

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

SMITHKLINE BEECHAM,)
CORPORATION,)
d/b/a GLAXOSMITHKLINE,)
SMITHKLINE BEECHAM PLC, and)
GLAXO GROUP LIMITED, d/b/a)
GLAXOSMITHKLINE,)

Plaintiffs,)

v.)

CIVIL ACTION NO. 1:07cv1008 (JCC/TRJ)
[Consolidated with No. 1:07cv846]

JON W. DUDAS, in his official capacity as)
Under-Secretary of Commerce for)
Intellectual Property and Director of the)
United States Patent and)
Trademark Office, and)

UNITED STATES PATENT AND)
TRADEMARK OFFICE,)

Defendants.)

**DEFENDANTS’ RESPONSE TO BRIEF FOR *AMICUS CURIAE* AMERICAN
INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF THE
“GSK” PLAINTIFFS’ MOTION FOR A TEMPORARY RESTRAINING ORDER
AND PRELIMINARY INJUNCTION**

Although this Court has not yet ruled on the motion of the American Intellectual Property Law Association (“AIPLA”) to file an amicus brief in support of Plaintiffs’ motion for a temporary restraining order and preliminary injunction, Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively the “USPTO” or the “Office”) feel compelled to respond to the most egregious errors and exaggerations in AIPLA’s brief and the four

declarations accompanying it. The USPTO continues to oppose AIPLA's motion on the grounds set forth in its previously-filed Opposition (Dkt. No. 35).¹

In its brief, AIPLA argues that the new procedural rules that the USPTO promulgated in order to promote the quality and efficiency of the patent examination process, reduce the backlog of patent applications awaiting examination, and improve the quality of issued patents ("Final Rules")² will cause irreparable harm to patent applicants and are contrary to the public interest. All of the reasons that AIPLA offers, however, rely on mischaracterizations of the Final Rules. The USPTO has already explained why the Final Rules are not retroactive. See Defendants' Opposition to Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction (Dkt. No. 48), p. 32-35. This brief addresses some of AIPLA's other serious errors.

I. THE FINAL RULES WILL NOT CAUSE APPLICANTS TO PERMANENTLY LOSE PATENT PROPERTY RIGHTS, BUT INSTEAD WILL HELP APPLICANTS SECURE PATENT PROTECTION FOR THEIR INVENTIONS IN MORE EFFICIENT AND EFFECTIVE WAYS.

According to AIPLA, applying the Final Rules to pending patent applications will have a retroactive effect and will compel owners of intellectual property to: "(1) abandon pending patent claims, (2) abandon entire patent applications, and (3) surrender currently existing claim scope without adequate opportunity for consideration by the [Office]." AIPLA Br. at 4. The Final Rules do not compel any of these results, and we address each in turn.

¹ The filing of this brief is not a concession that the filing of AIPLA's putative amicus brief merely three business days before oral argument is without prejudice to the USPTO. Rather, the USPTO files this brief – despite the prejudice it has incurred in doing so – because it feels compelled to ensure that the Court is not misled by AIPLA's erroneous statements. AIPLA's arguments in its Reply Memorandum (Dkt. 51) for why the USPTO would not be prejudiced by its untimely filing are clearly meritless.

² See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications; Final Rules, 72 Fed. Reg. 46716 (Aug. 21, 2007).

A. The Final Rules Do Not Compel the Abandonment of Pending Claims.

None of the Final Rules require an applicant to abandon pending claims. Under Final Rule 75, an application may routinely claim up to five independent claims and up to twenty-five total claims. Final Rule 75(b)(1), 72 Fed. Reg. at 46836. If an applicant wishes to pursue more than five independent and/or more than twenty-five total claims, the applicant is not compelled to abandon claims. Rather, he or she has more than one option. First, the applicant could file an examination support document, which provides information about the claims to the Office to facilitate examination of the claims. *Id.*; *see also* 72 Fed. Reg. at 46721. Second, the applicant could file a suggested restriction requirement, wherein the applicant explains that the claims cover more than one independent or distinct invention and thus should be divided into a corresponding number of divisional applications. Final Rule 142(c), 72 Fed. Reg. at 46842. Each divisional application, in turn, may contain up to five independent claims and/or twenty-five total claims without an examination support document.

