No. 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, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent & 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

AMICUS CURIAE BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF APPELLEES

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October 3, 2008

CERTIFICATE OF INTEREST

Counsel for amicus curiae the Pharmaceutical Research and Manufacturers of America certifies the following:

1. The full name of every party or amicus represented in this appeal is:

Pharmaceutical Research and Manufacturers of America ("PhRMA")

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:

The party listed above is the real party in interest.

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:

PhRMA has no parent corporation, and no publicly held company owns 10% of more of its stock. PhRMA is a membership organization, however, and its members include companies that have issued stock or debt securities to the public. A list of PhRMA's members follows this certificate.

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:

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Dated: October 3, 2008

PHRMA MEMBERS

MEMBERS

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Bayer HealthCare Pharmaceuticals

Boehringer Ingelheim Pharmaceuticals, Inc.

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Takeda Pharmaceuticals North America, Inc.

Valeant Pharmaceuticals International

Wyeth
Wyeth Pharmaceuticals
Wyeth Research

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STATEMENT OF INTEREST OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a non-profit organization representing the country's leading pharmaceutical and biotechnology research companies. PhRMA serves as the pharmaceutical industry's principal policy advocate, advancing public policies that foster continued medical innovation.[1]

Developing new drugs and taking them through clinical trials and the rigorous regulatory approval process is a time-consuming, expensive, and financially risky enterprise. In 2007 alone, PhRMA members invested an estimated $44.5 billion in discovering and developing new medicines. *See* http://www.phrma.org/about_phrma. A 2004 Department of Commerce study estimated that the average cost of bringing a new drug to market is approximately $1.3 billion, including the costs for unsuccessful drugs.[2] Another study notes that it takes approximately sixteen years to bring a new chemical entity to market and that "only a fraction of drugs in the R&D 'pipeline' ever succeed in making it to

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[1] A list of PhRMA members, including plaintiff-appellee GlaxoSmithKline, can be found above with PhRMA's Certificate of Interest.

[2] *See* U.S. Dep't of Commerce, Int'l Trade Admin., *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation* 30-31 (Dec. 2004), *available at* http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf.

market."[3] The patent laws reflect Congress's determination that the protections and corresponding incentives they provide are essential to encouraging costly, time-consuming, and high-risk research and development.

All parties have consented to the filing of this brief.

INTRODUCTION

Congress has authorized the Patent and Trademark Office (PTO) to promulgate certain procedural rules, but it has retained for itself the authority to fashion substantive patent law. The district court held that the PTO lacked authority to promulgate the "Final Rules" under review—which limit the number of continuation applications, requests for continued examination (RCE), and claims that an applicant may file in the ordinary course—because they are substantive. That conclusion was correct for at least two reasons.

First, as the district court concluded, the Final Rules are substantive because they change pre-existing law in a way that affects the rights of patent applicants. As explained below, the Final Rules are contrary to sections 120 and 112 of the Patent Act. Indeed, because the rules not only represent a change in the law, but are also inconsistent with the Patent Act, they are contrary to law under § 706 of the Administrative Procedure Act (APA).

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[3] Giaccotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & Econ. 195, 196 & n.2 (2005).

Second, the Final Rules are substantive because they have the effect of altering the careful balance of intellectual property protection enacted by Congress in the patent laws. The rules, if allowed to stand, would substantially erode longstanding patent prosecution law and would, for the first time, significantly impede the ability of patent applicants to file as many continuation applications and claims as necessary to protect their inventions. The substantive impact of the Final Rules is well illustrated by their effect on inventors of new pharmaceutical products. The rules that existed prior to the Final Rules helped to ensure that those who were willing to undertake the painstaking and financially risky process of developing and bringing to market new drugs could do so with the knowledge and confidence that, if successful, they would obtain the rewards that come with patent protection. These rights—altered by the Final Rules—are a critical element of the structure that encourages the commitment of the enormous resources required to develop new drugs and thereby advance the public health.

ARGUMENT

I. THE PTO'S FINAL RULES WOULD SUBSTANTIALLY REDUCE THE SCOPE OF PATENT PROTECTION FOR NEW INVENTIONS

To determine whether the challenged rules exceed the PTO's rulemaking authority or are contrary to the Patent Act, it is necessary to consider the significant impact that the rules will have on inventors. The impact of the rules on the pharmaceutical industry is illustrative.

A. The Limit On Continuations Would Significantly Impair Patent Rights Of Pharmaceutical Companies

In the pharmaceutical industry, continuation practice is essential. Given the enormous expense and risk involved in developing new drugs, once a potentially valuable compound is discovered, the company cannot put off filing an application; such a delay could risk that prior art, such as the publication of an article, would preclude the company from obtaining patent protection. On average, it takes approximately 15 years to develop and bring a new drug to market. Early in this process, pharmaceutical companies will often identify a group of related promising drug candidates (a "genus" of compounds) to include in a patent application. This application sets the priority date for all the compounds disclosed in the application and provides the inventor with protection against various statutory bars to patentability.

