2016-1284

# United States Court of Appeals for the Federal Circuit

HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC, Plaintiffs-Appellees,

v.

## TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Defendants-Appellant.

Appeal from the United States District Court for the District of New Jersey in Nos. 3:11-cv-03962-MLC-DEA, 3:11-cv-05579-MLC-DEA, 3:13-cv-05815-MLC-DEA, Judge Mary L. Cooper.

#### BRIEF OF AMICUS CURIAE CONGRESSMAN LAMAR SMITH IN SUPPORT OF APPELLEES

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April 21, 2016

# United States Court of Appeals for the Federal Circuit

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, 16-1284

## **CERTIFICATE OF INTEREST**

Counsel for the amicus curiae Congressman Lamar Smith certifies the following:

1. The name of every party or amicus represented by me is:

Congressman Lamar Smith

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Congressman Lamar Smith

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Not Applicable

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me or are expected to appear in this Court are:

Not Applicable

Date: April 21, 2016

/s/ Robert A. Armitage Signature of counsel

Robert A. Armitage

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#### **INTEREST OF AMICUS**

Congressman Lamar Smith served as Chairman of the Committee on the Judiciary of the U.S. House of Representatives during the pendency of various patent reform bills, including H.R. 1249, enacted as the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011). He was lead sponsor of the bill and managed consideration of the bill in the House through the debate on the House floor.

His sole interest in this appeal is that 35 U.S.C. § 102(a)(1), as enacted under H.R. 1249, be interpreted in a manner faithful to the legislative text. He has no personal interest in the result of this appeal. No party to this appeal drafted any portion of this brief or contributed any money towards its preparation or filing. Both appellants and appellees have consented to the filing of this brief.

#### SUMMARY OF ARGUMENT

This appeal should be decided by holding nothing more than 35 U.S.C. § 102(a)(1) means what it plainly says. Subject matter can qualify as prior art under § 102(a)(1) only if a disclosure has made the subject matter "available to the public." This overarching public availability limitation applies to "public use" and "on sale" activities, thereby

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eliminating an aspect of the old patent statute that had treated certain nonpublic use or on-sale activities, when attributable to the inventor, as a forfeiture of the inventor's right to patent. In effect, § 102(a)(1) simply extends the long-recognized definition of "in public use or on sale" that applied under the old statute to activities unrelated to the inventor to inventor-related activities.

This § 102(a)(1) limitation is confirmed in the new patent statute itself in two subparagraphs of § 102(b) that make reference to § 102(a)(1) prior art as subject matter that been "public disclosed." To a similar effect is language, added by H.R. 1249 to 35 U.S.C. § 273, that identifies § 102(a)(1) prior art as subject matter "disclosed to the public."

The most relevant legislative history for H.R. 1249's amendment enacting § 102(a)(1) confirms that all § 102(a)(1) prior art is limited to publicly available subject matter. This history is found in H.R. 1249's committee report and the H.R. 1249 floor debates.

Contentions that Congress did not fully understand or appreciate the consequences of changing the patent law in this respect fail to recognize that repeal of the forfeiture bar was widely supported within the patent community and consistent with recommendations made by the National Academies for harmonizing U.S. patent law with that of other countries.

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#### ARGUMENT

#### I. H.R. 1249 Limits 35 U.S.C. § 102(a)(1) Prior Art To Disclosures "Available To The Public".

H.R. 1249 repealed 35 U.S.C. § 102 and substituted a new provision specifying that prior art can arise only from only two sources. One source of prior art consists of *non-public disclosures* made through patent filings. The other source is *public disclosures*, *i.e.*, disclosures "available to the public." Subject matter that is in public use or sale can now constitute prior art only if it is available to the public. This *publicness* limitation for use/on-sale activities to qualify as prior art formerly applied only to activities not inventor-related. Under H.R. 1249, the same standard now applies to inventor-related activities as well. By so extending the existing publicness limitation to inventor-related activities, H.R. 1249 has the effect of ending the "forfeiture" of the inventor's right to patent that had applied under old § 102, based upon the inventor's secret use/on-sale activities taking place more than one year before seeking a U.S. patent.

#### A. "Publicly Disclosed," "Disclosed to the Public," And "Available To The Public" Are Each Used To Describe The "Publicness" Limitation On 35 U.S.C. § 102(a)(1) Prior Art.

