Practice

The Final Rules' substantive impact on patent rights can best be shown by explaining their effect on BIO's members. In most circumstances, biotechnology companies cannot risk delaying the filing of a patent application in order to be sure they can satisfy the PTO's new "could not have previously been submitted

standard" for filing more than two continuations. The proposed standard requires prescience from applicants to know, at filing, which of several disclosed embodiments will be commercially successful, or to delay filing a patent application until further product development work confirms which embodiments hold commercial promise. Despite the Government's attempts to downplay the substantive effect of the Final Rules on patent rights, *see, e.g.*, Appellants' Br. 14, 24 (characterizing the Final Rules as not governing substantive criteria of patentability); *id.* at 31-32, 37-38 (arguing that any infringement on substantive patent rights is merely incidental), the fact is that delays in filing patent applications increase an applicant's risk of losing priority and, therefore, patentability. Furthermore, the competition for investment dollars, and the culture of peer-reviewed publication of research findings in the life sciences, drive biotechnology companies to file patent applications early in the development cycle to protect the invention and to generate interest among, or to satisfy milestones required by, investors. Because of these realities, biotechnology companies properly file applications long before the technology has advanced to clinical trials, manufacturing, or commercialization.

As noted, patentability of biotechnology inventions tends to be more complex than in many other areas. Biotechnology inventions 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 can be discovered only over time and must be 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 learn the claimed invention and relevant prior art, 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 substantive harm to inventions involving 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.

At the time of filing of an initial patent application, a biotechnology company often does not yet know which of several disclosed alternative embodiments of the invention will ultimately be developed commercially. Under the Final Rules, 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. This change to "existing law or policy" simply is beyond the PTO's limited rulemaking authority. *See Cooper Technologies*, 536 F.3d at 1336.

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 indications—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? Should the applicant forgo specific protection for the most promising treatments and instead rely on broad claims that may be more vulnerable to invalidity attacks? In biotechnology, realization of a commercially viable product requires significantly more testing in animals and Food and Drug Administration ("FDA") approval, which are more than what is required for obtaining a patent. *See, e.g.*, *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) ("FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws." (citing *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994))). Because the lengthy animal and human clinical trials are extremely resource-intensive, applicants currently may pursue different products serially over time, using continuations and robust claim sets to cover the various embodiments. The reverse is not possible. Applicants cannot wait until clinical trials are done and then pursue patent protection.

For example, an antibody product initially pursued for treating one type of cancer was later developed for the treatment of other types of cancer. Both indications were disclosed in the initial patent application, and otherwise would have been dedicated to the public if not claimed in continuations. *See Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., Inc.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002)

("[W]hen a patent drafter discloses but declines to claim subject matter, . . . this action dedicates that unclaimed subject matter to the public.") Similarly, other antibodies, developed through clinical trials and initially claimed for the treatment of rheumatoid arthritis, were subsequently pursued for the treatment of other originally disclosed diseases such as Crohn's disease, psoriasis, and sarcoidosis, which had been claimed in continuation applications. However, if the Final Rules had been in place, they may have prevented the biotechnology companies from filing the continuations with claims to such medically valuable uses whose commercial value was not initially pursued.

Development-stage companies need patent protection not only for the initial commercial embodiment of their inventions, whose prosecution may use up the limited continuations available under the Final Rules, but also for commercial embodiments whose importance only becomes clear after investing in additional research and development. As such, the vastly restricted continuations (and claims) practice under the Final Rules robs such companies of much of the flexibility and longevity needed to protect their investigational products and bring their technology to fruition that they currently enjoy. This is precisely the type of substantive impact on patent rights that cannot be affected through PTO rulemaking.

B. The 5/25 Rule Severely Restricts the Ability of Biotechnology Companies to Develop Full Claim Sets

Claims practice under the Final Rules will allow only five independent and twenty-five total claims to be examined per application before an Examination Support Document ("ESD") is required (the "5/25 Rule"). Filing an ESD, however, will simply not be an option for many applicants. The ESD's searching requirement is so vague that applicants can essentially never know whether they are in compliance with it, as noted by Appellees GlaxoSmithKline. GlaxoSmithKline Br. 49-52. Furthermore, the reality of frequent inequitable conduct allegations in life sciences patent litigation will inevitably force patent applicants to choose between abandoning claims or increasing their vulnerability to later unenforceability attack. Thus, the 5/25 Rule also represents a dramatic change to existing patent law and policy, and the District Court correctly concluded that the Rule was beyond the PTO's authority to make.