At this early stage, the commercially relevant aspect of an invention is often uncertain, and it may not become clear until much later in the regulatory process, even after testing has taken place or the invention is initially commercialized. Thus, inventors often need to file a patent application with a broad disclosure of a genus of compounds and known species, with the plan to prosecute a patent for one disclosed compound and then prosecute patents for additional compounds from that genus as necessary.

Continuation practice allows applicants to prosecute claims for these alternate compounds and is thus critical to pharmaceutical companies. Indeed, a continuation application is generally the only means to seek a patent for the compounds disclosed but not claimed in the original application. The applicant could not obtain a patent simply by filing a new application because the new application would not be entitled to the earlier filing date. Without the earlier filing date, publications and other prior art between the original filing date and the new application date—including the publication of the original application itself—could pose an insurmountable obstacle to patentability. Absent the availability of continuation applications, patent applicants and the public could lose the benefit of important medicines because the applicants might not take on the costs and risks of development absent the patent's promise of some period of exclusivity.

Even beyond the vital pursuit of patents for additional compounds within a genus disclosed in a previously-filed application, continuation applications play a number of other critical roles. For example:

Filing a continuation to preserve remaining claims. Often an examiner will allow certain claims but not all claims. Continuation applications offer applicants the ability to pursue the remaining claims while also obtaining a patent on allowed claims. This ability to proceed along two tracks is important. It allows a company,

for example, to obtain patent rights on portions of an invention, which the company can then use to help finance further development.

Submission of data in support of nonobviousness. If the examiner rejects a claim as obvious, the applicant can argue that the examiner is incorrect in light of the art or the law or the applicant can submit additional evidence, including data addressing objective or "secondary" considerations showing non-obviousness, such as commercial success, skepticism or praise for the invention, or acceptance (in the form of licenses). *Graham v. John Deere Co. of Kan.*, 383 U.S. 1, 17-18 (1966); *see also, e.g.*, 2 Chisum, *Chisum on Patents* § 5.05 (2007) (discussing secondary considerations). If the applicant decides to argue that the examiner is wrong and receives a final rejection, then any such evidence of objective and/or secondary considerations can only be considered if the applicant is allowed to file a continuation application or RCE. This data can take time to collect.

Submission of data required by the patent examiner to confirm usefulness or effectiveness. The PTO may, at times, decide that an application did not include sufficient data to support the usefulness of the claims. *See generally* Manual of Patent Examining Procedure § 2107 (8th ed. 2001). Obtaining data supporting patentability may require more time than that provided to the applicant to respond.

If so, the applicant can use a continuation application or RCE to provide the supplemental data.

Filing an information disclosure statement. At any time during patent prosecution, additional prior art (such as articles, papers, patents, or other products) may come to the attention of the applicant. The applicant has a continuing duty to disclose material information to the PTO. But the examiner, after certain points in the prosecution, need not consider the submitted prior art. The solution is often to re-file as a continuation or RCE and to disclose the reference at the start of the continued prosecution.

Triggering an interference. In order to trigger an interference, the interfering claims should correspond exactly or substantially. If patent prosecution has ceased after final office action, the applicant cannot, as of right, have claim amendments entered into the application. The way to trigger an interference under these circumstances is to file a continuation application and to copy or substantially copy the claims from the competing application into the new application. Pharmaceutical companies are in a constant race to develop new products, and thus interferences are critical to determine proper inventorship.

Allowing a subsequent assignee or exclusive licensee to seek a continuation. Often, government and non-profit organizations, including universities, engage in pharmaceutical research. These entities may license their inventions to others in

exchange for funding for more research. The licensees, however, may be focused on particular aspects of the invention and will need to ensure that the corresponding claims are prosecuted. This may mean that the licensee must add, or have the licensor add, additional claims.

Under the Final Rules, applicants' ability to use continuations in these important ways would be dramatically undercut. In most, if not all, of the scenarios described above, the PTO might well determine that in some sense the applicant "could" have submitted the amendment, argument, or evidence earlier, rendering a "petition" for relief from the cap unavailing.

Indeed, the PTO has made clear that it will not permit successive continuation applications in many circumstances where they previously have performed a critical role. *See, e.g.*, 72 Fed. Reg. 46,716, 46,772-46,777 (Aug. 21, 2007). In the commentary accompanying the Final Rules, for example, the PTO noted that it "is not likely to grant a petition" where "some of the claims in the prior application are rejected and other claims are allowed, and [the] applicant wishes to appeal the rejected claims and obtain a patent on the allowed claims." *Id*. at 46,774. The PTO also indicated that it "will likely not grant . . . a petition [for relief from the cap] for submitting an information disclosure statement (IDS) or an amendment necessitated by (or in view of) newly discovered prior art." *Id*. at 46,773.