The table below offers a summary of the two categories of disclosures that can represent prior art under 35 U.S.C. § 102(a), as well as the operation of the relevant prior art exceptions under 35 U.S.C. § 102(b):

<b>PRIOR ART:</b>	§ 102(a)(1)	§ 102(a)(2)	
DISCLOSURES	Public disclosures—	Non-public disclosures—	
QUALIFYING	under (a)(1) must be	through patent filings under	
AS PRIOR ART	"available to the public"	(a)(2) that later publish/issue	
<b>EXCEPTIONS:</b>	§ 102(b)(1)	§ 102(a)(2)/§ 102(b)(2)	
INVENTOR'S	1-Year "Grace period"	"Same inventive entity"	
Own	under (b)(1)(A) excludes	non-public patent filings	
DISCLOSURES	(a)(1) <i>public disclosures</i>	excluded under (a)(2) itself	
DERIVATION	Included explicitly	Included explicitly	
PROTECTION	under (b)(1)(A)	under (b)(2)(A).	
NEW JOINT	Joint inventor's prior	Joint inventor's non-public	
INVENTOR	public disclosures	prior patent filings excluded	
EXCLUSION	excluded under (b)(1)(A)	under (b)(2)(A)	
INDEPENDENT	Applies under $(b)(1)B)/(b)(2)(B)$ when the inventor's		
DISCLOSURE	publicly disclosed subject matter is later disclosed by		
EXCLUSION	another inventor during the (b)(1)(A) "grace period"		

The first row of the above table describes the public and non-public disclosures that may qualify as prior art. The non-public prior art disclosures under 35 U.S.C. § 102(a)(2) arise from non-public patent filings

based upon the date they were effectively filed, provided such patent filings later publish or issue as U.S. patents. Public disclosures qualifying as prior art are those under 35 U.S.C. § 102(a)(1) that are "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public."

The shaded portions of the table above relate to various aspects of the inventor's so-called "grace period" protection. The § 102(b)(1)(A) "grace period" is triggered when (and only when) the inventor has made a § 102(a)(1) public disclosure before making a patent filing. Under § 102(b)(1)(A), such inventor-made disclosures are excluded as prior art if less than one year from the inventor's patent filing.<sup>1</sup>

When H.R. 1249 was enacted, it modified the old § 102's "grace period." in two respects. First, it made explicit the formerly implicit prior art exclusion for disclosures that were derived from the inventor, but not made by the inventor.<sup>2</sup> Second, it provided an enhancement of the "grace

<sup>&</sup>lt;sup>1</sup> As noted in the table above, § 102(a)(2) itself eliminated the inventor's own prior patent filings as prior art, precluding any need for a § 102(b) exception to do so.

<sup>&</sup>lt;sup>2</sup> The explicit derivation language in § 102(b)(1)(A) reads, "by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor."

period" that excluded a joint inventor's<sup>3</sup> public disclosures as prior art if made during the "grace period" prior to the joint inventor's later patent filing.<sup>4</sup>

In addition, H.R. 1249 addressed an extremely rare situation in which a second inventor, acting independently, has made a disclosure of the same subject matter that the "grace period" inventor had earlier disclosed to trigger the start of the "grace period." H.R. 1249 incorporated an "independent disclosure exclusion" in 35 U.S.C. § 102(b)(1)(B) and § 102(b)(2)(B) eliminating such subsequent disclosures as prior art. Since they would not have constituted prior art under the old patent statute's "grace period,"<sup>5</sup> § 102(b)(1)(B) and § 102(b)(2)(B) do no more than continue a prior art exclusion afforded under old § 102.

<sup>&</sup>lt;sup>3</sup> This enhancement of the "grace period" protection was made through the addition of the words "or a joint inventor" at two locations in § 102(b)(1)(A).

<sup>&</sup>lt;sup>4</sup> Parallel statutory exclusions were provided in § 102(b)(2)(A) that applied to § 102(a)(2) prior art.

<sup>&</sup>lt;sup>5</sup> Under the 35 U.S.C. § 102 (2002), an inventor who had triggered the start of the one-year "grace period" by publicly disclosing an invention was entitled to rely on a date no later than this "grace period" disclosure date as its "date of invention" to eliminate any later, independent disclosure of the same subject matter during the 1-year "grace period" as prior art under either old 35 U.S.C. § 102(a) (2002) or 35 U.S.C. § 102(e) (2002).