The 5/25 Rule will prevent a biotechnology applicant from using so-called "genus" and "species" claims to describe their inventions, which they currently can do. 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. However, the Final Rules effectively eliminate the ability of patent applicants to develop such strategies to fully protect their inventions.

Genus and species claims are also 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 licensees 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 method claims. With flexible use of claims (and continuations), specific aspects of the invention each 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. The 5/25 Rule will extend across all co-pending, 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. Thus, the 5/25 Rule effectively prevents applicants from prosecuting *parallel* continuations-in-part ("CIPs") or continuations with any patentably indistinct claim for the purpose of capturing improvements or other aspects of the invention. 72 Fed. Reg. 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 well-meaning applicants who, far from engaging in "unfocused" or "abusive" prosecution tactics, wish to prosecute multiple embodiments 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 non-provisional priority application) is consumed by the time it takes to sequentially prosecute its one or more parent applications. 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, particularly applicants in biotechnology and other high technology areas that require more claims to adequately cover the scope of the invention. These changes clearly are substantive—they alter "existing law or policy" in ways that affect "individual rights and obligations." *Cooper Technologies*, 536 F.3d at 1336 (internal quotation marks omitted). As such, they are beyond the PTO's limited rulemaking authority.

C. The Adverse Effects of the Final Rules Reach Well Beyond Their Immediate Effects on an Applicant's Ability to Patent His Invention

As suggested in the preceding discussion, what happens in the PTO affects biotechnology companies beyond just their immediate ability to obtain a patent. 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 irreversible 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 CIP applications. Because the limitations in the Final Rules related to continuations, CIPs, and claim 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

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

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 FDA review. *See* Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 470, 472 (2007). Biotechnology companies 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 the 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 claim 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 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

[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).

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 claim sets in the Final Rules will limit the patent protection for these discoveries, technology transfers by universities to biotechnology companies will be stifled, thus frustrating the goals of the Bayh-Dole Act, 35 U.S.C. §§ 200-12, and inhibiting innovation, applied research and development, and the development and spread of new technologies.

[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.

III. The Deference for Which the Government Argues Is Inappropriate

As discussed in the preceding section, Congress granted the PTO limited rulemaking authority to issue rules related to the processes by which it grants and issues patents, *i.e.*, "procedural-type" rules. This limited authority is consistent with the PTO's role in implementing the patent statutes—"the granting and issuing of patents," 35 U.S.C. § 2(a)(1)—a largely administrative role.

Congress has given the federal courts, and this Court in particular, a significant role in implementing and interpreting the patent statutes. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996) (noting that one of the reasons that Congress created the Federal Circuit was to increase uniformity in patent law). In terms of the patent prosecution process in the PTO, a disappointed applicant can appeal the decision of the Board of Patent Appeals and Interferences ("BPAI") to this Court. 35 U.S.C. § 141. The decision on appeal governs further proceedings in the PTO. *Id.* § 144. Congress created a private right of action for patent infringement—an important need not met by the PTO—and gave the federal district courts exclusive original jurisdiction over infringement actions, including the power to determine the validity of issued patents and to construe claims. *Id.* § 281; 28 U.S.C. § 1338(a).

In addition, Congress has given applicants a means to obtain a patent regardless of a PTO decision denying a patent. Section 145 creates a civil action

against the Director of the PTO through which applicants can obtain a patent in the United States District Court for the District of Columbia. "An action under [35 U.S.C.] § 145, however, is not merely a form of administrative review." *Takeda Pharm. Co. v. Dudas*, 511 F. Supp. 2d 81, 86 (D.D.C. 2007) (determining patentability of claims rejected in PTO *de novo* in view of new evidence).

Thus, in key respects, the PTO is not like the typical federal administrative agency. First, Congress gives most administrative agencies general rulemaking authority to implement the statutes they are charged with administering. *See Pesquera Mares Australes Ltda. v. United States*, 266 F.3d 1372, 1381 n.6 (Fed. Cir. 2001) (contrasting PTO's lack of substantive rulemaking authority with the Department of Commerce's possession of such authority); *Small v. United States*, 158 F.3d 576, 581 n.1 (Fed. Cir. 1998) (contrasting PTO's lack of substantive rulemaking authority with the Secretary of the Air Force's possession of such authority). An agency can resolve policy issues within the scope of its rulemaking authority. Richard J. Pierce, Jr., ADMINISTRATIVE LAW TREATISE § 3.3, at 143 (4th ed. 2002) ("[P]olicy disputes *within the scope of authority Congress has delegated to an agency* are to be resolved by agencies rather than by courts." (emphasis added)) (discussing *Chevron v. Nat'l Res. Def. Council*, 467 U.S. 837 (1984)). The typical federal agency with broad rulemaking authority thus has a considerable

range of areas in which it can exercise its policy making authority. On the other hand, with its limited rulemaking authority, the PTO has considerably less range.