Likewise, the PTO stated that it is doubtful that the exception can be satisfied where an applicant seeks (1) to "file broader claims, when [the] applicant recently discovered a limitation in an allowed claim that was unduly limited," (2) to "pursue broader claims, or claim aspects of the invention that are disclosed, but not claimed, in the prior-filed application," (3) to provoke an interference, (4) to "correct the inventorship of the application due to information discovered after prosecution of the application has closed," or (5) to show that "clinical trials indicate the previously unclaimed subject matter may be useful." 72 Fed. Reg. at 46,774-46,776. Thus, by imposing a cap of two continuations, the Final Rules would have a significant impact on the ability of pharmaceutical companies and other patent applicants to obtain essential patent protection.

Changes to the continuation rules, moreover, are not needed to create incentives for patent applicants to proceed with expedition. In 1994, Congress amended the Patent Act to change the term of patents from seventeen years from issuance of the patent to twenty years from the filing of the patent application. *See* Pub. L. No. 103-465 § 532, 108 Stat. 4809, 4984 (1994). For patents subject to this rule that issue from continuation applications, the term runs from the filing of the initial application. *See* 35 U.S.C. § 154(a)(2). For this reason, patent

applicants have every incentive to expedite issuance of their patents.[4] Indeed, instead of creating this incentive, the harsh and risky consequences of the Final Rules will inevitably cause applicants to delay filing an application in the first place, with a consequent chilling effect on the disclosure of scientific information that would provide the basis for future innovation.[5]

B. The Limitation On Claims Would Undermine Inventors' Ability To Fully Protect Their Inventions

Imposing arbitrary limits on the number of claims that an inventor may include, without undertaking the risk and burden of preparing an Examination Support Document (ESD), would also substantially alter patent prosecution law and practice. It would have particularly harsh consequences for pharmaceutical manufacturers.

New pharmaceutical and biotechnology inventions are extremely complex and multifaceted: "The very nature of pharmaceutical and biotechnology inventions dictates a number of useful embodiments." May 3, 2006 Comments of

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[4] The fact that a pharmaceutical patent has, on occasion, been held invalid, *see* Br. of Amici Curiae Pub. Patent Found. et al. 20-21, 25-26 (citing two cases), is of course no reason to conclude that pharmaceutical companies "repeatedly" assert invalid patents, much less that they "abuse[]" existing patent prosecution procedures.

[5] Nor can the Final Rules be defended on efficiency grounds; continuation practice plays a vital role in the patent approval process by providing the patent examiners with opportunities to become more educated about an application, leading to better patents and, in turn, a more efficient process.

Amylin Pharmaceuticals, Inc. at 1.[6] A single composition "may be useful to treat several indications, be formulated for different modes of administration, have different dosing regimes, and alternative means of manufacture." *Id.* A single innovation "may encompass numerous variants each with its own set [of] useful properties." *Id.* The PTO noted that another commenter observed that "in chemical or pharmaceutical applications full protection requires [an] applicant to claim a chemical substance, a composition containing the substance, [the] method of making the substance, the chemical substance prepared by a claimed process and at least one method of use, where there is varying scope within each category of invention." 72 Fed. Reg. at 46,788.

Because pharmaceutical inventions are so complex, "[a] biopharmaceutical applicant . . . often needs more than 10 *independent* claims . . . to protect complex, multi-faceted inventions." May 3, 2006 Comments of Maxygen, Inc. at 16 (emphasis added). For this reason, pharmaceutical companies commenting on the proposed rules urged the PTO to *increase* the number of claims permitted, rather

[6] Comments on PTO's proposed claim limitation rule can be accessed at http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_claims/claims_comments.html.

than follow through with its plan to lower the number of independent claims permitted. *See id.* at 17; May 3, 2006 Comments of Pfizer Inc. at 4.[7]

Under the Final Rules, however, a patent applicant may exceed five independent claims or twenty-five total claims only if it files an ESD. 37 C.F.R. § 1.75(b)(1). In light of the increased risks that would be incurred by complying with the broad and vague requirements for filing an ESD, this "option" is illusory, leaving the applicant covered by the claim limitations. The Final Rules impose the following obligations:

> An examination support document must include a pre-examination search statement, a listing of references deemed most closely related to the subject matter of the claims, an identification of all of the claim limitations that are disclosed in the references, a detailed explanation particularly pointing out how each of the independent claims is patentable over the cited references, and a showing of where each claim limitation finds support under 35 U.S.C. 112, ¶ 1, in the application and any prior-filed application.

