UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
(Alexandria Division)

TRIANTAFYLLOS TAFAS, Plaintiff, v. JON W. DUDAS et al., Defendants.	No. 1:07cv846-JCC-TRJ
SMITHKLINE BEECHAM CORPORATION et al., Plaintiffs, v. JON W. DUDAS et al., Defendants.	No. 1:07cv1008-JCC-TRJ

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

MISCELLANEOUS

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 members lead the way in discovering and developing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA serves as the pharmaceutical industry's principal policy advocate, advancing public policies that foster continued medical innovation and educating the public about the drug development and discovery process. A list of PhRMA members can be found at http://www.phrma.org.

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 2006 alone, PhRMA members invested an estimated $43 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 each new drug to market is approximately $1.3 billion, including the costs for unsuccessful drugs.[1] 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 market."[2] It is estimated that only one in 5,000 compounds to enter preclinical testing ever reaches consumers.[3]

The patent laws are the foundation of the system of incentives that Congress has

---

[1] *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/drugpricing study.pdf.

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

[3] Tommy Thompson, Secretary, Dep't of Health & Human Servs., *Address at the Milken Institute Global Conference* (Apr. 26, 2004), available at http://www.hhs.gov/news/speech/2004/040426.html.

established to ensure that successful inventors will have a limited period of time during which they hold the exclusive right to market their inventions at prices sufficient to help recover the substantial costs of their efforts and to spur future invention. These incentives work—it is estimated that PhRMA companies currently have over 2,000 new medicines in development. *See* PhRMA, *New Drug Approvals in 2006*, available at http://www.phrma.org/files/NDA2006.pdf. Changes to the patent system that undermine efforts to obtain meaningful and complete patent protection—particularly changes that affect the application rules midstream—jeopardize the interests of PhRMA members and the public health alike.

INTRODUCTION

The newly promulgated Patent and Trademark Office (PTO) rules arbitrarily limiting the number of continuation applications, requests for continued examination (RCE), and claims that an applicant may file in the ordinary course[4] are unlawful and, accordingly, must be set aside. These new rules, if allowed to stand, would substantially erode longstanding patent prosecution law permitting applicants to file as many continuation applications and claims as necessary to protect their inventions. As a result of the nature of new drug development and the pharmaceutical industry, the pre-existing rules are of vital importance to pharmaceutical companies. They help ensure that those who are willing to undertake the painstaking and financially risky process of developing and bringing to market new drugs, can do so with the knowledge and confidence that, if successful, they will obtain the rewards that come with patent protection. They are a critical element of the structure that encourages commitment of the

[4] *See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications*, 72 Fed. Reg. 46,716-46,843 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1).

enormous resources required to develop new drugs and thereby advance the public health.

As explained below, the limits on both continuation applications and the number of claims that may be filed are contrary to the express provisions of the Patent Act and binding precedent. Moreover, because both rules apply to already-filed applications, they have substantial impermissible retroactive effects. Finally, the claims limitation rule must be vacated because it cannot stand once the limit on continuation applications falls and because the PTO failed to provide proper notice of the final rule it adopted.

ARGUMENT

I. THE PTO'S NEW RULES WILL HAVE A SIGNIFICANT ADVERSE IMPACT ON PROSECUTION OF PHARMACEUTICAL PATENTS

To determine whether the PTO's new rules are arbitrary and capricious or contrary to law, it is helpful to consider how the new rules would affect patent prosecution in practice. An overview of some of the more significant implications of the rules on prosecution of pharmaceutical patents is set forth below.

A. Pharmaceutical Companies Depend Upon Multiple Continuation Applications

In the pharmaceutical industry, continuation practice is particularly important. 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. As a result, at a relatively early stage of research and development, pharmaceutical companies will often identify a group of related potential 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. Each of the structurally related

compounds ("species") could be subject to future development. But, 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 development of the invention or 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 additional of the disclosed compounds as necessary.

Continuation practice allows applicants to go back and prosecute these alternate compounds and is thus critical to pharmaceutical companies. Indeed, a continuation application is 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 may 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 serve a number of critically important 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, at times, critical to pharmaceutical companies. 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 on other unpatented claims. Allowing the applicant to continue to prosecute unallowed claims while proceeding with the allowed claims helps to justify and support further investment.