Because H.R. 1249's independent disclosure exclusion applied only to "grace period" inventors, the statutory text implementing this exclusion was limited in a manner to avoid the possibility that this exclusion might apply to an inventor who had, for example, made an earlier non-public, patent-filing disclosure that was of no relevance to the "grace period." Expanding the independent inventor exclusion to non-public disclosures, *e.g.*, an inventor's earlier patent filing, would have produced manifestly undesirable consequences.<sup>6</sup>

The H.R. 1249 statutory text applies the exclusion only if "the subject matter [independently] disclosed had, before such [independent] disclosure, been *publicly disclosed* by the inventor..."<sup>7</sup> (emphasis supplied). The term *publicly disclosed*—rather than just the unmodified term "disclosed"—was used in the new statute to assure this remedial provision applied broadly enough to encompass all § 102(a)(1)-type disclosures, but could not be

<sup>&</sup>lt;sup>6</sup> One such consequence of removing a subsequent disclosure as prior art is that it would have allowed the "grace period" inventor to then manipulate the start of the 20-year patent term through a later patent filing that would otherwise be barred by such subsequent disclosure.

<sup>&</sup>lt;sup>7</sup> 35 U.S.C. § 102(b)(1)(B). A parallel provision appears in 35 U.S.C. § 102(b)(2)(B), "the subject matter [independently] disclosed had, before such [independently disclosed] subject matter was effectively filed under subsection (a)(2), been *publicly disclosed* by the inventor..."

asserted based upon an inventor's § 102(a)(2)-type non-public disclosure. In this manner it reflects *the equivalency between the* § 102(a)(1) *disclosures constituting prior art and publicly disclosed subject matter.* 

This same equivalency arises from the use of the term "disclosed to the public" in H.R. 1249's amendment to the prior user defense to patent infringement.<sup>8</sup> Under H.R. 1249, the old invention-date qualification for the defense<sup>9</sup> was repealed and in its place a new provision was enacted to assure that an inventor who made use of the § 102(b)(1)(A) grace period before filing for a patent would secure immunity from the applicability of the prior user defense to the same extent as though a patent been sought on the date the "grace period" commenced.

The statute lays out this rule through a reference to "the date on which the claimed invention was *disclosed to the public* in a manner that qualified for the *exception from prior art under section 102(b)*."<sup>10</sup> Since the "grace period" exception from prior art under § 102(b) applies only to § 102(a)(1) prior art, this provision—like the § 102(b)(1)(B) and § 102(b)(2)(b)

<sup>&</sup>lt;sup>8</sup> 35 U.S.C. § 273.

<sup>&</sup>lt;sup>9</sup> The prior user must have "acting in good faith, actually reduced the subject matter to practice at least 1 year before the effective filing date of such patent..." 35 U.S.C. § 273 (b)(1) (1999).

<sup>&</sup>lt;sup>10</sup> 35 U.S.C. § 273(a)(2)(B). (emphasis added.)

provisions above—reflects the identity in meaning between disclosures representing § 102(a)(1) prior art and subject matter "disclosed to the public."

Taken collectively, H.R. 1249's consistent use of the terms "publicly disclosed," "disclosed to the public," and "available to the public" conclusively demonstrates that the publicness requirement that formerly limited use/on-sale activities not related to the inventor now applies to inventor-related activities.

### B. The Contention That H.R. 1249's Use Of "Publicly Disclosed" Implies 35 U.S.C. § 102(a)(1) Prior Art Includes Non-Public Disclosures Is Based On An Incomplete Understanding Of H.R. 1249's Statutory Framework.

The foregoing analysis equating § 102(a)(1) prior art with subject matter "publicly disclosed" and "disclosed to the public" reflects two predicates. First, all § 102(a) prior art now arises from disclosures (albeit not all disclosures qualify as § 102(a) prior art). Second, the terms "disclosed" and "disclosures" in § 102(b) and § 273 have their plain, dictionary meaning—*to make known*.

As to the first predicate, under the old statute not all prior art arose through "disclosures."<sup>11</sup> H.R. 1249, however, amended 35 U.S.C. § 103 to confirm that all H.R. 1249 § 102 prior art would arise through disclosures. H.R. 1249 removed old § 103's<sup>12</sup> characterization of subject matter "described as set forth in section 102" as constituting prior art and limited § 103's reference to § 102 prior art subject matter as that "*disclosed* as set forth in section 102…"<sup>13</sup>

With respect to the second predicate, the terms "disclosed" and "disclosure" had long been used in the patent statute with their plain, dictionary meanings. For example, these terms are specifically used to reference a *patent filing* and its technical contents in 35 U.S.C. § 122, *i.e.*, a patent applicant seeking to avoid the otherwise mandatory publication of an application for patent must certify "that the invention *disclosed in the application* has not and will not be the subject of an application filed in another country..."<sup>14</sup> To a similar effect is 35 U.S.C. § 132, dealing with the

<sup>&</sup>lt;sup>11</sup> The mere *making* of (rather than *disclosing*) an invention could be a source of prior art under 35 U.S.C. § 102(g)(1) (2002).