72 Fed. Reg. at 46,718.

The required "pre-examination search" is particularly onerous. The Final Rules specify that the search "must involve U.S. patents and patent application publications, *foreign patent documents*, and *non-patent literature*." 37 C.F.R § 1.265(b) (emphasis added). Moreover, the search "must be directed to the

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[7] Although it is possible that the PTO will issue restriction requirements, mitigating the consequences of the limits on the number of claims, the applicant will have no way of knowing at the outset what the PTO will do and, in any event, the restrictions may not sufficiently divide the claims to make the claim limit feasible.

claimed invention and encompass all of the limitations of each of the claims (whether in independent or dependent form), giving the claims the broadest reasonable interpretation." *Id.* Despite the fact that foreign patent documents must be searched, an applicant is not entitled automatically to rely on a foreign patent office's search report. *See* 72 Fed. Reg. at 46,742.

As the head of GlaxoSmithKline's intellectual property department explained before the district court, under this regulation it is possible that an applicant must search *all* foreign patent documents (even if that requires searching *manually*) as well as perform manual searches in university libraries to find "non-patent literature." Decl. of Sherry M. Knowles in Support of Pl.'s Mot. for a TRO and Prelim. Inj. ¶ 47 (Oct. 15, 2007) (A1562-A1563). The PTO's response, moreover, provided little reassurance: PTO confirmed that "the areas where the most closely related art is likely to be found" must be "included within the search," regardless of whether that would require manual searches in foreign patent offices and universities in any part of the world. Decl. of Andrew I. Faile ¶¶ 7, 23 (Oct. 26, 2007) (A1094-A1095, A1099-A1103). The PTO also confirmed the sweeping scope of the phrase "non-patent literature": It includes all "printed matter that is not a patent document." *Id.* ¶ 23 (A1099-A1103).

An applicant submitting an ESD must also run the risk that it will face claims that its patent is unenforceable on the basis of "inequitable conduct."

Twenty years ago, this Court observed that "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague." *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). Unfortunately, often-meritless charges of inequitable conduct persist. *See* Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 Berkeley Tech. L.J. 147, 148 (2005) ("The practice of asserting a defense of inequitable conduct, regardless of the merits of the defense in a given case, has reached the breaking point.").[8]

In light of the frequency of baseless inequitable conduct allegations, simply filing a document as intricate as an ESD poses enormous risks, creating a severe disincentive to exercising this supposed "option," making the PTO's claim limitations rule an absolute (or near absolute) restriction in practice.

II. THE CHALLENGED RULES ARE IN EXCESS OF THE PTO'S AUTHORITY AND CONTRARY TO LAW BECAUSE THEY ARE INCONSISTENT WITH THE PATENT ACT

The Final Rules are both beyond the PTO's authority under 35 U.S.C. § 2(b)(2) and "contrary to law" under the APA because they violate provisions of the Patent Act.

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[8] *See also* Hanft & Kerns, *The Return of the Inequitable Conduct Plague: When "I Did Not Know" Unexpectedly Becomes "You Should Have Known,"* 19 No. 2 Intell. Prop. & Tech. L.J. 1 (2007).

A. The District Court Correctly Concluded That The PTO Lacks Authority To Promulgate "Substantive" Rules That Change Existing Law And Affect Individual Rights

1. This Court in *Merck & Co. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996), held that the PTO lacks "substantive" rulemaking authority under 35 U.S.C. § 2(b)(2):

> As we have previously held, the broadest of the PTO's rulemaking powers—35 U.S.C. § 6(a) [the predecessor to § 2(b)(2)]—authorizes the Commissioner to promulgate regulations directed only to "the conduct of proceedings in the [PTO]"; it does NOT grant the Commissioner the authority to issue substantive rules. *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 930 [] (Fed.Cir. 1991).

80 F.3d at 1549-1550 (emphasis in original). In *Animal Defense Fund*, the Court had noted that a "substantive declaration with regard to the Commissioner's interpretation of the patent statutes" does not fall within the agency's authority to regulate the "conduct of proceedings" before the office. 932 F.3d at 930. In finding that the PTO acted in excess of its authority, the district court here simply followed these controlling precedents. *Tafas v. Dudas*, 541 F. Supp. 2d 805, 811-813 (E.D. Va. 2008).