Second, Congress has given the courts a much more substantial and direct role in implementing the patent statutes than it typically does with respect to other statutes. Typically, the role of the courts is limited to reviewing agency action under the statute. Under the patent statutes, the courts play this role, but they also have jurisdiction to grant patents and determine patent rights. Thus, courts have the critical role of developing substantive patent law where necessary to implement the policy choices made by Congress, as was done, for example, with regard to subject matter eligibility. *See Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (reversing PTO decision affirming examiner's rejection of claims to genetically engineered bacterium, and stating that "Congress intended statutory subject matter to 'include anything under the sun that is made by man'"); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130-31 (1948) (holding invalid claims to a mixture of bacteria reciting that each strain not inhibit any other strain's naturally occurring property); *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998) (holding that a computer algorithm can be patented where it produces "a useful, concrete and tangible result" (internal quotation marks omitted)). But certain policy questions, as the courts have acknowledged, are reserved exclusively for Congress. *See In re Hogan*, 559 F.2d

595, 604 n.13 (CCPA 1977) ("The 24 years of pendency herein may be decried, but a limit upon continuing applications is a matter of policy for the Congress, not for us." (citing *In re Henriksen*, 399 F.2d 253, 262 (CCPA 1968))).

Finally, unlike many other areas of law, Congress has consistently developed patent law based on its own policy judgments, and has directed the PTO accordingly. For example, recent legislation has altered rules to determine patent term and prior art, *inter partes* reexamination procedures, patent application publication, and created provisional applications. *See* Uruguay Round Agreements Act of 1994, Pub. L. No. 103-465, 108 Stat. 4809; American Inventors Protection Act of 1999, Pub. L. No. 106-113, 113 Stat. 1537-44; Intellectual Property and High Technology Technical Amendments Act of 2002, Pub. L. No. 107-273, 116 Stat. 1757-1922; 35 U.S.C. § 103(c).

In its brief, the Government partially recognizes the very limited policy making role of the PTO. *See* Appellants' Br. at 33-34 ("The Court's declaration [in *Merck & Co. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996),] that the USPTO does not have 'any general substantive rulemaking power' and cannot 'issue substantive rules' was not meant to demarcate the precise boundaries of Section 2(b)(2) or its predecessor, but instead conveyed only that the Office does not have a roving commission to make freestanding pronouncements (at least binding ones) regarding the meaning of substantive provisions of the patent statute."). And yet,

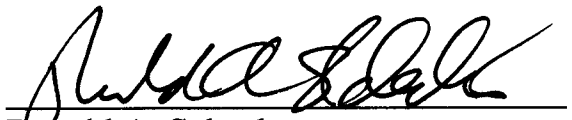
the Government argues for substantial deference as if the PTO were like other federal agencies with broad rulemaking and policy making authority. But, as discussed above, this Court has repeatedly held that it lacks substantive rulemaking authority. Furthermore, Congress has given the PTO a limited role in implementing the patent statutes, and has given the federal courts a much broader role. Accordingly, the substantial deference for which the Government argues is inappropriate.

CONCLUSION

For the foregoing reasons, the district court decision in this case should be affirmed.

Respectfully submitted,

October 3, 2008



Ronald A. Schechter
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington D.C. 20004
Tel: (202) 942-5160
Fax: (202) 942-5999
Attorney for *Amicus Curiae*
Biotechnology Industry Organization

David R. Marsh
Matthew M. Shultz
Kristan L. Lansbery
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington D.C. 20004
Tel: (202) 942-5000
Fax: (202) 942-5999
Of Counsel for *Amicus Curiae*
Biotechnology Industry Organization

FORM 19. Certificate of Compliance With Rule 32(a)

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) or FRAP 28.1(e).