<sup>&</sup>lt;sup>12</sup> 35 U.S.C. § 103 (2004).

<sup>&</sup>lt;sup>13</sup> In amending § 103, H.R. 1249 changed the phrase "disclosed or described" to the word "disclosed."

<sup>&</sup>lt;sup>14</sup> 35 U.S.C. § 122(b)(2)(B)(i).

amendment of a pending patent application, "No amendment shall introduce new matter into the *disclosure of the invention*."<sup>15</sup> Other provisions of the patent statute similarly reference a patent filing as a disclosure or the contents of the application as subject matter disclosed.<sup>16</sup>

H.R. 1249's amendment of § 102, in choosing to use these very same terms that had long been used elsewhere in the statute, avoided any possible statutory ambiguity or confusion because such words could have no different meaning in § 102 than they had—and would have—elsewhere in the statute. Hence, giving effect to the "available to the public" limitation in § 102(a)(1) produces no uncertainty, ambiguity, or inconsistency in the statutory framework—the language and structure of § 102 as amended by H.R. 1249 operates in complete harmony with the remaining statute by treating § 102(a)(1) prior art as limited to public disclosures.

<sup>15</sup> 35 U.S.C. § 132(a).

<sup>16</sup> 35 U.S.C. § 113 (limiting the use of patent drawings made after the patent filing "to overcome any insufficiency of the specification due to lack of an *enabling disclosure* or otherwise *inadequate disclosure* therein" or "to supplement the *original disclosure* thereof…"), 35 U.S.C. § 112(a) (referencing an "application for patent for an invention *disclosed* in the manner provided by the first paragraph of section 112 of this title…"), 35 U.S.C. § 182 ("[t]he invention *disclosed in an application for patent* subject to an order made pursuant to section 181…"), and 35 U.S.C. § 251(a) (permitting the USPTO to "reissue the patent for the invention *disclosed in the original patent*…") (emphasis supplied)

The IPP Brief,<sup>17</sup> however, contends otherwise. It posits that § 102(a)(1) prior art cannot be—as the statute says on its face it must be limited to subject matter "available to the public" because so limiting § 102(a)(1) prior art is "inconsistent with the language and structure" of H.R. 1249.<sup>18</sup>

The core of the problem with the IPP Brief's analysis is its unsupportable contention that "disclosures" as used in § 102(b) means "prior art events."<sup>19</sup> If the term "disclosure" means—as the IPP Brief apparently suggests—"to be made prior art," then other statutory provisions containing this term (*e.g.*, § 112, § 113, § 122, § 132, § 182, and § 251) become uninterpretable.

More significantly, the use of the term "disclosed" in the H.R. 1249amended version of § 103—if construed as a reference to § 102 "prior art events"—would render the words in the statute that follow "disclosed," *i.e.*, "as set forth in section 102," entirely unnecessary. Indeed, the IPP Brief

<sup>17</sup> Brief of *Amici Curiae* 42 Intellectual Property Professors, *Helsinn Healthcare S.A., Roche Palo Alto LLC v. Teva Pharms. USA, Inc, Teva Pharms. Ind., Ltd.* (Fed. Cir.) (No. 2016-1284), herein the "IPP Brief."
<sup>18</sup> Id. at 2.
<sup>19</sup> Ibid.

explains why its own proposed construction of the terms "disclosed" and "disclosure" cannot be squared with § 103, *i.e.*, by rendering words in a statute superfluous, the IPP Brief's construction "conflicts with the wellknown canon that all words in a statute are presumed to have meaning, and interpretations that render a word redundant are to be disfavored."<sup>20</sup>

While the IPP Brief contains an extensive analysis in support of the proposition that "the term 'disclosure' has long been understood by patent lawyers and this Court as synonymous with 'prior art references,"<sup>21</sup> the only statutory provisions referenced in the brief's analysis are the version of § 103 that was *repealed* by H.R. 1249 and old 35 U.S.C. § 102(f)<sup>22</sup>, a statutory provision also repealed by H.R. 1249. Significantly, the version of § 103 enacted under H.R. 1249 that clearly demands the opposite conclusion is nowhere mentioned—and the IPP brief nowhere discusses the collection of statutory provisions in which the terms "disclosed" and "disclosure" appear with an entirely inconsistent meaning.

The IPP Brief uses this misconstruction of the term "disclosed" as meaning "prior art disclosures" to errantly conclude that "publicly

<sup>20</sup> *Ibid*.

<sup>&</sup>lt;sup>21</sup> *Id.* at 11-12.