The PTO now contends that *Merck* "has little bearing on the issues of rulemaking authority in this case" because in that case the PTO supposedly "was not engaged in rulemaking at all." Br. for Appellants 32; *see also id.* at 23. But the PTO offers no explanation why the determination at issue in *Merck*—published at 60 Fed. Reg. 30,069 (June 7, 1995)—was not a rule. The determination was

issued after notice and comments. *See* 60 Fed. Reg. at 30,069; 60 Fed. Reg. 15,748 (Mar. 27, 1995) ("Request for comments"). And it set forth "an agency statement of general . . . applicability and future effect designed to implement, interpret, or prescribe law or policy," 5 U.S.C. § 551(4) (defining "rule")—namely, a rule for calculating the expiration date of a class of patents subject to extension under both the Hatch-Waxman Act and the Uruguay Round Agreements Act. *See* 60 Fed. Reg. at 30,069; *Merck*, 80 F.3d at 1546.

The district court's conclusion that the PTO lacks authority to promulgate substantive rules finds further support in this Court's recent decision in *Cooper Technologies Co. v. Dudas*, 536 F.3d 1330 (Fed. Cir. 2008). In that case, this Court gave deference to the position taken by the PTO in a rule governing inter partes reexamination before the office. In concluding that deference was owed to this procedural rule, the Court first confirmed that "[t]o comply with section 2(b)(2)(A), a Patent Office rule must be 'procedural.'" *Id.* at 1335. Citing *Merck*, the Court explained: "We have also previously held that 35 U.S.C. § 2(b)(2) does not authorize the Patent Office to issue 'substantive' rules." *Id.* at 1336.[9]

2. In determining whether the Final Rules were "substantive," the district court asked whether they "change[d] existing law and alter[ed] the rights of

[9] *In re Van Ornum*, 686 F.2d 937 (C.C.C.P. 1982), is not to the contrary. As the court explained in that case, the requirement adopted by the PTO to implement terminal disclaimers was, in fact, already assumed by the case law. *See id.* at 948.

applicants." 541 F. Supp. 2d at 814. The PTO asserts that this is the standard for distinguishing between substantive and *interpretive* rules, not *procedural* rules. Br. for Appellants 34-36. But that contention is belied by this Court's decision in *Cooper Technologies*. There, the Court applied the same test as the district court for purposes of determining the reach of the PTO's authority under § 2(b)(2):

> We have previously held that 35 U.S.C. § 2(b)(2) does not authorize the Patent Office to issue "substantive" rules. . . . "A rule is 'substantive' when it 'effects a change in existing law or policy' which 'affect[s] individual rights and obligations.'" *Animal Legal Def. Fund*, 932 F.2d at 927[].

536 F.3d at 1336. That the procedural rule at issue in *Cooper Technologies* was an "interpretative" rule, and that this Court contrasted "interpretative" rules of this type to "substantive" rules, does not change the fundamental fact that the PTO lacks authority to promulgate rules that "change in existing law or policy" and that "affect individual rights." *Id.*

The PTO argues that it is entitled to promulgate procedural rules that "change the law." Br. for Appellants 35. If the PTO means simply that it may amend its own procedural rules, that is, of course, correct. But, as explained below, the Final Rules do not merely alter previously issued PTO procedural regulations. They impose significant new constraints on the ability of patent applicants to obtain protection for their inventions, and they contradict statutes

enacted by Congress and judicial decisions interpreting those provisions. For that reason, they exceed the PTO's authority.

B. The District Court Correctly Determined That The Final Rules Are Contrary To The Patent Act

The district court correctly concluded that both of the principal Final Rules—the limit on continuations and on claims—are contrary to the Patent Act. Accordingly, the rules necessarily "change existing law," and indeed are "contrary to law."

1. The Rules Concerning Continuation Applications Are Contrary To The Plain Language Of Section 120 Of The Patent Act

Under the plain language of the Patent Act, the PTO may not impose the arbitrary limits on continuation applications provided for in the Final Rules. Section 120 of the Patent Act provides in relevant part:

> An application for patent for an invention disclosed in . . . an application previously filed . . . , which is filed by an inventor or inventors named in the previously filed application *shall have the same effect*, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 120 (emphasis added). Thus, as the district court explained, under the statute, continuation and continuation in part applications "'shall have' the benefit of the priority date of the initial application." 541 F. Supp. 2d 814. The law

imposes no numerical limits, but rather affirmatively contemplates the filing of multiple continuation applications. So long as the statutory requirements are met, the applicant is due the benefit of the earlier filed application.

Contrary to the PTO's assertions, the case law confirms this plain-language reading of § 120. In *In re Henriksen*, 399 F.2d 253 (C.C.P.A. 1968), the Court of Customs and Patent Appeals rejected an effort of the PTO to restrict an applicant to a sequence of no more than three applications: "there is no statutory basis for fixing an arbitrary limit to the number of prior applications" that may be filed and retain the benefit of the priority date. *Id*. at 254. The *Henriksen* court looked to the language of the statute, the legislative history (indicating that § 120 was intended to codify pre-existing case law), and prior case law, treatises, and practice establishing that prior to the enactment of the statutory provision in 1952, the applicant was not limited to three applications. *Id*. at 256-260.