Submission of post-filing evidence to confirm enablement of an invention: Under the patent laws, an applicant is required to satisfy the enablement requirement—namely, that the disclosure provide enough information to allow someone "skilled in the art" to "make and use" the invention. 35 U.S.C. § 112. Applicants have been allowed to submit with a continuation application or RCE evidence, not previously available, demonstrating that the disclosure in an application was, in fact, sufficient to let others skilled in the art make and use the invention. *See generally* Manual of Patent Examining Procedure (MPEP) § 2164.05.

Submission of animal or clinical testing data or other data required by the patent examiner to confirm usefulness or effectiveness: In order to obtain a patent, the applicant must demonstrate that the invention is "useful." 35 U.S.C. § 101. The PTO may, at times, decide that an application did not include sufficient data to support the usefulness of the claims. For example, evidence such as human clinical data might not be available for several years, in part because of the regulatory requirements of the FDA. If an application is submitted without certain data and the examiner requests it, then the applicant can use a continuation application or RCE to provide this additional data. *See generally* MPEP § 2107.

Submission of data in support of nonobviousness: During patent prosecution, the applicant must establish that "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole" would not have been "obvious at the

time the invention was made." 35 U.S.C. § 103. If the examiner rejects the claims on a § 103 basis, 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.*, 2-5 Donald S. Chisum, *Chisum on Patents* § 5.05 (2007) (discussing secondary considerations); *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1478-1479 (Fed. Cir. 1984) (skepticism). If the applicant decides to argue that the examiner is wrong and receives a final rejection, then any such evidence of secondary considerations can only be considered if the applicant is allowed to file a continuation application or RCE.

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. *See* 37 C.F.R. § 1.56. 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: Interference practice is a means of determining, during the course of prosecution, who was the first to invent. *See* 35 U.S.C. § 135. In order to trigger an interference, the interfering claims should be identical. 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 the claims from the competing application into the new application. Pharmaceutical companies are in a constant race to develop new products—

interferences are thus 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 other companies 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. This practice, again, requires the use of continuation applications.

In all of these ways, continuation applications play an important role in the prosecution of patents in the pharmaceutical industry. Moreover, changes to the continuation rules 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* PL 103-465 § 532,108 Stat 4809, 4984 (Dec. 8, 1994). For patents subject to that 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. The fact that a pharmaceutical patent has, on occasion, been held invalid, *see* Br. for Amici Curiae Pub. Patent Foundation et al. at 14-15, 17-18 (citing two cases), is of course no reason to conclude that pharmaceutical companies "repeatedly" assert invalid patents, much less that they "abus[e]" existing patent prosecution procedures.[5] Finally, there is no reason to think the new

[5] The reference in the Public Patent Foundation brief (at 4) to increased prescription drug spending since 1990 leaves a flawed impression. Amici, for example, fail to note that a significant portion of the increased spending is due to the introduction of new drugs for conditions that were previously largely untreatable, such as HIV, as well as the increased use of existing drugs to better control conditions such as diabetes. Nor do they account for the

limit on continuations is necessary to combat so-called "predatory claiming," *see* Br. of Amicus Curiae Micron Tech. at 3, which is more appropriately addressed through the written description requirement of § 112 of the Patent Act, rather than with arbitrary limits on continuations that prevent inventors from obtaining patents on their inventions. Even if further limitations were warranted, they would surely be *substantive* measures that must be enacted, if at all, by Congress, not the PTO.

B. Pharmaceutical Companies Depend Upon Multiple Claims

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, would also substantially alter patent prosecution law and practice. This change, moreover, if allowed to take effect, would have particularly harsh consequences for members of PhRMA.

New pharmaceutical and biotechnology inventions are extremely complex and multifaceted. As one pharmaceutical company explained to the PTO, "[t]he very nature of pharmaceutical and biotechnology inventions dictates a number of useful embodiments." May 3, 2006 Comments of 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.* Moreover, "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,

---

reduction in other health care costs resulting from the use of drugs, such as those to treat high blood pressure, asthma, or other serious conditions.

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

where there is varying scope within each category of invention." 72 Fed. Reg. at 46,788.

Because pharmaceutical inventions are so complex, numerous claims are often necessary to obtain appropriate protection. As one company explained, "[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 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.

Moreover, the need to file numerous claims is heightened by the limitation on continuation practice imposed under the new rules. Under prior practice, a pharmaceutical company did not need to attempt to claim in the initial application every possible relevant "species" compound disclosed in a patent application. Rather, the company could continue to conduct the research and testing necessary to determine which aspects of its invention are most viable and then file a continuation claiming those specific compounds. But if a company must claim every possibly important aspect of an invention earlier in the process because of limitations on continuations, the number of claims required will be much greater.