<sup>&</sup>lt;sup>22</sup> 35 U.S.C. § 102(f) (2002).

disclosed" necessarily implies, first, that non-public disclosures can constitute prior art (or "publicly" would be superfluous) and, second, that § 102(a)(1) prior art specifically must be inclusive of non-public disclosures. The foregoing analysis is correct in only one respect. It is self-evident that prior art under § 102(a)(2) can arise from non-public disclosures, *i.e.*, confidential patent disclosures that represent prior art as of their disclosure date in the United States Patent and Trademark Office under § 102(a)(2). However, simply because all § 102(a)(2) prior art result from non-public disclosures does not support the conclusion that the term "publicly disclosed" in § 102(b) demands that § 102(a)(1) prior art also include nonpublicly disclosed subject matter.

The IPP Brief further supports its errant contention by asserting that the independent disclosure exclusion is a "super' grace period" that must be "earned' by an act that goes beyond mere prior disclosure by the inventor."<sup>23</sup> Supposedly, therefore, the "grace period"—and § 102(a)(1) prior art—must cover both public disclosures that earn the "super grace period" and non-public activities that do not. The "super grace period" conjecture, while assuredly creative, is at odds with the actual effect of this

<sup>23</sup> *Id.* at 3-4.

provision. As discussed above, this exception is far from "super" as it merely eliminates as prior art subject matter that was inherently excluded as prior art under the old patent statute's "grace period."

The ultimate flaw in the reasoning from the IPP Brief is evidenced by the proposed alternative statutory language that it posits Congress might have enacted that could have avoided the term "publicly" altogether: "An inventor's disclosure also eliminates prior art status for subject matter disclosed after the inventor's disclosure." However, this proposed language is defective in at least two respects. First, it opens the door to an inventor asserting that a non-public disclosure—one that does not trigger the start of the inventor's one-year "grace period"—is all that is needed to exclude a later *public disclosure* of another inventor as prior art. Most particularly, it would allow the inventor to rely on an earlier patent filing in order to do so—with the undesirable consequences referenced above.

Second, it is at best vague as to what subject matter is to be eliminated as prior art. To fix it would require further limitation along the following lines: "An inventor's *public* disclosure would eliminate prior art status for *the same* subject matter disclosed *during the one-year 'grace period*' after the inventor's *public* disclosure." In sum, a proper and complete analysis of the new statutory

framework resulting from H.R. 1249 demands the opposite conclusion from

that contended in the IPP Brief.

### II. The Legislative History Of H.R. 1249 Confirms That 35 U.S.C. § 102(a)(1) Is To Be Limited To Disclosures Available To The Public.

H.R. 1249 was introduced on March 30, 2011.<sup>24</sup> With respect to its

§ 102(a)(1) provisions, the most relevant legislative history is to be found in

the H.R. 1249 House Report<sup>25</sup> and the bill's House floor debate.<sup>26</sup>

### A. The House Report on H. R. 1249, Inclusive Of Its Reference To A Senate Colloquy On 35 U.S.C. § 102(a)(1), Confirms That A "Public Disclosure" Is Synonymous With A 35 U.S.C. § 102(a)(1) Prior Art Disclosure.

The H.R. 1249 House Report, in discussing § 102(a)(1), notes that

"[p]rior art will be measured from the filing date of the application and will

typically include all art that *publicly exists* prior to the filing date, other than

<sup>&</sup>lt;sup>24</sup> H.R. 1249, 112<sup>th</sup> Cong. (March 30, 2011) (as introduced), http://www.gpo.gov/fdsys/pkg/BILLS-112hr1249ih/pdf/BILLS-112hr1249ih.pdf.

<sup>&</sup>lt;sup>25</sup> "Only one committee report, H.R. REP. NO. 112-98 (2011), was issued by a committee during the Congress in which [H.R. 1249] was enacted." Joe Matal, A Guide to the Legislative History of the America Invents Act: Part I of II, 21 Fed. Cir. B.J. 435, 453 (2012).

<sup>&</sup>lt;sup>26</sup> 157 CONG. REC. H4420–H4452 (daily ed. June 22, 2011) and H4481– H4500 (daily ed. June 23, 2011).

disclosures by the inventor within 1 year of filing." The report continues with the observation that "the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that *it must be publicly accessible*."

The discussion of prior art in the House report concludes with a commentary on the inventor's one-year "grace period" and a footnoted reference to earlier the Senate colloquies addressing a related and contemporaneous patent reform bill that contained identical changes to § 102, *i.e.*, "See generally 157 CONG. REC. S.1496-97 (daily ed. March 9, 2011), S. 1370-71 (daily ed. March 8, 2011)."<sup>27</sup>

In the course of the Senate colloquies cited in the House Report, Sen. Kyl provides an extensive discussion of the policy rationale for the elimination of non-public uses and offers for sales as bearing on patentability under the new first-inventor-to-file regime,<sup>28</sup> while Sen. Leahy

<sup>&</sup>lt;sup>27</sup> H.R. REP. NO. 112-98, p. 43 (footnote 20).