Seeking to avoid the consequences of *Henriksen,* the PTO argues that *In re Bogese II*, 303 F.3d 1362 (Fed. Cir. 2002), limits *Henriksen*'s holding to the proposition that §120 does not itself cap the number of continuation applications that may be filed. But *Bogese II* merely concluded that the PTO could rely on prosecution laches to reject an application. And *Bogese II*'s discussion of *Henriksen* actually reinforces the problems with the Final Rules' approach; the court distinguished *Henriksen* on the ground that, in applying the doctrine of

prosecution laches to the case at hand "the PTO did not adopt a mechanical rule based on a misconstruction of the [Patent Act]." *Id.* at 1368 n.6. The Final Rules, however, are not an individualized application of prosecution laches, but rather precisely the sort of "mechanical bar" that is not permitted under either *Henriksen* or *Bogese II*.

The PTO's attempts to show that the Final Rules do not impose absolute limits merely highlight how mechanical the Final Rules are. The PTO argues (Br. 42-43) that because an applicant can "petition" for the right to file additional continuation applications, the rule is flexible in its application. The PTO's interpretation of the standard for succeeding on such a petition, however, ensures that the Final Rules do impose very real limits. To exceed the default limits, an applicant must file a petition explaining why the "amendment, argument, or evidence sought to be entered *could not have been submitted* during the prosecution of the prior-filed application." 72 Fed. Reg. at 46,839 (emphasis added). But, as discussed above, the PTO's response to comments demonstrates that the "could not have been submitted" requirement will impose a significant barrier on typical continuation practice. Thus, the district court properly found that the "standard of the petition and showing requirement effectively imposes a hard limit on additional applications." 541 F. Supp. 2d at 815.

Because the petition provision offers little hope of mitigating the harsh consequences of the PTO's mechanical limits on continuation applications, the Final Rules would deprive applicants of their statutory right to file as many continuation applications as necessary to obtain fair and complete patent protection. This would go well beyond the case-by-case application of prosecution laches that was approved in *Bogese II*.

2. The Patent Act Does Not Permit The PTO To Limit The Number Of Claims That May Be Filed In The Ordinary Course

The Patent Act does not authorize the PTO to limit the number of claims a patent applicant may file. Section 112 of the Act provides, without limitation, that the specification in a patent application "shall conclude with *one or more* claims." 35 U.S.C. § 112 (emphasis added). Applying § 112, the Court of Customs and Patent Appeals has concluded that "an applicant should be allowed to determine the necessary number and scope of his claims, provided he pays the required fees and otherwise complies with the statute." *In re Wakefield*, 422 F.2d 897, 900 (C.C.P.A. 1970). Indeed, as the district court observed, 541 F. Supp. 2d at 816, this has been the Court of Customs and Patent Appeals' view since 1938. *See In re Clark*, 97 F.2d 628, 631 (C.C.P.A. 1938). The Final Rules, which impose arbitrary limits on the number of claims, thus find no authorization in the governing or controlling statutes or case law.

The PTO contends that the Final Rules are not contrary to § 112 or the case law because they do not impose an absolute limit on the number of claims that may be filed, since applicants can provide an Examination Support Document (ESD) if they wish to file additional claims. However, as the district court found, in practice the claim limitation rule "imposes a mechanical limit" providing an absolute (or near-absolute) bar. 541 F. Supp. 2d at 816; *see also supra* pp. 12-14.

Prior to the promulgation of these rules, it was well established that a patent applicant has "'no duty to conduct a prior art search.'" *Frazier v. Roessel Cine Photo Tech., Inc.*, 417 F.3d 1230, 1238 (Fed. Cir. 2005) (quoting *FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 526 n. 6 (Fed. Cir. 1987)). The decision to deviate from this settled rule and to expose applicants to the increased risk of claims of inequitable conduct associated with filing an ESD cannot be justified as a mere procedural rule. Thus, the district court concluded that "the ESD requirement changes existing law and alters the rights of applicants under the current statutory scheme by shifting the examination burden away from the USPTO and onto applicants." 541 F. Supp. 2d at 816.

Finally, the PTO's reliance on *In re Rubinfield*, 270 F.2d 391 (C.C.P.A. 1959), is misplaced. As the court explained in that case, imposing a one-claim limit on *design* patents has no substantive impact. S*ee id.* at 395-396. A design patent can involve only a single inventive concept, which can be protected by a

single claim. The same cannot be said of the claims limits at issue here—the inventive concepts in a utility application typically require numerous claims and thus the limits have a substantive impact.

