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Via Electronic Mail

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The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Mail Stop Comments – Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn.: Mary C. Till, Senior Legal Advisor, Office of Patent Legal Administration,
Office of the Deputy Commissioner for Patent Examination Policy

Re: Eli Lilly and Company (Lilly) Supplemental Comments to the United States Patent and Trademark Office (Office) Notice of Proposed Examination Guidelines Entitled: Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act

Dear Under Secretary Kappos:

Lilly appreciates the opportunity to submit supplemental comments in response to the United States Patent and Trademark Office's ("USPTO" or "Office") Request for Comments on the Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act that appeared at 77 Fed. Reg. 43759-43773 (July 26, 2012) under the extension of time for responses that appeared at 77 Fed. Reg. 61735 on October 11, 2012.

On October 4, 2012, Lilly made an original submission and has had the opportunity to review submissions made by others. As a result of this review, it appeared desirable for us to express our views on one issue where conflicting viewpoints have been expressed. For this reason, this supplemental submission addresses the issue of whether the provisions in subparagraph (B) of §102(b)(1) and §102(b)(2), when addressing the "subject matter disclosed" by (or at the behest of) the inventor, is to be construed as the statute was written or should be construed far more

Answers that matter.

broadly. The broad construction would augment the literal language of the statute to encompass a non-statutory “fudge factor.”

In construing the statute to include such a non-statutory “fudge factor,” an inventor would be given leeway, for the purpose of evading the prior art effect with respect to a subsequent patent filing, of not only the “subject matter disclosed” by the inventor in an earlier publication (what the statute dictates is the scope of the provision), but also any and all obvious variants of such subject matter, *e.g.*, any additional, non-disclosed embodiments that would represent merely non-substantial changes from the subject matter disclosed.

Lilly’s view is that the statute should be applied as written by Congress. If construed to encompass a non-statutory “fudge factor,” the provision would reach nonsensical results. Such a construction would mean that an inventor could more readily avoid prior art by merely publishing on subject matter instead of making a prompt patent filing. Congress could never have intended that an inventor who proceeds to promptly seeking a patent should be disadvantaged relative to an inventor who merely published on limited subject matter and then belatedly seeks a broader patent, only after the public disclosure of the independent work of others. In hopes of preventing such absurd prospects in the implementation of the AIA by the Office, Lilly’s detailed comments follow.

1. Following a “Fudge Factor” Approach Is Unnecessary to Assure the AIA “Grace Period” Functions Fully and Fairly to Bar the Inventor’s Own Work as Prior Art and Meets the Limited Objective of Congress to Protect Publishing Inventors Against Intervening Public Disclosures Representing the Independent Work of Others

The fudge-factor proponents rely heavily on AIA legislative history for construing the subparagraph (B) provisions, to the exclusion of simply applying the statutory provisions as written. However, the legislative history that is most frequently cited by fudge-factor proponents clearly relates – and was intended to relate – exclusively to the subparagraph (A) provisions of §§102(b)(1) and (2). Unlike the subparagraph (B) provisions, the subparagraph (A) provisions are the ones that deal with the inventor’s “grace period.” The subparagraph (B) provisions are different and distinct from the “grace period” provisions – they provide an added layer of protection for inventors.

The “grace period” by itself serves one and only one function. It allows an inventor to have its own work disregarded as prior art. For example, when an inventor’s own work is directly disclosed by the inventor (or the inventor’s work is disclosed by someone else) in an earlier (pre-patent filing) publication, then the subject matter disclosed directly (or indirectly) by the inventor is entirely disregarded as prior art.

Thus, as a technical matter, the subparagraph (B) provisions of §102(b) have nothing whatsoever to do with the “grace period.” Instead, the subparagraph (B) provisions provide an

additional “prior art” protection based upon the independent work of others, rather – than is the case with “grace period” protection – the work of the inventor itself.