Moreover, Final Rule 75 does not apply to all applications; it only applies to (i) applications filed before November 1 where the Office has not begun the examination process (*i.e.*, the patent examiner has not mailed a first Office action on the merits); and (ii) applications filed after November 1. 72 Fed. Reg. at 46716. Thus, for applications filed before November 1 where examination has begun (*i.e.*, the patent examiner has mailed a first Office action on the merits), an applicant can present more than five independent and more than twenty-five claims without submitting either an examination support document or a suggested requirement for restriction. Hence, the applicability of Final Rule 75 is far more limited than APLA suggests and will not have the draconian consequences it envisions, particularly during the pendency of this litigation.

B. The Final Rules Do Not Compel the Abandonment of Entire Patent Applications.

None of the Final Rules require an applicant to abandon entire patent applications. Instead, the Final Rules simply regulate the procedures under which an applicant can file continuation and continuation-in-part applications and requests for continued examination. Specifically, under Final Rules 78 and 114, an applicant may file two continuation or continuation-in-part applications and one request for continued examination in an application family as a matter of right; an applicant may make a third or subsequent continuation or continuation-in-part application filing or second or subsequent request for continued examination filing by submitting a petition to the Office showing why the amendment, argument, or evidence sought to be entered could not have been presented earlier. Final Rule 78(d)(1)(i) & (iv), 72 Fed. Reg. at 46838-839; Final Rule 114(f) & (g), 72 Fed. Reg. at 46841. Thus, in a particular application family, an applicant has the opportunity to automatically have at least four filings (i.e., parent application, two continuation or continuation in part applications, and one request for continued examination) and maybe even more with a grantable petition. See e.g., 72 Fed. Reg. 46767-779 (discussing how the Office will decide petitions); see also “Frequently Asked Questions,”³ at 20-21 (last updated 10.22.07) (providing a listing of factors that the Office will take into consideration in deciding whether to grant a petition). Further, Final Rules 78 and 114 are not applicable to all patent applications. They only apply to those applications filed on or after November 1; they do not apply to applications filed before November 1. 72 Fed. Reg. at 46716-717. Accordingly, here again, AIPLA has dramatically overstated the effects of the Final Rules.

³ <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/ccfrfaq.pdf>

C. The Final Rules Do Not Require Existing Claim Scope to be Surrendered Without Adequate Opportunity for Consideration.

None of the Final Rules require an applicant to surrender existing claim scope without an adequate opportunity for consideration. As explained above, under Final Rule 75, an applicant who wishes to have more than five independent and/or more than twenty-five claims examined in an application may file an examination support document. Final Rule 75(b)(1), 72 Fed. Reg. at 46836. Also as explained above, under Final Rules 78 and 114, an applicant who has exhausted the two continuations and/or continuation-in-part applications and the one request for continued examination available as a matter of right may file a petition explaining why the four rounds of examination already received did not present an adequate opportunity for consideration. Final Rule 78(d)(1)(iv), 72 Fed. Reg. at 46839; Final Rule 114 (g), 72 Fed. Reg. at 46841. If that petition is denied in a final agency action, the applicant may request reconsideration and then may file an action under the Administrative Procedure Act, 5 U.S.C. §§ 701-706, in district court challenging the denial. See 35 U.S.C. § 704. Hence, the Final Rules afford an applicant at least three procedural avenues to pursue protection of existing claim scope.

II. THE SUGGESTED RESTRICTION REQUIREMENT OF FINAL RULE 142(C) WILL NOT DESTROY INTELLECTUAL PROPERTY BUT RATHER OFFER APPLICANTS A NEW AVENUE FOR PURSUING MULTIPLE INVENTIONS NOT AVAILABLE UNDER CURRENT RULES

AIPLA contends that the suggested restriction requirement available under Final Rule 142(c) will destroy an applicant's intellectual property in the form of either a reduced number of claims, or no claims at all, for the multiple inventions claimed in an application because the Office is not required to accept the suggestion. AIPLA Br. at 7. AIPLA's concern is again unjustified. At the outset, AIPLA's contention fails to recognize that an applicant is granted a patent on an invention. See 35 U.S.C. §§ 101, 102, 103 & 112 (all referencing "invention" in the

singular). There is no statutory requirement mandating the Office to examine an application that contains multiple inventions. See 35 U.S.C. § 121 (“If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.”) (emphasis added). The Office may do so for efficiency reasons, as long as the examiner would not confront a significant burden. See U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure (“MPEP”) § 803 (8th ed. 2001, rev. Aug. 2006). Accordingly, an applicant can ensure that all of his or her distinct and independent inventions will be preserved for examination by preparing a separate application for each invention. If those applications do, in fact, claim patentably distinct inventions, then the applicant will be entitled to file two continuation and/or continuation-in-part applications and one request for continued examination in each application family.