C. The Final Rules Affect The Rights Of Patent Applicants

As explained in detail in Section I above, the Final Rules affect the rights of patent applicants. By sharply limiting the number of continuations and claims that may be filed as a matter of course, the rules impair the ability of inventors to protect the full scope of their inventions. Moreover, notwithstanding the "petition" provision, the new PTO limit on continuation applications would foreclose applications currently available to inventors in a number of different situations. Likewise, due to the extreme burden and risk associated with filing an ESD, the new claim limit would also substantially impair patent protection.

III. THE FINAL RULES ARE ALSO SUBSTANTIVE AND IN EXCESS OF THE PTO'S AUTHORITY BECAUSE THEY ALTER THE BALANCE OF PATENT PROTECTION STRUCK BY CONGRESS

The Final Rules are also impermissibly substantive because they have the effect of altering the balance of patent protection carefully calibrated by Congress.

A. PTO Rules Are Substantive If They Have The Effect Of Altering The Scope Of Patent Protection Afforded By Congress

1. The Court Should Take Policy Considerations Into Account When Determining Whether PTO Rules Are Substantive Or Procedural

In some cases, it requires little inquiry to determine whether a rule promulgated by the PTO is substantive or procedural. *See, e.g.*, *Merck*, 80 F.3d at 1550 (rule governing length of patent term was substantive); *Lacavera v. Dudas*, 441 F.3d 1380, 1383 (Fed. Cir. 2006), *cert. denied*, 127 S. Ct. 1246 (2007) (rule governing attorney appearances before the PTO was procedural); *Stevens v. Tamai*, 366 F.3d 1325, 1333 (Fed. Cir. 2004) (rule requiring party to interference proceedings to submit translation of foreign patent applications was procedural). In other cases, however, determining whether a rule is "procedural" or "substantive" requires a "functional" approach. *See Chamber of Commerce of the United States v. United States Dep't of Labor*, 174 F.3d 206, 211 (D.C. Cir. 1999) ("the question whether a rule is substantive or procedural for the purposes of § 553(b) is functional, not formal"). A leading administrative law treatise has described the approach to determining whether a rule is substantive or procedural under § 553 of the APA as follows:

> If the characterization is fairly debatable, the court considers the purpose for which it is being asked to characterize the rule . . . . With this purpose and implication of its choice of labels in mind, the court then looks at the rule to see whether its impact on substantive rights is so great that it should be adopted only after notice and comment. If it

> reaches that conclusion, the court resolves the analytically intractable characterization problem by labeling the rule "substantive."

Pierce, *Administrative Law Treatise* § 6.5, at 351 (4th ed. 2002).

Thus, to determine whether a rule is substantive for purposes of § 553 of the APA, courts have asked whether the rule "has a 'substantial impact' upon private parties.'" *Chamber of Commerce*, 174 F.3d at 211 (quoting *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987)); *see also Pickus v. United States Board of Parole*, 507 F.2d 1107, 1113 (D.C. Cir. 1974) ("any action which goes beyond formality and substantially affects the rights of those over whom the agency exercises authority" is not procedural). In contrast, a "procedural rule is one that does not itself 'alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency." *Chamber of Commerce*, 174 F.3d at 211 (quoting *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980)).

2. Congress Has Left To Itself The Important Role Of Balancing Intellectual Property Protection And Public Disclosure

In distinguishing between substantive and procedural *patent* rules, a court should consider the congressional policy of calibrating *by statute*, not administrative fiat, the level of substantive protection to be afforded inventors. The Constitution empowers Congress to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive

Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. As this Court has recognized, "[i]nventors are impelled to invest in creative effort by the expectation that, through procurement of a patent, they will obtain a federally protected 'exclusive right' to exclude others from making, using, or selling embodiments of their invention." *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007).

Under the patent laws, immediate public disclosure "is the price paid for the exclusivity secured." *Eldred v. Ashcroft*, 537 U.S. 186, 216 (2003). "The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-151 (1989).

Congress has approached drug development with particular care, modifying and supplementing the general patent laws with a detailed set of rules directed specifically toward pharmaceuticals. In 1984, for example, the Hatch-Waxman Act[10] addressed the significant interplay between the patent laws and the FDA review process, extending the patent terms for drugs to compensate for the period

[10] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in relevant part at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282).

that the drug is subject to FDA review and involved in pre-approval clinical testing. 35 U.S.C. § 156. Recognizing their centrality to the public health, Congress has revisited these issues multiple times,[11] offering additional incentives in the form of statutory marketing exclusivity in certain circumstances.[12]

Of particular importance here, it is Congress, and not the PTO, that crafts this balance. Congress has set the general patent rules and determined the circumstances that warrant deviation from these general rules. Moreover, Congress has specifically denied the PTO the authority to shape substantive patent law. The PTO was established for limited purposes: It "(1) shall be responsible for the granting and issuing of patents and the registration of trademarks; and (2) shall be responsible for disseminating to the public information with respect to patents and trademarks." 35 U.S.C. § 2(a). Although Congress granted the PTO a number of powers, it withheld the authority to promulgate substantive regulations affecting the scope of protection afforded to inventors. Thus, in this case, the PTO

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[11] *See, e.g.*, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended at 21 U.S.C. § 355(j)(5)(C)(i), and 35 U.S.C. § 271(e)(5)) (*inter alia*, refining provisions relating to patent protection and the entry of generic products).

