April 9, 2012

Via electronic mail to: patent_trial_rules@uspto.gov

Mail Stop Patent Board
Director of the United States Patent
and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Lead Judge Michael Tierney
Patent Trial Proposed Rules

Re: Request for Comments on Proposed Rulemaking
Rules of Practice for Trials Before the Patent Trial and Appeal Board
and Judicial Review of Patent Trial and Appeal Board Decisions

Dear Judge Tierney:

Asklepion Pharmaceuticals, LLC, and Neos Therapeutics, Inc., thank the United States Patent and Trademark Office (USPTO) for the opportunity to comment on the proposed Rules of Practice for Trials Before the Patent Trial and Appeal Board under the America Invents Act (AIA) as set forth at 77 Fed. Reg. No. (27), 6879 ff. (Thursday, February 9, 2012).

Asklepion Pharmaceuticals, LLC, was created in 2006 to fulfill opportunities for drug research and development for patients with liver based diseases, regardless of the potential market size. Since then, Asklepion has entered into relationships with various universities and hospitals to develop drugs for both very large patient populations as well as for small subsets of patients. Many of the more prevalent disorders and the needs of those patients have already been addressed by large pharmaceutical companies. However, there are also conditions with substantial unmet medical needs. Patents are integral to Asklepion's approach to developing products which serve these needs.

Neos Therapeutics, Inc., develops proprietary drug delivery technologies that enable the creation of stable controlled release (CR) products; CR liquids and CR oral disintegrating tablets (ODTs), with suitable flavors and mouth feel. These innovative delivery technologies address the needs of growing pediatric and geriatric patient populations, especially those with central nervous system disorders or an inability to swallow tablets and capsules. Neos licenses its delivery technology platform to pharmaceutical and OTC drug companies in addition to developing and marketing our own pipeline of CR liquids and CR ODTs. Patents on their proprietary technologies are important to Neos' business model.

As small, specialty pharmaceutical companies, both Asklepion and Neos depend on intellectual property for access to capital and to preserve the position in the marketplace that their research provides for them. Therefore, they are both concerned that the Trial Rules proposed by the

USPTO fairly balance the needs of both patent owners and their competitors. In view of that concern, they submit the following comments for consideration by the USPTO on the proposed Rules of Practice for Trials Before the Patent Trial and Appeal Board.

Comment on the USPTO's Proposed Trial Rules for Inter Partes and Post-Grant Proceedings

Section 42.73(d)(3)(ii) -- (a) Is there any need or authority granted to the USPTO to extend estoppel beyond res judicata *or issue preclusion in view of a final decision in an* inter partes *or post-grant review?*
(b) Should estoppel prevent a patentee from pursuing a separately patentable claim in another proceeding simply because such claim(s) "could have been filed" in the inter partes *or post-grant review proceeding?*

Proposed § 42.73(d) is directed to the estoppels incorporated into *inter partes* and post-grant review proceedings under the AIA. Proposed § 42.73(d)(1) implements 35 U.S.C. §§ 315(e)(1) and 325(e)(2) concerning estoppel of petitioners, and Proposed § 42.73(d)(2) implements 35 U.S.C. § 135(d) concerning estoppel of the losing party in a derivation action. For § 42.73(d)(3), which concerns patent owner estoppel, however, there is no statutory basis for the extent of patent owner estoppel proposed in § 42.73(d)(3). Proposed § 42.73(d)(3) appears to be an attempt to state the effects of *res judicata* which would apply to a patent owner who lost an *inter partes* review or post-grant review under the AIA. However, the proposed rule goes well beyond the scope of common law *res judicata* and, in fact, abrogates substantive rights which would otherwise be available to the patent owner.

The patent owner and the USPTO are parties to any *inter partes* or post-grant review proceedings under the AIA, and under existing law pre-dating the AIA, a final agency action by the USPTO that cancels or refuses entry of a claim or denies an amendment to the specification or drawing would preclude the patent owner from pursuing the same amendment or a substantially similar claim in any subsequent action before the USPTO. Proposed § 42.73(d)(3)(i) and (iii) merely restate this existing law, and because they do not effect any substantive changes, they may be appropriate for inclusion in this rule to clarify the situation for the USPTO's employees and customers. However, Proposed § 42.73(d)(3)(ii), in conjunction with limitations on amendment during *inter partes* or post-grant review proceedings imposed, respectively, by Proposed §§ 42.121(a) and (c)(1) and 42.221(a) and (c)(1), would implement substantive changes by eliminating the patent owner's right to claims to which the patent owner

would otherwise be entitled, and these substantive changes are not required or authorized under the AIA and have no other statutory basis.

