

From: Christopher Mizzo
Sent: Wednesday, April 09, 2008 7:23 PM
To: Markush.Comments
Cc: John Desmarais
Subject: Additional Comments of GlaxoSmithKline in Response to U.S. Patent and Trademark Notice of Proposed Rulemaking

Attn: Kathleen Kahler Fonda, Legal Advisor
Office of the Deputy Commissioner for Patent Examination Policy

Dear Ms. Fonda,

Attached please find the Additional Comments of GlaxoSmithKline in Response to U.S. Patent and Trademark Office Notice of Proposed Rulemaking -- "Examination of Patent Applications That Include Claims Containing Alternative Language," 73 Fed. Reg. 12,679 (Mar. 10, 2008).

Respectfully submitted,

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April 9, 2008

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The Honorable Jon Dudas
U.S. Patent & Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450

Attn: Kathleen Kahler Fonda
Legal Advisor
Office of the Deputy Commissioner for Patent Examination Policy

Re: Additional Comments of GlaxoSmithKline in Response to U.S. Patent and Trademark Office Notice of Proposed Rulemaking – “Examination of Patent Applications That Include Claims Containing Alternative Language,” 73 Fed. Reg. 12,679 (Mar. 10, 2008)

Dear Ms. Fonda:

GlaxoSmithKline, through its counsel Kirkland & Ellis LLP, submits these additional comments on the proposed rules regarding claims containing alternative language pursuant to the PTO’s reopened comment period. *See Examination of Patent Applications That Include Claims Containing Alternative Language*, 73 Fed. Reg. 12,679-684, 12,680 (Mar. 10, 2008).

Introduction

In response to the PTO’s initial Notice of Proposed Rulemaking, *see Examination of Patent Applications That Include Claims Containing Alternative Language*, 72 Fed. Reg. 44,992-45,001 (Aug. 10, 2007), GlaxoSmithKline (“GSK”) submitted comments expressing an array of concerns with the proposed rules, including that the rules (1) would affect substantive rights of applicants provided by 35 U.S.C. § 112; (2) are not supported by findings indicating that they are necessary or would have their intended effect; (3) are inconsistent with the PTO’s oft-stated goal of harmonization; (4) are inconsistent with *In re Harnisch*, 631 F.2d 716 (C.C.P.A. 1980); (5) are subjective and do not provide applicants with fair notice; and (6) would increase the administrative burden on the PTO. *See Comments of GlaxoSmithKline in response to U.S.*

Patent and Trademark Office Notice of Proposed Rulemaking – “Examination of Patent Applications That Include Claims Containing Alternative Language” (Oct. 15, 2007). Similarly, the Pharmaceutical Research and Manufacturers of America (“PhRMA”) submitted comments, which GSK extensively contributed to, that thoroughly documented numerous concerns with the proposed rules. *See Comments of the Pharmaceutical Research and Manufacturers of America in response to U.S. Patent and Trademark Office – Notice of Proposed Rulemaking “Examination of Patent Applications That Include Claims Containing Alternative Language,” 72 Fed. Reg. 44992 (August 10, 2007)* (Oct. 9, 2007). GSK reiterates these previously submitted concerns and incorporates them herein by reference.

GSK submits these additional comments to address the PTO’s purported legal basis for these proposed rules. The PTO may not exceed the bounds of its rulemaking authority—a principle that was recently reemphasized in *Tafas (GSK) v. Dudas*, Nos. 1:07cv846 and 1:07cv1008, -- F. Supp. 2d --, 2008 WL 859467 (E.D. Va. April 1, 2008) (hereinafter “*GSK*, -- F. Supp. 2d --, at ___”). For the following reasons, GSK believes that these proposed rules exceed the boundaries of the PTO’s rulemaking authority and, if made final, would be contrary to law.

The PTO Lacks Legal Authority For These Rules

In attempting to justify its authority to promulgate these proposed rules, the PTO merely stated in its initial Notice of Proposed Rulemaking that it was accepting *Harnisch*’s “invit[ation]” for the PTO “to exercise its rule making authority . . . to anticipate and forestall the ‘procedural problems’ surrounding Markush claims.” *See* 72 Fed. Reg. at 44,999. But, in the Federal Register notice reopening the comment period, the PTO expanded upon its *Harnisch*-based legal justification, asserting for the first time that it possesses the legal authority for these proposed rules under Sections 2, 112, 121, and 131 of the Patent Act. *See* 73 Fed. Reg. at 12,680. GSK respectfully submits that neither *Harnisch* nor any of the newly cited statutory provisions authorize these rules.

Decisions of the PTO’s reviewing court are clear that 35 U.S.C. §§ 112 and 121 cannot serve as a basis for limiting a Markush claim to a single invention. *See In re Wolfrum*, 486 F.2d 588, 591 (C.C.P.A. 1973) (rejecting the PTO’s argument that Section 112 provides a basis for rejecting a single claim that encompasses a plurality of inventions); *In re Weber*, 580 F.2d 455, 458-59 (C.C.P.A. 1978) (rejecting the PTO’s argument that Section 121 provides a basis to reject a single claim for encompassing a plurality of inventions); *In re Watkinson*, 900 F.2d 230, 232 (Fed. Cir. 1990) (stating that it is “*never* proper” to reject a Markush claim under Section 121) (emphasis in original); 72 Fed. Reg. at 44,993 (admitting that the “CCPA clearly enunciated its view that these statute-based rejections were improper”). Section 131 cannot provide a basis for these proposed rules because that section only relates to the PTO’s obligations to examine applications and issue a patent when an applicant is entitled. *See* 35 U.S.C. § 131 (“The Director shall cause an examination to be made of the application and the alleged new invention; and if on

such an examination it appears that the applicant is entitled to a patent under the law, the Commissioner shall issue a patent therefor.”).