[12] *See, e.g.*, 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii) (five years exclusivity for new chemical entities not previously approved by the FDA); *id.* § 355(c)(3)(E)(iii)-(iv), (j)(5)(F)(iii)-(iv) (three years exclusivity to reward additional clinical testing for new indications or to develop new dosages); *id.* § 355a (six months additional exclusivity for pediatric clinical testing); *id.* § 360cc (seven years exclusivity for "orphan drugs" used to treat rare diseases).

is relegated to relying on its authority to promulgate regulations governing various ministerial issues, such as "the conduct of proceedings in the Office," the "processing of patent applications," and "the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office." *Id.* § 2(b)(2)(A), (C), & (D). In fact, Congress has considered granting the PTO substantive rulemaking authority—including the authority to limit continuation applications—but thus far has declined to do so.[13]

* * *

In light of congressional policy favoring alteration of the scope of patent protection by statute, not rule, the Court should conclude that PTO rules are impermissibly substantive if they have *the effect* of changing the scope of patent protection afforded to inventors.

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[13] Patent reform legislation introduced in 2005, for example, would have granted the PTO the authority "by regulation [to] limit the circumstances under which an application for patent, other than a divisional application that meets the requirements for filing under section 121, may be entitled to the benefit under section 120 of the filing date of a prior-filed application." H.R. 2795 § 8 (June 8, 2005). A bill introduced in the Senate in 2006 would have added the following provision to § 3 of title 35: "In addition to the authority conferred by other provisions of this title, the Director may promulgate such rules, regulations, and orders as the Director determines appropriate to carry out the provisions of this title . . . ." S. 3813 § 9 (Aug. 3, 2006). Neither of these bills was enacted. *See also* H.R. 1908 § 14 (Sept. 7, 2007) (passed House but not Senate).

B. The Final Rules Alter The Scope Of Protection Afforded By Patents

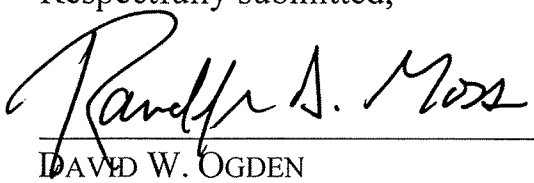
As explained above, the Final Rules have a significant *substantive* impact on inventors. The rules do not merely "alter the manner in which the parties present themselves or their viewpoints" to the PTO. *Chamber of Commerce*, 174 F.3d at 211 (quoting *Batterton*, 648 F.2d at 707). They alter the patent protection that inventors are able to obtain. In numerous situations where inventors currently rely upon continuation applications to protect their inventions, the Final Rules would foreclose those applications. And in situations where inventors require more claims than the Final Rules would effectively permit, the rules will decrease patent protection.

The PTO and its amici argue that the Final Rules are necessary to address what they consider to be "abuse" of the patent system. *See* Br. for Appellants 5-6; Br. of Amici Curiae Pub. Patent Found. et al. 11-17, 25-26; Br. Amici Curiae of Intell. Prop. and Admin. Law Profs. in Support of Appellants 19-23. But determining whether such "abuse" exists, *but see supra* n. 4, and whether curbing it justifies eroding the patent protection afforded to inventors is a substantive determination for Congress, not the PTO, to make.

CONCLUSION

For the foregoing reasons, the Court should affirm the district court's judgment.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that on October 3, 2008, I caused two copies of the foregoing Amicus Curiae Brief of the Pharmaceutical Research and Manufacturers of America in Support of Appellees and one copy of the appearances of David W. Ogden, Randolph D. Moss, Donald R. Steinberg, Brian M. Boynton, and Anne K. Small to be served via first-class mail on the following parties:

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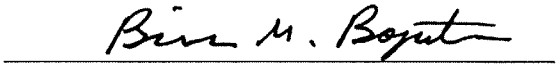

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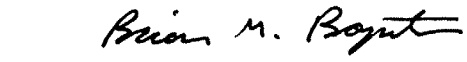
CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(7)(B), the brief contains 6,885 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2000 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(a)(7)(B), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.



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