For these reasons, the PTO's new claims limitation rule threatens to have a significant adverse impact on the pharmaceutical industry.

II. THE CHALLENGED PTO RULES ARE ARBITRARY AND CAPRICIOUS AND CONTRARY TO LAW

Under both the Patent Act and binding precedent, the PTO lacks authority to effect the fundamental change to patent prosecution practice described above.

A. The Rules Concerning Continuation Practice Exceed The PTO's Authority

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 new 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, under the statute, where an inventor files an application for an invention, and that same inventor disclosed the same invention in a prior application, the later application *shall* be treated "as though filed on the date of the prior application." *Id.* The law imposes no numerical limits. To the contrary, the statutory reference to "the first application *or . . . an application similarly entitled to the benefit of the filing date of the first application*," *id*. (emphasis added), 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.[7]

The case law confirms this reading of § 120. In *In re Henriksen*, 399 F.2d 253, 256 (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: "[U]nder [§ 120], in view of its long-standing interpretation by the Patent Office and patent bar, there is *no statutory basis* for fixing an arbitrary limit to the number of prior applications through which a chain of codependency may be traced to obtain the benefit of the filing date of the earliest of a chain of

[7] Similarly, as explained by GSK, the PTO's new limitation on RCE's is contrary to § 132(b) of the Patent Act.

copending applications, provided applicant meets all the other conditions of the statute." *Id*. at 254 (emphasis added).[8] In reaching this conclusion, the 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 256-60.[9]

The Federal Circuit's decisions in *Symbol Technologies., Inc. v. Lemelson Medical, Education & Research Found.*, 277 F.3d 1361, 1363, 1366 (Fed. Cir. 2002), and *In re Bogese II*, 303 F.3d 1362, 1367 (Fed. Cir. 2002), do not undercut either the plain language of § 120 or *In re Henriksen*'s status as binding precedent. *Symbol Technologies* merely recognized the defense of prosecution laches in an infringement action based on the applicant's delay in prosecution before the PTO. *Bogese II* relied on *Symbol Technologies* to conclude that the PTO could rely on prosecution laches to reject an application. Critically, the *Bogese II* court distinguished *In re Henriksen* on the ground that the application of prosecution laches there was not a "mechanical rule based on a misconstruction of the [Patent Act]." 303 F.3d at 1368 n.6. The new rules, however, are a mechanical bar to continuation applications that Congress chose to permit.

The PTO contends that the new rules do not impose absolute limits because an applicant can "petition" for the right to file additional continuation applications. *See* Def. Opp. to Pl. Mot. for TRO and Prelim. Inj. at 26 (Oct. 28, 2007). But the PTO's interpretation of the standard for succeeding on such a petition ensures that the new rules impose *de facto* limits. To exceed the

---

[8] Decisions of the Court of Customs and Patent Appeals constitute binding precedent in the Federal Circuit, which hears appeals in all cases "arising under any Act of Congress relating to patents." *See BMW Mfg. Corp. v. United States*, 241 F.3d 1357, 1362 n.3 (Fed. Cir. 2001); 28 U.S.C. § 1295(a)(1); *id.* § 1338(a).

[9] The Court should reject the PTO's contention that § 112, § 121, and § 251 of the Patent Act support its two-continuations limit. If the PTO's interpretation of those sections were correct, it would foreclose (or would permit the PTO to foreclose) *any* continuations, which is plainly contrary to § 120.

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). The PTO's response to comments demonstrates that the "could not have been submitted" requirement will, in application, impose a substantial barrier on typical continuation practice.

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.*, *id*. 46,772-46,777. In the commentary accompanying the final rule, 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 ["could not have been submitted"] petition 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." *Id*. at 46,774-46,776.

Because the petition provision offers little hope of mitigating the harsh consequences of the PTO's mechanical limits on continuation applications, the new rules would fundamentally alter patent prosecution practice, particularly in the pharmaceutical industry, and would deprive

applicants of their statutory right to file as many continuation applications as necessary to obtain fair and complete patent protection.