The scope of claim amendments allowed the patent owner during *inter partes* or post-grant review proceedings are limited by the proposed rules. Proposed §§ 42.121(c)(1) and 42.221(c)(1) require that each amended claim must "respond to a ground of unpatentability involved in the trial." Taken literally, this would appear to forestall adding new dependent claims during the *inter partes* or post-grant review proceeding, since the claim from which these new claims depend must have already addressed the ground of unpatentability for that claim to be allowed in the post-grant proceeding. The Practice Guide for Proposed Trial Rules, 77 Fed. Reg. 6875 (proposed Feb. 9, 2012), in Section II. G., p. 6875, column 1, asserts "a general presumption that only one substitute claim would be needed to replace each challenged claim." This presumption and the proposed rules would appear to prevent the filing of more than one amended claim, even if the patent owner has more than one theory of patentability, where alternative theories call for alternative claim limitations.

Thus, the proposed rules appear to unduly limit the patent owner's options and rights when there may be alternative bases for patentability of an invention. Below are two examples showing when a patent owner, who pursued one theory of patentability in a granted patent and would normally have the right to pursue one or more alternative theories of patentability in divisional applications, would be precluded from exercising this right by Proposed § 42.73(d)(3).

Example A -- Genus/Species

Under the proposed rules, if a patent under *inter partes* or post-grant review claims a generic invention and discloses more than one patentably distinct species, the patent owner must choose between filing an amended genus claim and filing a claim directed to <u>only one</u> of the patentably distinct species. Dependent claims to one or more patently distinct species would not "respond to a ground of unpatentability" as required in Proposed §§ 42.121(c)(1) and 42.221(c)(1), because patentability issues must be addressed by the independent claim from which those claims depend. However, if the patent owner chooses to file an amended genus claim and is unsuccessful, Proposed § 42.73(d)(3)(ii) precludes pursuing the patentably distinct species claims in a divisional or related application, because the patentee <u>could have filed</u> a species claim instead of the genus claim during the post-grant procedure. Thus, according to Proposed

§ 42.73(d)(3)(ii), the patent owner must choose a single claim among the group that includes the generic claim and each of the separately patentable species, even though the entire group could otherwise be pursued by the patent owner in one or more divisional applications.

Example B -- Alternative grounds for patentability

Under the proposed rules, if a patent owner has two alternative theories for overcoming a ground for unpatentability, whether he can pursue one or both theories will depend on whether at least one theory requires an amendment that would broaden the patented claim in some respect. If one claim is broader than the patented claim in at least some aspect, then that broader claim can be pursued in a divisional or related application, whether or not the other claim is refused in the post-grant proceedings. This is because an amendment which broadens a granted patent is not permitted under 35 U.S.C. § 316(d)(3) or 326(d)(3), and therefore the amendment could not have been filed in the *inter partes* or post-grant review proceeding. On the other hand, if both alternative amended claims are narrower than the claim challenged in the *inter partes* or post-grant review proceeding, then either alternative claim "could have been filed in response to [a] properly raised ground of unpatentability", and under Proposed § 42.73(d)(3)(ii), if one of the alternative amended claims is refused in the post-grant proceeding, the claim not filed in the post-grant proceeding cannot be pursued in a divisional application. Thus, whether or not both alternative claim amendments can be pursued would depend on whether a limitation unrelated to the ground of unpatentability is broader or narrower than the granted claim, and thus, the patent owner's right to choose how he claims his invention may be arbitrarily restricted for reasons unrelated to the actual patentability of the claim.

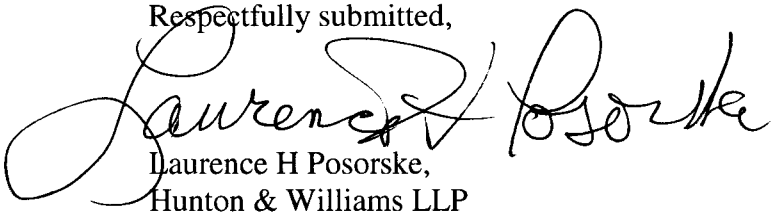
As demonstrated by the above two examples, Proposed § 42.73(d)(3)(ii) reduces a patent owner's right to pursue alternative approaches to overcoming a challenge to a patented claim. When a proposed regulation changes the rights of a party before an agency, that regulation is substantive. *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008), *citing Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991). The Federal Circuit has held that the USPTO does not have the authority to promulgate regulations with substantive effect. *Koninklijke Philips Elec. NV v. Cardiac Sci. Operating Co.*, 590 F.3d 1326, 1336 (Fed. Cir. 2010), citing *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996). Therefore, Proposed § 42.73(d)(3)(ii) would exceed USPTO rulemaking authority if it became a final rule.

In both of the above examples, there does not appear to be any good policy reason for limiting the patent owner's right to pursue alternative bases for patentability. In addition, there is no statutory basis for a broadened estoppel applying to the patent owner in any *inter partes* or post-grant review proceeding under the AIA. Therefore, it is recommended that the USPTO consider eliminating Proposed § 42.73(d)(3) in its entirety from the final rules, or at the very least, eliminate Proposed § 42.73(d)(3)(ii).

To the extent that the USPTO has any questions or requests further information regarding the foregoing or any of the other Proposed Rules, please contact the undersigned representative from Hunton & Williams.

On behalf of Asklepion and Neos, we appreciate the opportunity afforded us to submit comments on this Proposed Rulemaking.

Respectfully submitted,



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