Turning to AIPLA’s specific concern regarding Final Rule 142(c), AIPLA is correct that an examiner is not required to accept an applicant’s suggested restriction requirement. See Final Rule 142(c), 72 Fed. Reg. at 46842. However, that does not mean that the multiple independent or distinct inventions in a particular application will not be divided into separate divisional applications, each of which may contain up to five independent claims and twenty-five total claims. The Final Rules explain that an examiner, who does not accept an applicant’s suggested restriction requirement, may nevertheless issue one of his or her own, dividing the multiple claimed inventions in a different way than proposed by the applicant. See Final Rules, 72 Fed. Reg. at 46741. Furthermore, if the applicant disagrees with the restriction requirement issued by the examiner, the applicant may file a petition under 37 C.F.R. § 1.181(a). And, as noted earlier, if the Office denies such a petition, the applicant can request reconsideration as well as seek judicial review. Thus, it is not a foregone conclusion that an applicant will be forced to sacrifice

any of the multiple claimed inventions in a single application just because an examiner does not accept an applicant's suggested restriction requirement.

III. PATENT APPLICANTS CAN COMPLY WITH THE EXAMINATION SUPPORT DOCUMENT REQUIREMENT OF FINAL RULE 265 WITHOUT ENCOUNTERING A HOBSON'S CHOICE

AIPLA argues that filing an examination support document will create a high risk of misstatements about the claims and prior art, which will increase the likelihood of inequitable conduct, which will diminish the value of issued patents.⁴ AIPLA Br. at 7-8. Or, according to AIPLA, if an applicant elects not to submit an examination support document and create "a record potentially damaging to the patent property," he or she will have to "abandon one's rights altogether." AIPLA Br. at 8. The attenuated series of events that AIPLA predicts will follow from filing an examination support document rings of the familiar nursery rhyme "for want of a nail, the kingdom was lost." In preparing an examination support document pursuant to Final Rule 265, all that an applicant (or counsel representing an applicant) is required to do is provide a statement that a preexamination search was conducted, identify the search parameters, provide a listing of reference(s) uncovered by the search that the applicant deems to be the most closely related to the claimed invention, and give an explanation as to why the claimed invention is patentable over the listed references. Final Rule 265(a), 72 Fed. Reg. at 46842. As explained in the Final Rules, the information provided in an examination support document is intended to assist examiners in performing the search and examination of the claimed invention. 72 Fed.

⁴ Inequitable conduct occurs when a patent applicant misrepresents material facts, fails to disclose material information, or submits false material information, with an intent to deceive. See Nilssen v. Osram Sylvania, Inc., --- F.3d ---, 2007 WL 2937322, at *4 (Fed. Cir. Oct. 10, 2007). A finding that an applicant has engaged in inequitable conduct may result in implicated patents becoming unenforceable. See id. at *4-*5; see also 37 C.F.R. § 1.56 (2006).

Reg. at 46721. It is not intended to trap applicants or their counsel into committing inequitable conduct, contrary to what AIPLA would like this Court to believe.

To meet the requirements of Final Rule 265, an applicant simply has to offer truthful statements of fact about the scope of the references as compared with the scope of the claimed invention, consistent with what an applicant (and counsel) are already required to do in submitting any document to the USPTO. See 37 C.F.R. 1.56(a) (“Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office . . .”). Hence, the examination support document requirement of Final Rule 265 raises no Hobson’s choice.

IV. THE IDENTIFICATION REQUIREMENT AND REBUTTABLE PRESUMPTION OF FINAL RULE 78(F) PREVENT DUPLICATIVE EXAMINATION OF THE SAME INVENTION

AIPLA charges that the identification of patentably indistinct claims requirement set forth in Final Rule 78(f)(1) and the rebuttable presumption of patentably indistinct claims set forth in Final Rule 78(f)(2) “is not only expensive, but invites assertion of new invalidity arguments, not to mention inequitable conduct claims.” AIPLA Br. at 9. Once again, AIPLA’s challenge is misplaced. The requirements in Final Rules 78(f)(1) and (f)(2) work in tandem with Final Rule 75. That is, for purposes of determining whether an application contains more than five independent and/or more than twenty-five total claims, the Office will count all the claims in a first application together with all the claims in a second or a third or a fourth, etc., application if the applications contain a patentably indistinct claim. The Office is not using the information gleaned from the identification requirement of Final Rule 78(f)(1) to gin up reasons why an invention is unpatentable. Moreover, the current rules require an applicant to eliminate patentably indistinct claims from all but one application. See 37 C.F.R. § 1.78(b) (2006)

(“Where two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.”).