2. The Rules Governing Continuation Practice Are Impermissibly Retroactive

Under settled principles of administrative law, agencies lack authority to promulgate retroactive rules unless Congress expressly grants the agency that extraordinary authority. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). Here, there is no question that the PTO lacks retroactive rulemaking authority. The question, then, is whether the new rules are retroactive within the meaning of *Bowen*.

A rule is retroactive if it, inter alia, "impose[s] new duties with respect to transactions already completed." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994). The PTO rules impose new duties for applicants who filed their parent application, and any continuation applications, prior to issuance of the rules. Those applicants surrendered their property rights—trade secrets, *see Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984); 35 U.S.C. § 122(b)(1)—in exchange for a full and fair opportunity to seek patent protection for their inventions.[10] Particularly as applied to the pharmaceutical industry, the new rules reach back and affect critically important decisions that applicants made prior to issuance of those rules and in reliance on long-standing procedures.

As explained above, pharmaceutical companies often file patent applications on a group of potential new drugs. They may pursue one or a few of the several species disclosed, and in so doing may use continuation applications for the reasons detailed above—to overcome certain objections, to preserve remaining claims after some but not all are allowed, or to trigger an

[10] It cannot seriously be contended that pharmaceutical companies voluntarily choose to disclose their patent applications. Publication is required under U.S. law if the applicant also seeks foreign patent protection, which can be essential to protect multi-billion dollar investments.

interference, for example. For many pending applications, more than two continuations will already have been filed. The new rules, however, apply to these pending applications, essentially cutting off the ability to file more than one more additional continuation application. There are a number of reasons why more than one more continuation application may be necessary. But, under the new rules, continuation applications would not be available in such circumstances.

Before the PTO announced its rule, a multitude of inventors filed patent applications that will result in disclosure of their inventions, previously trade secrets, with the settled understanding that, if the statutory requirements are met, continuations would be permitted. Changing the process midstream eliminates important protections that the applicants relied upon when they chose to subject their invention to disclosure. Even if future applicants could adjust their strategy and practices to avoid the need for more than two continuation applications—and it seems doubtful that they can do so, at least without exacting a substantial toll on the discovery and development of new drugs—those adjustments are inapplicable or unavailable to companies with pending applications.

B. PTO's Claim Limitation Rule Violates The APA And Must Be Set Aside

The PTO's claims limitation rule fares no better than the cap on continuations.

1. 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 that may be filed by a patent applicant. 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). The PTO's arbitrary claims limit thus finds no authorization in § 112 and *Wakefield*. Because the ability to file multiple claims is so important to patent applicants, limiting the number of claims that may be filed directly affects substantive rights. But as explained by plaintiff GSK, the PTO altogether lacks *substantive* rulemaking authority. For this reason, the new claim limitation rule cannot stand.[11]

The PTO contends that the new rule is not contrary to § 112 or *Wakefield* because it does 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. In practice, however, the claim limitation rule is likely to function as an absolute (or near-absolute) bar. Under the new rule, a patent applicant may exceed five independent claims and twenty-five total claims only if it files an ESD. 37 C.F.R. § 1.75(b)(1). But the tremendous burdens and risks associated with filing an ESD are likely to render this "option" illusory.

The scope of an applicant's obligations in filing an ESD under the new rule is broad:

> 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 regulation specifies that the search "must involve U.S. patents and patent application

---

[11] *In re Rubinfield*, 270 F.2d 391 (C.C.P.A. 1959), is not to the contrary. *Rubinfield* was decided before the Federal Circuit held in *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-1550 (Fed. Cir. 1996), that the PTO lacks "any general substantive rulemaking power." Moreover, as the court explained in that case, *see Rubinfield*, 270 F.2d at 395-396, imposing a one-claim limit on *design* patents has no substantive impact and, in the context of a design patent, merely reinforces the policy of limiting a patent application to a single invention, *see* 35 U.S.C. § 121.

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 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 GSK's intellectual property department has explained, 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). 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). 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.