Properly viewed, therefore, the “grace period” under the AIA operates in exactly the same manner as it applies under pre-AIA patent law. The “grace period” – both under the AIA and the pre-AIA law – provides 100% protection against the inventor having its own work used against it, irrespective of who discloses such work or how it comes to be disclosed during the “grace period” in the pre-filing disclosure.

While both pre-AIA and the AIA statute have what could be regarded as a *perfect* “grace period,” the statutory version in the AIA, if anything, is superior to pre-AIA law. The new law quite explicitly deals with “indirect” disclosures that, even if made by others, must be attributable back to the inventor because they are the inventor’s own work. The AIA makes explicit what was merely implicit in pre-AIA law.

Thus, “grace period” – either pre-AIA law or under the AIA itself – provides 0% protection from public disclosures arising from independently created work of others. That said, both the AIA and pre-AIA law have provisions in which such public disclosures of others’ independent work can be disregarded as prior art. However, the statutory schemes under the AIA and pre-AIA law are vastly different.

What the new subparagraph (B) provisions provide in terms of an ability to disregard independent work of others as prior art serves as a replacement for what 35 U.S.C. §102(g) (and related “invention date” provisions of pre-AIA law) provided. In a nutshell, both the subparagraph (B) provisions and pre-AIA “invention date” provisions provide a vehicle by which the pre-filing public disclosures, representing work developed by others, can be disregarded as prior art.

Viewed in this manner, any contentions from the fudge-factor proponents that the “grace period” under the AIA would be gutted appears by applying the subparagraph (B) provisions as written in the new statute appear to be doubly flawed. First, under both the AIA and pre-AIA versions of §102, the “grace period” provisions function identically – they operate identically and have identical effect. Second, both AIA law and pre-AIA law limit the ability of an inventor to avoid an intervening public disclosure of someone else’s independent work.

Thus, contentions of “grace period” gutting simply ignore the first point and, as to the second point, disregard the impact of §102(g) prior art (prior-invention “prior art”) that must be considered whenever there is an intervening public disclosure based upon the independent work of others. Indeed, the pre-AIA law does not go nearly as far in protecting inventors against independent work of others as prior art as some fudge-factor proponents urge that the subparagraph (B) provisions should go to remove such work of others as prior art!

Indeed, in key respects applying the subparagraph (B) provisions as written and as manifestly intended by Congress would in many circumstances provide inventors with more useful and effective protection from invalidating prior art compared to current law. The manner in which the AIA operates in this respect is more fully set out below.

Hence, rather than gutting the “grace period,” the AIA, applying the statute as written, maintains, if not enhances, the “grace period,” and – under many fact situations – otherwise improves the prospects for obtaining a valid patent compared to current law.

2. Compared to pre-AIA §102(g) Law, the New §102 Provisions – Applied as Written – Provide Fair and Often Superior Protection for Inventors

Pre-AIA §102(g) limits the ability of inventors to secure a valid patent in every situation where subparagraph (B) would apply under the AIA. Section 102(g) applies both where there are disclosures of independent work of others that are identical to subject matter an inventor has earlier published and to the situation where there are obvious variations of the inventor’s earlier-published subject matter. Under pre-AIA patent law, such types of intervening disclosures of independent work of others typically portend patent disaster given the operation of pre-AIA §102(g)’s prior invention “prior art” provisions.

Under pre-AIA 35 U.S.C. §102(g), inventors faced a potentially mortal risk to patentability if the intervening public disclosure was on either the same subject matter as the earlier publication of the “grace period” inventor or directed to an obvious variation of that earlier-published subject matter. A pre-AIA inventor cannot secure a valid patent in the situation where there is either type of intervening disclosure (same or obvious variation) absent being able to antedate the U.S. *invention date* for the other person’s independent work – not just the *date of publication*. This is the first-to-invent principle at work.

Thus, even if someone publicly discloses its independently developed subject matter that is only a trivial or insubstantial variation of the inventor’s earlier-published work, such a public disclosure (since it is of subject matter “not abandoned, suppressed or concealed) constitutes prior art as of its U.S. invention date. In such a situation, the date of invention may well be prior to the invention date of the earlier-publishing inventor given that the respective public disclosures must have taken place within a matter of months from one another in order for this scenario to arise.