Accordingly, both now and in the Final Rules, the Office is attempting to prevent duplicative examination of the same invention based on objective criteria.

V. THE FINAL RULES DO NOT AFFECT PATENT APPLICANTS’ ABILITY TO PRESENT CLAIMS TO MULTIPLE PATENTABLY INDISTINCT EMBODIMENTS OF A SINGLE INVENTION

AIPLA alleges that a patent applicant can protect only five of the multiple patentably indistinct embodiments of an invention, and fifteen over time in an application family, disclosed in the specification of an application. AIPLA Br. at 8-9. AIPLA’s argument is an utter distortion of Final Rule 75. That rule merely sets a threshold on the number of claims that an applicant can file in an application without submitting an examination support document to aid the examiner in examining the claims. It does not prescribe how an applicant may use the claims to protect multiple patentably indistinct embodiments of an invention. An applicant may claim the patentably indistinct embodiments of his or her invention in a variety of ways within the five independent claims and twenty-five claims paradigm. AIPLA, however, appears to imply that an applicant can only present multiple patentably indistinct embodiments of a single invention via independent claims, *i.e.*, one embodiment per independent claim. Even if that were the case, which it is not, an applicant can file an examination support document and avail himself of as many independent claims as desired. Accordingly, AIPLA’s argument about multiple patentably indistinct embodiments is a red herring.

William LaMarca
Associate Solicitors

Jennifer M. McDowell
Associate Counsel

United States Patent and Trademark Office

CERTIFICATE OF SERVICE

I hereby certify that on October 30, 2007, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following:

Elizabeth Marie Locke
Kirkland & Ellis LLP
655 15th St NW
Suite 1200
Washington, DC 20005
Email: elocke@kirkland.com

Craig Crandell Reilly
Richard McGettigan Reilly & West PC
1725 Duke St
Suite 600
Alexandria, VA 22314
Email: craig.reilly@rnrwlaw.com

Daniel Sean Trainor
Kirkland & Ellis LLP
655 15th St NW
Suite 1200
Washington, DC 20005
Email: dtrainor@kirkland.com

Counsel for Plaintiffs SmithKline Beecham Corp. d/b/a GlaxoSmithKline, SmithKline Beecham PLC, and Glaxo Group Limited, d/b/a GlaxoSmithKline

Thomas J. O'Brien
Morgan, Lewis & Bockius
1111 Pennsylvania Ave, NW
Washington, DC 20004
Email: to'brien@morganlewis.com

Counsel for Putative Amicus American Intellectual Property Lawyers Association

Dawn-Marie Bey
Kilpatrick Stockton LLP
700 13th St NW
Suite 800
Washington, DC 20005
Email: dbey@kslaw.com

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

James Murphy Dowd
Wilmer Cutler Pickering Hale & Dorr LLP
1455 Pennsylvania Ave NW
Washington, DC 20004
Email: james.dowd@wilmerhale.com

Counsel for Putative Amicus Pharmaceutical Research and Manufacturers of America

Randall Karl Miller
Arnold & Porter LLP

1600 Tysons Blvd
Suite 900
McLean, VA 22102
Email: randall_miller@aporter.com

Counsel for Putative Amicus Biotechnology Industry Organization

I also caused a copy of this filing to be sent by electronic mail to:

Joseph Dale Wilson, III
Kelley Drye & Warren LLP
Washington Harbour
3050 K Street NW
Suite 400
Washington, DC 20007
Email: jwilson@kelleydrye.com

Counsel for Plaintiff Triantafyllos Tafas, 1:07cv846

Rebecca M. Carr
Pillsbury Winthrop Shaw Pittman, LLP
2300 N Street, NW
Washington, DC 20037
Rebecca.carr@pillsburylaw.com

Scott J. Pivnick
Pillsbury Winthrop Shaw Pittman
1650 Tysons Boulevard
McLean, Virginia 22102-4856
Scott.pivnick@pillsburylaw.com

Counsel for Putative Amicus Elan Pharmaceuticals, Inc.

/s/

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

Counsel for All Defendants