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." As the PTO recognized, a patent applicant is guilty of inequitable conduct if it makes a misrepresentation or omission of material fact to the PTO with an intent to deceive. 72 Fed. Reg. at 46,801-46,802 (citing *Impax Labs, inc. v. Aventis Pharm., Inc.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006)). Almost 20 years ago, the Federal Circuit 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, e.g.*, *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1372 (Fed. Cir. 2003) (Newman, J., dissenting). Writing in 2005, one commentator noted that "[t]he practice of asserting a defense of inequitable conduct, regardless of the merits of the defense in a given case, has reached the breaking point."[12] As of 2007, the trend had only continued.[13]

As PhRMA explained in its comments to the PTO, the requirement that an applicant undertake a prior art search "would expose the patentee in subsequent patent litigation to a charge of inequitable conduct based on an inadequate search, where additional art comes to light during the litigation (often as the result of heroic and expensive searches by the accused infringer)." May 2, 2006 Comments of PhRMA at 11. Among other things, an applicant could be accused of searching the wrong places, searching at the wrong time, and searching with respect to fewer than all of the limitations of each of the claims (*see* 37 C.F.R. § 1.265(b)). In light of the frequency of baseless inequitable conduct allegations, simply filing a document as intricate as an ESD poses significant risks. Because of the risks and burdens associated with submitting an ESD, there is a disincentive to exercising this supposed "option," making the PTO's claim limitations rule an absolute (or near absolute) restriction in practice.

Even if filing an ESD were a meaningful option, moreover, the PTO's new rule would still constitute impermissible substantive rulemaking. 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.*

---

[12] Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 Berkeley Tech. L.J. 147, 148 (2005).

[13] *See* James E. Hanft & Stacey S. 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 (Feb. 2007).

Hennessy Indus., Inc., 836 F.2d 521, 526 n. 6 (Fed. Cir. 1987)). The decision to deviate from this settled practice and to expose applicants to the substantial increased risk of claims of inequitable conduct associated with filing an ESD cannot be justified as a mere procedural rule.

2. The Claims Limitation Rule is Impermissibly Retroactive

The PTO does not dispute that under *Bowen*, discussed above, it lacks authority to promulgate retroactive rules without express authority from Congress. That is essentially the end of the inquiry. Under the *Landgraf* standard, the claims limitation rule operates retroactively. *See* 511 U.S. at 280. The rule applies to "any nonprovisional application filed before November 1, 2007, in which a first Office action on the merits was not mailed before November 1, 2007." 72 Fed. Reg. at 46,716. By expressly governing previously filed applications the claims limitation rule undeniably attaches new legal consequences to past actions. For example, an application filed the day before the new rule was promulgated that contained 6 independent claims or 26 total claims would have been perfectly acceptable at the time of filing. But then, a day later, upon promulgation of the new rule, the application would suddenly be noncompliant.

This change in the law is no trivial matter. As explained above, the ability to file multiple claims is, at times, critical to pharmaceutical companies. As this court has observed, when inventors decide to file a patent application, they "sacrifice their trade secrets . . . in exchange for a guarantee from the PTO that [they] will have a full and fair opportunity to seek a spectrum of patent protection adequate to protect [their] investments." Oct. 31, 2007 Mem. Op. at 28-29 (internal quotation marks omitted). Inventors operating under the old rules might have broadly disclosed their invention in the application secure in the knowledge that there would be no limit on the number of claims they could assert in order to properly protect the disclosed invention. But under the PTO's view, an inventor's expectations could be upended as the inventor is forced to choose among (1) withdrawing the application and thereby losing the

existing priority date, (2) withdrawing claims and thus sacrificing protection of the invention, or (3) filing an ESD and thereby risking unenforceability from having to run the gauntlet of baseless inequitable conduct allegations. Under settled law, the PTO was without authority to impose such retroactive consequences.

3. The Claim Limit Cannot Stand Apart From The Restriction On Continuation Applications

If the Court concludes that the rule limiting continuation applications must be set aside (as it should), then the rule limiting the number of claims should fall as well, because it cannot function as intended absent a limitation on continuation applications. The PTO purportedly adopted the restrictions on the number of continuation applications and claims that may be filed "[i]n view of the need for a better focused and effective examination process to reduce the large and growing backlog of unexamined applications." 72 Fed. Reg. at 46,717. But limiting the number of claims that may be filed in a single application would not decrease the PTO's examination workload absent a corresponding limit on the number of continuation applications.

Absent a limit on continuation applications, an inventor can file scores of different claims over a period of years notwithstanding a limit on the number of claims that may be presented in a single application. Indeed, the PTO emphasized in the final rulemaking the interrelatedness of the two rules, stating numerous times that in light of the rule permitting two continuation applications, "an applicant may present up to fifteen independent claims and seventy-five total claims to a single patentably distinct invention." *Id.* at 46,721; *see also id.* at 46,718; 46,725; 46,795; 46,801; 46,832; 46,833. For these reasons, if the rule on continuation applications is vacated, the claim limit rule must also be vacated as arbitrary and capricious.