<sup>&</sup>lt;sup>28</sup> "I emphasize these points about the bill's imposition of a general public availability standard and its elimination of secret prior art because they are no small matter. A contrary construction of section 102(a)(1), which allowed private and non-disclosing uses and sales to constitute invalidating prior art, would be fairly disastrous for the U.S. patent system." 157 CONG. REC. S1371 (daily ed. March 8, 2011) (statement of Sen. Jon Kyl).

explains the term "public disclosure" is synonymous with a disclosure under  $\$ 102(a)(1)^{29}$  Sen. Hatch follows with an equally unequivocal interpretation of \$ 102(a)(1)'s public disclosure limitation in the context of the parallel \$ 102(b)(1) "grace period" provision,<sup>30</sup> This colloquy footnoted in the House report concludes with Sen. Leahy's concurrence with Senator Hatch, noting the overarching requirement in \$ 102(a)(1) for public availability and the overruling of prior inconsistent case law.<sup>31</sup>

The House report and its reference to the Senate colloquies leave nothing to the imagination as to the meaning to be given to 102(a)(1). They do not leave the door open to any speculation as to H.R. 1249's

<sup>&</sup>lt;sup>29</sup> "[A]nd by a 'public disclosure' I mean one that results in the claimed invention being 'described in a printed publication, or in public use, on sale, or otherwise available to the public" 157 CONG. REC. S1496 (daily ed. March 9, 2011) (statement of Sen. Patrick Leahy).

<sup>&</sup>lt;sup>30</sup> "But, the important point is that if an inventor's disclosure triggers the 102(a)[(1)] bar with respect to an invention, which can only be done by a disclosure that is ... made available to the public..." 157 CONG. REC. S1496 (daily ed. March 9, 2011) (statement of Sen. Orrin Hatch).

<sup>&</sup>lt;sup>31</sup> "One of the implications of the point we are making is that subsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art." 157 CONG. REC. S1496 (daily ed. March 9, 2011) (statement of Sen. Patrick Leahy)

intended effect in reforming the patent laws to limit § 102(a)(1) prior art to publicly available subject matter.

### B. The H.R. 1249 House Floor Debate Further Confirms Non-Public Uses And Offers For Sale Lie Outside the 35 U.S.C. § 102(a)(1) Prior Art Provisions Requiring Public Availability.

Rep. Smith described the manner in which H.R. 1249 would change § 102 patent law during the House floor debate, "Madam Chair, contrary to current precedent, in order to trigger the bar in the new 102(a)[(1)] in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date."<sup>32</sup> The statement of Rep. Smith was made in the context of a colloquy on the interplay between the "grace period" protection under § 102(b)(1) and the § 102(a)(1) prior art provisions that trigger the possible need for "grace period" protection.

Rep. Smith noted, "We intend for there to be an identity between 102(a) and 102(b). If an inventor's action is such that it triggers one of the bars under 102(a), then it inherently triggers the grace period subsection 102(b)."<sup>33</sup>

<sup>&</sup>lt;sup>32</sup> 157 CONG. REC. H4429 (daily ed. June 22, 2011) (statement of Rep. Lamar Smith).

<sup>&</sup>lt;sup>33</sup> *Ibid*.

A responsive statement by Rep. Bass confirmed this relationship, "The legislation intends parallelism between the treatment of an inventor's actions under 102(a) and 102(b). In this way, small inventors and others will not accidentally stumble into a bar by their pre-filing actions. Such inventors will still have to be diligent and file within the grace period if they trigger 102(a); but if an inventor triggers 102(a) with respect to an invention, then he or she has inherently also triggered the grace period under 102(b)."<sup>34</sup>

In a subsequent floor statement, Rep. Lofgren asserted that "[o]ffers for sale that are not public"<sup>35</sup> would be outside the § 102(b)(1) "grace period." Her conclusion is consistent with the Smith-Bass colloquy since all non-public uses for sales are necessarily outside the § 102(a)(1) prior art provisions and the "grace period" provisions, therefore, are of no relevance to such a non-public disclosure.

In sum, the most relevant legislative history can only be understood to mean that use/on-sale activities "that are not public" are not within the scope of 102(a)(1)'s provisions demanding public availability.

<sup>&</sup>lt;sup>34</sup> 157 CONG. REC. H4429 (daily ed. June 22, 29011) (statement of Rep. Karen Bass).