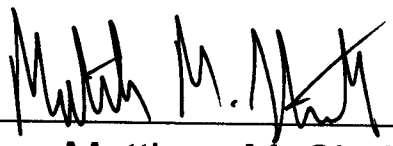
☑ The brief contains [*6,041*] words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii), or

☐ The brief uses a monospaced typeface and contains [*state the number of*] lines of text, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or FRAP 28.1(e) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6).

☑ The brief has been prepared in a proportionally spaced typeface using
[*Microsoft Word 2003*] in
[*14 point Times New Roman Font*], or

☐ The brief has been prepared in a monospaced typeface using
[*state name and version of word processing program*] with
[*14 point Times New Roman Font*].

(s) 

Matthew M. Shultz
(Name of Attorney)

Amicus, Biotechnology Industry Organization
(State whether representing appellant, appellee, etc.)

October 3, 2008
(Date)

CERTIFICATE OF SERVICE

I certify that 12 true and correct copies, with one original, of the attached Brief of *Amicus Curiae* Biotechnology Industry Organization were sent on October 3, 2008 by hand delivery, for filing to the following:

Jan Horbaly, Clerk
United States Court of Appeals
for the Federal Circuit
717 Madison Place, N.W., Room 401
Washington, DC 20439

I further certify that two true and correct copies of the attached Brief of *Amicus Curiae* Biotechnology Industry Organization were sent by Federal Express, overnight delivery, on October 3, 2008 to each of the following attorneys of record and pro se *amicus* at the addresses below:

Christopher Mizzo
Kirkland & Ellis LLP
655 15th Street, N.W.
12th Floor
Washington, DC 20005
(202) 879-5000
(202) 879-5200 (fax)

Counsel for Plaintiff - Appellees Glaxo Group Limited, SmithKline Beecham Corp., SmithKline Beecham PLC

Joshua Waldman
U.S. Department of Justice
950 Pennsylvania Ave., N.W.
Room 7232
Washington, D.C. 20530

Counsel for Defendants - Appellants Jon W. Dudas, Under Secretary of Commerce for Intellectual Property; United States Patent and Trademark Office

Steven J. Moore
Kelley, Drye &Warren LLP
400 Atlantic Street
Stamford, CT 06484
(203) 324-1400
(203) 327-2669 (fax)

Counsel for Plaintiff - Appellee Triantafyllos Tafas

Daniel B. Ravicher
Public Patent Foundation
1375 Broadway, Suite 600
New York, NY 10018
(212) 545-5337
(212) 591-6038 (fax)

Counsel for Amicus AARP; Computer & Communications Industry Assoc., Consumer Watchdog; Essential Action; Initiative for Medicines, Access and Knowledge; Prescription Access Litigation; Public Knowledge; Public Patent Foundation; Research on Innovation; Software Freedom Law Center

Mark A. Lemley
Stanford Law School
559 Nathan Abbott Way,
Stanford, CA 94605-8610
(650) 725-2749

Counsel for Amicus Intellectual Property and Administrative Law Professors

Mark Fox Evens
Thelen, Reid & Priest, LLP
701 Eighth Street, NW
5th Floor
Washington, DC 20001-3721

Counsel for Amicus AmberWave Systems, Corp; Fallbrook Technologies Inc.; InterDigital Communications LLC; Nano-Terra Inc.; Tessera, Inc.

Robert Christian Bertin
Swidler Berlin LLP
3000 K Street, NW
Suite 300
Washington, DC 20007-5116
(202) 373.6672
r.bertin@bingham.com

Counsel for Amicus Bar Association of the District of Columbia

Dawn-Marie Bey
King & Spalding LLP
1700 Pennsylvania Avenue
Suite 200
Washington, DC 20006
(202) 626-8978
(202) 626-3737 (fax)
dbey@kslaw.com

Counsel for Amicus Hexas, LLC; The Roskamp Institute; Tikvah Therapeutics, Inc.

Scott Jeffrey Pivnick
Pillsbury Winthrop Shaw Pittman LLP
1650 Tysons Blvd., Suite 1400
McLean, VA 22102
(703) 770-7864
scott.pivnick@pillsburylaw.com

Counsel for Amicus Elan Pharmaceuticals, Inc.