Although *Harnisch* suggested that the PTO could use its rulemaking authority to address procedural problems associated with Markush claims, *Harnisch* is equally clear that the PTO's authority is limited to its rulemaking powers under 35 U.S.C. § 2. See *Harnisch*, 631 F.2d at 722 n.6 (noting that the PTO “may wish to anticipate and forestall procedural problems [associated with Markush claims] by exercising *its rulemaking powers under 35 U.S.C. § 6(a)* [now codified at § 2]”) (emphasis added). In addition, *Harnisch* adhered to earlier decisions that held that the PTO could not rely on Sections 112 and 121 to reject a Markush claim because it comprises a plurality of inventions. See *Harnisch*, 631 F.2d at 721-22. Thus, *Harnisch* does not vest the PTO with any additional authority to promulgate regulations concerning Markush claims.

As a result, the PTO lacks the authority to promulgate these proposed rules unless it can point to authority in 35 U.S.C. § 2. However, Section 2 “does NOT grant [the PTO] the authority to issue substantive rules.” *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (emphasis in original). As recently explained, the PTO's rulemaking authority under Section 2 “is limited to rules governing the ‘conduct of proceedings’ before the Office[;] the USPTO does not have authority to issue substantive rules, and it does not have the authority to make substantive declarations interpreting the Patent Act.” *GSK*, -- F. Supp. 2d --, at *6 (citing *Merck*, 80 F.3d at 1549-50; *Animal Legal Def. Fund v. Quigg*, 952 F.2d 920, 930 (Fed. Cir. 1991)).

These proposed rules are substantive because they affect an applicant's rights and obligations. See *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979); *Animal Legal Def. Fund*, 952 F.2d at 927. The Patent Act expressly vests with the applicant the right to define his invention. See 35 U.S.C. § 112 ¶ 2 (“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which *the applicant* regards as his invention.”) (emphasis added). Under that provision, it is well established that an applicant has a statutory right to “set the metes and bounds of ‘his invention’ as he sees them,” and the scope of the subject matter claimed “is governed not by the examiner's conception of the ‘invention’ but by that ‘which the applicant regards as his invention.’” *Wolfrum*, 486 F.2d at 591. Proposed Rules 75 and 140, however, and by way of example, limit an applicant's right to claim the full scope of his invention by limiting each claim to “a single invention.” By prohibiting a single claim from encompassing more than one invention, the proposed rules will force an applicant to divide his heretofore permissible claim into multiple claims in an effort to try to obtain the full scope of patent coverage for his invention. See 73 Fed. Reg. at 12,681 (“In this case of an intra-claim restriction, applicants who wish to pursue patent protection for the full scope covered by their initial application would have to file a divisional application for each additional invention defined in that original claim.”). At a minimum, the resulting fragmentary claims may not equal the applicant's original claim because the whole of a Markush claim may

be greater than the sum of its individual parts. *See Weber*, 580 F.2d at 458. Thus, if finalized, these proposed rules would doubtlessly affect an applicant's rights under the Patent Act. These proposed rules are, therefore, substantive and beyond the bounds of the PTO's statutory authority. *See GSK*, -- F. Supp. 2d --, at *6.

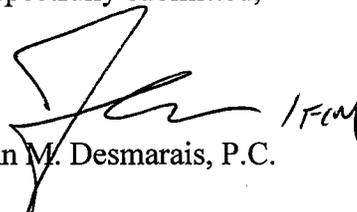
Moreover, the two Federal Register notices addressing these proposed rules do not indicate that the PTO understood and adhered to the limitations on its rulemaking authority. In fact, in litigation dealing with other rulemaking, the PTO advocated that it was not bound by *Merck's* statement that the PTO lacks general substantive rulemaking authority because that statement was mere *dicta*. *See GSK* -- F. Supp. 2d --, at *6 (rejecting the PTO's contention that the holding in *Merck* was mere *dicta*). The PTO's positions in that litigation and in the notices of proposed rulemaking dealing with these proposed rules reflect a fundamental misunderstanding of its limited rulemaking authority.

Because the PTO has misperceived the limits of its rulemaking authority when proposing these rules, the issuance of the proposed rules as final would render them arbitrary and capricious. *See SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943); *Prill v. NLRB*, 755 F.2d 941, 948 (D.C. Cir. 1985). Thus, the proper approach is for the PTO to withdraw these proposed rules and determine whether there are any alternative language reforms that it can implement consistent with its limited rulemaking authority.

Conclusion

While GSK appreciates the administrative concerns expressed in the PTO's original Notice of Proposed Rulemaking, these proposed rules go too far. The rules diminish applicants' statutory rights and, thus, exceed the PTO's limited authority to promulgate regulations. In light of this, and for the reasons set forth in its October 15, 2007 comments to the PTO and PhRMA's October 9, 2007 comments to the PTO, GSK encourages the PTO to withdraw these rules and consider less burdensome alternatives that are consistent with the PTO's limited rulemaking authority. GSK looks forward to your thoughtful consideration of these issues and remains available to discuss these matters at your convenience.

Respectfully submitted,


John M. Desmarais, P.C. JFM