<sup>&</sup>lt;sup>35</sup> 157 CONG. REC. H4430 (daily ed. June 22, 2011) (statement of Rep. Zoe Lofgren).

#### C. The IPP Brief Advances An Incomplete And Otherwise Deficient Analysis Of The Legislative History That Led To The Enactment Of 35 U.S.C. § 102(a)(1).

The IPP Brief, while it addresses the issue of legislative history that might be used to interpret H.R. 1249's amendments to § 102, is silent on the actual legislative history of H.R. 1249 itself. The brief says nothing about what Congress did starting from H.R. 1249's introduction in Congress in March of 2011 through to its enactment in September. Instead, the brief confines its discussion of legislative history to statements and reports relating to patent bills introduced earlier in time, but never enacted into law.

For example, the IPP Brief cites to the House report accompanying the Patent Reform Act of 2007 in support of the contention that Congress intended that § 102(a)(1) should be read to encompass non-public prior art.<sup>36</sup> However, the actual amendment to § 102 in this 2007 bill is remarkably different from H.R. 1249's § 102(a)(1) amendment enacted into law. In the H.R. 1908 version of § 102(a)(1), the limiting phrase "or otherwise available to the public" nowhere appears. Moreover, the H.R. 1249 House Report, as quoted above, indicates that the House eventually rejected the 2007 approach to amending § 102(a)(1) set out in H.R. 1908 and instead returned

<sup>&</sup>lt;sup>36</sup> Patent Reform Act of 2007, H.R. 1908, 110th Cong.

to the principles laid out in the original patent reform bill introduced in 2005—the Patent Reform Act of 2005, H.R. 2795, 109<sup>th</sup> Cong.<sup>37</sup>

The IPP Brief also cites to the legislative history of the Patent Reform Act of 2010<sup>38</sup> (S. 515) and its Senate report to suggest that its use of the "available to the public" limitation in § 102(a)(1) did not eliminate the "forfeiture" rule.<sup>39</sup> The IPP Brief quotes from page 60 of the S. 515's Senate report to make this point, but makes no mention whatsoever of its most relevant commentary appearing in this report at page 6.

At page 6, the Senate report explains how the amended § 102(a)(1) text in S. 515 would change the law: "the 'in this country' limitation as applied to 'public use' and 'on sale' is removed, and *the phrase 'available to the public' is added* to clarify the broad scope of relevant prior art, *as well as to emphasize the fact that it must be publicly available.*" (emphasis added.)

Beginning on page 53, the S. 515 Senate report includes recommendations for further changes to the patent law. These are set out as minority views. At page 60 is a plea that the recommendations of both the

<sup>&</sup>lt;sup>37</sup> As noted in the IPP Brief at p. 5, H.R. 2795's § 102 amendment employed the catch-all "or otherwise publicly known" to accomplish the objective of eliminating all non-public § 102(a)(1) prior art.

<sup>&</sup>lt;sup>38</sup> Patent Reform Act of 2010, S. 515, 111th Cong.

<sup>&</sup>lt;sup>39</sup> S. Rep. No. 111-18 (2009).

National Academies and the ABA be included in the bill, specifically that *all* subjective elements in the patent law be repealed.

This commentary then explains the policy rationale for doing so—*i.e.*, for eliminating *all* subject elements from the patent laws—in a sentence (which the IPP Brief only partially quotes) that reads in full: "These [subjective] elements, such as various 'deceptive intent' exceptions and patent-forfeiture provisions that apply only to non-public prior art, no longer serve any meaningful purpose, are inconsistent with other industrialized nations' patentability standards, and add greatly to the burden and expense of patent litigation."<sup>40</sup>

In context, this sentence cannot be read to suggest or imply that S. 515's § 102(a)(1) amendment had failed to repeal the "forfeiture" rule. As quoted above in full, this sentence at page 60 did no more than describe in both general and specific terms what "subjective elements" were—and why they should *all* be repealed—including those not addressed in the thencurrent text of S. 515.

<sup>40</sup> *Id*. at 60.

Further, the IPP Brief references the prior art provisions of the Patent Reform Act of 2008<sup>41</sup> (S. 3600) and the floor statement of Sen. Kyl upon introduction.<sup>42</sup> While the IPP Brief correctly notes that Sen. Kyl's § 102(a)(1) provision omits the words "in public use" and "on sale," the IPP Brief fails to explain that it was the addition of the "otherwise available to the public" limitation into § 102(a)(1) that established the new prior art standard—the same standard carried over into H.R. 1249.