However, in the vast majority of circumstances, the earlier-publishing inventor remains in a state of “patentability limbo.” Its underlying U.S. invention date is unable to be discerned from the intervening public disclosure itself. Therefore, the inventor cannot be certain its patent will prove valid or can ever be successfully enforced.

As a result of the pre-AIA's prior invention "prior art" provisions, there was no subparagraph (B)-type protection of the breadth that fudge-factor proponents urge for implementing the AIA in the pre-AIA patent law. The profound difficulty that §102(g) imposes on inventors in the factual situation where subparagraph (B) would apply under the AIA arises whether an intervening public disclosure was of the same or an obvious variant of the subject matter that the earlier-publishing inventor had disclosed.

Hence, applying subparagraph (B) provisions as drafted and intended by Congress does not deprive inventors of any categorical protection against patent-invalidating prior art that pre-AIA law guaranteed.

In addition to ending the "patentability limbo," the AIA version of §102, by eliminating §102(g) prior art in its entirety, avoids completely the risk inventors face with "interloping" – the possibility that a rival seeing an inventor's publication will be spurred into a patent filing during the "grace period" interval of the earlier-publishing inventor. When a rival is spurred into such a patent filing under pre-AIA law, the result is that the spurred patent filer can readily gain the status of both first to file and presumptive first to invent. The earlier-publishing inventor who thereafter seeks a patent has (statistically at least) little prospect of securing a patent once beaten to the USPTO by the spurred patent filer.

Again, applying the subparagraph (B) provisions as drafted and intended by Congress provides an affirmative and complete protection against interlopers. Those who would condemn the USPTO's proposed implementation of the AIA, are simply ignoring the difficulties inventor's face under pre-AIA law and the inherent advantages inventor's enjoy under the AIA framework to reach an entirely erroneous conclusion that the AIA operates unfairly for inventors and does not go far enough in eliminating independent work of rival inventors as prior art.

Indeed, by eliminating the dilemma of the "patentability limbo" and the prospect of "interloping," the inventor protection from the disclosures of independent work of others under the AIA is, on balance, more secure for any earlier-publishing inventor than less secure. Those in the patent bar who are concerned with the limited reach of the subparagraph (B) provisions appear to be wholly disregarding how the pre-AIA §102(g) provisions operated to, at best, cast patentability of the earlier-publishing inventor's invention into doubt and subjected the earlier-publishing inventor to interloping.

Lilly would submit, when this comparison between pre-AIA §102 and the subparagraph (B) provisions (applied as written and intended by Congress) is made, it becomes clear that early-publishing inventors should have greater validity concerns under the pre-AIA law than will exist under the AIA provisions in §102, including the limited reach of the subparagraph (B) provisions. Most importantly, in the situation where subparagraph (B) was intended to apply – the publication of independent work of a rival inventor is encompassed by the earlier-

publishing inventor's disclosure – the patentability protection under subparagraph (B) is categorical and complete, which is a far superior outcome to the “patentability limbo” inflicted by pre-AIA §102(g).

3. Congress Could Not Rationally Have Intended to Eliminate Independent Work of Others As Prior Art with Respect to Subject Matter That an Earlier-Publishing Inventor Never Disclosed

With the improvement in the patentability prospects for inventors who publish before filing for a patent (occasioned by ending “patentability limbo” and the demise of the incentive for spurred patent filings given pre-AIA §102(g)), there is not one shred of evidence that Congress intended to go beyond this improvement in the law for earlier-publishing inventors by wiping out completely and categorically intervening disclosures of independent work of others as prior art where they include obvious variants of the earlier-publishing inventor's disclosure.

It makes no policy sense to expand this exception from prior art beyond the subject matter disclosed, specifically to expand the exemption to disregard any further disclosure of obvious variations of the earlier-publishing inventor's disclosure.