James Murphy Dowd
Wilmer Cutler Pickering Hale & Dorr LLP
1455 Pennsylvania Avenue, NW
Washington, DC 20004
(202) 942-8400
james.dowd@wilmerhale.com

Counsel for Amicus Pharmaceutical Research and Manufacturers of America

Craig James Franco
Odin Feldman & Pittleman PC
9302 Lee Highway
Suite 1100
Fairfax, VA 22031
(703) 218-2100
craig.franco@ofplaw.com

Counsel for Polestar Capital Associates, LLC; Norseman Group, LLC

Robert C. Gill
Saul Ewing LLP
2600 Virginia Avenue, NW
Suite 1000
Washington, DC 20037
(202) 337-8800
(202) 295-6705 (fax)
rgill@saul.com

Counsel for Amicus BioAdvance; Pittsburgh Life Sciences Greenhouse; Life Sciences Greenhouse of Central Pennsylvania

Charles Gorenstein
Birch Stewart Kolasch & Birch LLP
8110 Gatehouse Road
P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000
cg@bskb.com

Counsel for Amicus William Mitchell College of Law
Intellectual Property Institute of William Mitchell College of Law

Kevin Michael Henry
Sidley Austin Brown & Wood LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000
khenry@sidley.com

Counsel for Amicus Washington Legal Foundation

Jonathan Dyste Link
Townsend and Townsend and Crew LLP
1301 K Street, NW
9th Floor, East Tower
Washington, DC 20005
(202) 481-9900
(202) 481-3972 (fax)
jlink@townsend.com

Counsel for Amicus CFPH, LLC

David Wayne Long
Howrey Simon Arnold & White LLP
1299 Pennsylvania Avenue, NW
Washington, DC 20004
(202) 783-0800
longd@howrey.com

Counsel for Amicus Teles AG Informationstechnologien

Timothy A. Molino
Bingham McCutchen LLP
2020 K Street, NW
Washington, DC 20006
(202) 373-6161
(202) 373-6001 (fax)
timothy.molino@bingham.com

Counsel for Amicus Federation Internationale Des Conseils En Proprit Industrielle

Maurice Francis Mullins
Spotts Fain PC
411 E. Franklin Street
Suite 600
P.O. Box 1555
Richmond, VA 23218-1555
(804) 697-2069
(804) 697-2169 (fax)
cmullins@spottsfain.com

Counsel for Amicus Micron Technology, Inc.

Thomas J. O'Brien
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 739-5186
(202) 739-3001 (fax)
to'brien@morganlewis.com

Counsel for Amicus American Intellectual Property Law Association

Robert Emmett Scully, Jr.
Stites & Harbison, PLLC
1199 North Fairfax Street
Suite 900
Alexandria, VA 22314
(703) 739-4900
(703) 739-9577 (fax)
rscully@stites.com

Counsel for Human Genome Sciences, Inc.

Blair Elizabeth Taylor
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-7566
(202) 662-5669
(202) 778-5669 (fax)
btaylor@cov.com

Counsel for Intellectual Property Owners Association

Jackson David Toof
Arent Fox LLP
1050 Connecticut Avenue, NW
Washington, DC 20036-5339
(202) 857-6000
(202) 857-6395 (fax)
toof.jackson@arentfox.com

Counsel for Amicus Anchor Wall Systems, Inc.; Donaldson Company, Inc.; Ecolab Inc.; General Mills, Inc.; Valspar Corporation

John C. Maginnis, III
Maginnis Law Office
1350 Connecticut Avenue, N.W.,
Suite 301
Washington, DC 20036
(202) 659-4420
(202) 775-2463 (fax)
Maginnislaw2@verizon.net

Counsel for Amicus CropLife America

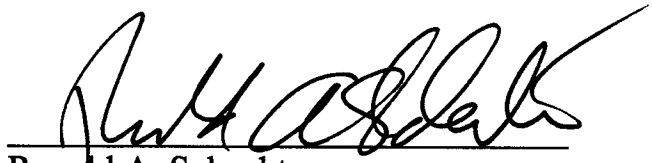
Ron D. Katznelson, Ph.D.
Bi-Level Technologies
1084 Valley Side Lane
Encinitas, California 92024
(760) 753-0668

Pro se Amicus

I further certify that two true and correct copies of the attached Brief of *Amicus Curiae* Biotechnology Industry Organization were sent by Federal Express, International Priority service, on October 3, 2008 to the following pro se *amicus* at the address below:

Robert Lelkes
Geigenbergerstr. 3
81477 Munich
Germany

Pro se Amicus



Ronald A. Schechter
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington D.C. 20004
Tel: (202) 942-5160
Fax: (202) 942-5999
Attorney for *Amicus Curiae*
Biotechnology Industry Organization