4. PTO's Final Rule Impermissibly Deviates From The Rule The PTO Initially Proposed

Finally, the claims limitation rule should be set aside because the PTO improperly

deprived interested parties of an opportunity to offer meaningful comment on the rule by substantially deviating in its final rule from the rule it had initially proposed. Because interested parties are entitled to fair notice, an agency "does not have carte blanche to establish a rule contrary to its original proposal." *Chocolate Mfrs. Ass'n v. Block*, 755 F.2d 1098, 1104 (4th Cir. 1985). A rule must be vacated and remanded for further comments and consideration if the final rule is not a "logical outgrowth" of the proposed rule. *Id.* at 1105.[14]

Here the final rule deviated substantially from the rule the PTO initially proposed. The PTO's proposed rule, while itself a significant restriction on the number of claims that could be filed, permitted an applicant to designate up to ten independent claims as "representative claims" that would be reviewed initially by the PTO without the necessity of filing an ESD. *See Changes to Practice for the Examination of Claims in Patent Applications*, 71 Fed. Reg. 61, 62 (Jan. 3, 2006); *see also* 72 Fed. Reg. at 46,718, 46,721. Under the proposed rule, moreover, there was no limitation on the number of dependent claims the PTO would review after considering the representative claims. *See* 71 Fed. Reg. at 62. In the final rule, however, the PTO changed course dramatically. Rather than allow ten independent claims to be designated as "representative claims," the PTO cut the number of permissible independent claims in half to five. *See* 72 Fed. Reg. at 46,721. By limiting the total number of claims that may be filed without an ESD, the PTO's final rule also had the effect of imposing, for the first time, a limit on the number of dependent claims that could be filed in the ordinary course. Accordingly, the PTO's final rule must be vacated and remanded to the agency for further proceedings.

CONCLUSION

[14] PTO's contention that it was not required to provide notice and accept comments is belied by the text of 35 U.S.C. § 2, which requires the PTO to comply with 5 U.S.C. § 553, and the PTO's own actions here—issuing a notice of proposed rulemaking and accepting comments.

For the foregoing reasons, Plaintiffs' motions for summary judgment should be granted.

Date: December 27, 2007

Respectfully submitted,

David W. Ogden
Randolph D. Moss
Brian M. Boynton
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
Tel.: (202) 663-6000
Fax: (202) 663-6363

Donald R. Steinberg
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel.: (617) 526-6000
Fax: (617) 526-5000

Anne K. Small
WILMER CUTLER PICKERING
HALE AND DORR LLP
399 Park Avenue
New York, NY 10022
Tel.: (212) 230-8800
Fax: (212) 230-8888

Of Counsel for Pharmaceutical Research and Manufacturers of America

_____/s/_____
James M. Dowd (VSB # 41406)
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
Tel.: (202) 663-6000
Fax: (202) 663-6363
James.Dowd@wilmerhale.com

Attorney for Pharmaceutical Research and Manufacturers of America

CERTIFICATE OF SERVICE

I hereby certify that on December 27, 2007, the foregoing pleading was electronically filed with the Clerk of Court using the CM/ECF system, which will send a notification of such filing to the following:

Craig Crandall Reilly
Richard McGettigan Reilly & West PC
1725 Duke St., Suite 600
Alexandria, VA 22314
Tel.: (703) 549-5353
Fax: (703) 683-2941
Email: craig.reilly@rmrwlaw.com

Counsel for GlaxoSmithKline Plaintiffs

Joseph D. Wilson
Kelley Drye & Warren LLP
3050 K St. N.W., Suite 400
Washington, DC 20007
Tel.: (202) 342-8504
Fax: (202) 342-8451
Email: jwilson@kelleydrye.com

Counsel for Plaintiff Tafas

Lauren A. Wetzler
Assistant United States Attorney
Justin W. Williams U.S. Attorney's Building
2100 Jamieson Avenue
Alexandria, VA 22314
Tel.: (703) 299-3752
Fax: (703) 299-3983
Email: Lauren.Wetzler@usdoj.gov

Counsel for Defendants

_____/s/_____
James M. Dowd (VSB # 41406)
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
Tel.: (202) 663-6000
Fax: (202) 663-6363
James.Dowd@wilmerhale.com

Attorney for Pharmaceutical Research and Manufacturers of America