One principle that ought to apply in this situation is that an inventor who did not publish, but instead sought a patent on the same subject matter, should not be placed in an inferior position to an inventor who published, but only later sought a patent. There is no indication that such an unprecedented outcome could ever have been congressional intent.

For an inventor who promptly sought a patent *in lieu of being an earlier-publishing inventor who only belatedly decided to seek a patent after review intervening publications of the independent work of others*, the subparagraph (B) provisions do not apply. Thus, any attempt by an inventor who promptly sought a patent to later expand its original patent filing to encompass obvious variations of the disclosure in the early patent filing would produce an effective filing date for any such new or modified claims so late in time that would render that any intervening publication of the independent work of a rival inventor prior art.

That prior art impact would destroy the patentability of any claim drafted more broadly than the subject matter disclosed in the earlier patent filing. In other words, there would be no added insulation against a prior art publication that consisted of any of the “obvious variations” of what was in the earlier patent filing. The earlier-filing inventor could not secure a patent except for claims supported in the original patent.

Under proposals for introducing a “fudge factor” into the “subject matter disclosed” edict, for the earlier-publishing inventor who only belatedly sought a patent, that same prior art dissolves in its entirety and the publishing inventor's belated patent filing with the broad claims can be rendered validly patentable. Indeed, the early-publishing inventor can secure a valid patent on

all the obvious variations from the intervening disclosures of the independent work of others.

This absurd result can happen because by publishing, in lieu of the original patent filing, the fudge-factor construction of subparagraph (B) would allow the intervening publication – including any merely obvious embodiments therein relative to the inventor’s earlier publication – to be removed as prior art.

Hence, what fudge-factor proponents are arguing is such a sweepingly broad construction of the subparagraph (B) provisions that, among the worst things any inventor might do in devising a patent strategy in a situation where there was concern over intervening work of others being published, would be to actually file for a patent. With the “fudge factor” imposed on the subparagraph (B) exceptions, undertaking a very limited publication and then waiting to determine what subsequent disclosures might build on that original disclosure would be a perfect patent strategy.

All such later developments in the art could be swept up in the inventor’s subsequent patent filing, with the inventor’s very early, very limited publication being the ticket to removing all this intervening prior art. The earlier publishing inventor, unlike an earlier patent-filing inventor would thereby be positioned to secure a valid patent on both the subject matter of its original patent filing and the obvious variations, something an earlier-filing, but not earlier-publishing inventor could not do.

The intent of the AIA was not to create a “publication strategy” in lieu of or in addition to a “patent-filing” strategy to best protect an invention. Hence, introducing the “fudge factor” is both unnecessary and undesirable if the objective is a fully effective “grace period.”

Thus, Congress, which under pre-AIA law never created such a sweeping and categorical exception from prior art as the fudge-factor proponents now seek, certainly could not have intended that the AIA should now do so.

Conclusion

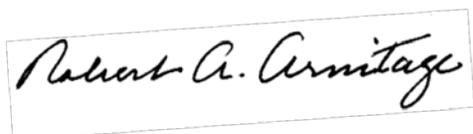
The fudge-factor proponents’ position is premised on a conclusion that the inventor’s “grace period” would be gutted absent an expansive and unjustifiable construction of the subparagraph (B) provisions. This contention ignores that the “grace period” protections under the AIA and pre-AIA law are substantively identical and provide complete and categorical protection for an earlier-publishing inventor.

It also ignores that the protection being sought by introducing a “fudge factor” against the earlier disclosures of the independent work of others is vastly more sweeping and categorical than exists under pre-AIA law. Indeed, applying the subparagraph (B) provisions as written and as intended would in fact provide superior protection compared to the pre-AIA law, which

typically results in “patentability limbo” when confronted with a pre-filing public disclosure of the independent work of a rival inventor.

Again, Lilly much appreciates the opportunity to provide its views on this topic.

Sincerely,

A handwritten signature in black ink, reading "Robert A. Armitage", enclosed in a thin black rectangular border. The signature is written in a cursive style.

Robert A. Armitage
Sr. Vice President – General Counsel