To this effect, Sen. Kyl noted that his "bill's proposed section 102(a)(1) amends the novelty condition of patentability by eliminating public use and the on-sale bar as independent bases of invalidity *and instead imposes a uniform test of whether art has been made available to the public*." (emphasis supplied)<sup>43</sup> H.R. 1249 likewise imposes the identical standard.

Finally, the IPP Brief criticizes reliance on floor statements of individual senators, quoting a commentator calling the actual statements of Senators Kyl, Hatch, and Leahy as "*faux* legislative history" given the

<sup>&</sup>lt;sup>41</sup> Patent Reform Act of 2008, S. 3600, 110th Cong.

<sup>&</sup>lt;sup>42</sup> 154 CONG. REC. S9982-93 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl).

<sup>&</sup>lt;sup>43</sup> 154 CONG. REC. S9992 (Sept. 27, 2008) (statement of Sen. Jon Kyl).

timing of these statements.<sup>44</sup> Nowhere in the IPP Brief is there an

acknowledgement, however, that the House report on H.R. 1249 cites to

these statements. Even if the senators may have been speaking only for

themselves and speaking belatedly, the legislative history of H.R. 1249-as

described in detail above-reflects the subsequent adoption of the views of

these Senators in the House report on the very bill that became law.

- III. Giving The Phrase "Or Otherwise Available To The Public" Effect As An Overarching Limitation On 35 U.S.C. § 102(a)(1) Prior Art Represents An Important Patent Reform That Has No Unsettling Effect On The Patent Laws.
  - A. Repealing The Body Of Law Relating To "Forfeiture" Leaves The Terms "Public Use" And "On Sale" With Long-Established, Long Settled Meanings.

The IPP Brief urges that the "available to public" limitation in

§ 102(a)(1) should be ignored because interpreting the phrase "in public use,

or on sale, or otherwise available to the public" to exclude non-public uses

and on-sale activities "will cause all manner of mischief,"45 be "so

disruptive,"<sup>46</sup> "would result in the overturning of a huge body of case law,"<sup>47</sup>

- <sup>45</sup> *Id.* at 9.
- <sup>46</sup> *Id.* at 10.
- <sup>47</sup> *Id.* at 11.

<sup>&</sup>lt;sup>44</sup> *Id.* at 7.

and "open to question" all the interpretations of the "on sale" doctrine.<sup>48</sup> As with other contentions in the IPP Brief, the notion that "disruptive and radical effects"<sup>49</sup> will result from giving effect to the words "available to the public" in § 102(a)(1) fails the test of close scrutiny.

For starters, it is worthwhile examining just how narrow the impact of H.R. 1249 is in eliminating *non-public* use/on-sale activities that existed under old § 102(b)<sup>50</sup>. First and foremost, *all* use/on-sale activities taking place outside the United States, whether public or not, were excluded from old § 102(b). Similarly, *non-public* use/on-sale activities taking place in the United States did not constitute prior art under old § 102(b), *except for those attributable to the inventor*.

Effectively, therefore, the old § 102(b) bar on the consideration of non-public use/on-sale activities applied universally, except to inventorrelated, U.S.-based activities. H.R. 1249 did no more than apply the existing definition for "in public use or on sale" activities as applied to non-inventor activities to inventor-related activities.

<sup>50</sup> 35 U.S.C. § 102(b) (2002).

<sup>&</sup>lt;sup>48</sup> *Id*. at 16.

<sup>&</sup>lt;sup>49</sup> *Id.* at 21.

This extension could have no disruptive potential for a simple reason. As applied to use/on-sale activities unrelated to the inventor, the definitions for the terms "in public use" and "on sale" under old § 102 were clear, settled, and wholly unambiguous. Under the established definition for activities unrelated to the inventor, these terms referenced only subject matter that had become *available to the public* through the use or sale.<sup>51</sup> In this regard, "when an asserted prior use is not that of the applicant, [old] § 102(b) is not a bar when that prior use or knowledge is not *available to the public*."<sup>52</sup>

#### B. The "Available To The Public" Limitation Was One Of Many Reforms To The Patent Law Under H.R. 1249 Undertaken To Make Patentability Determinations More Objective And Certain.

The IPP Brief contends that the decision of the trial court below "would radically rewrite the law of prior art."<sup>53</sup> Not so. It was Congress, not the trial court, that radically rewrote the law of prior art with the

<sup>&</sup>lt;sup>51</sup> W.L. Gore & Assocs. v. Garlock, 721 F.2d 1540 (Fed.Cir.1983).

 <sup>&</sup>lt;sup>52</sup> Woodland Trust v. Flowertree Nursery, Inc., 148 F. 3d 1368, 1371 (Fed. Cir. 1998)

<sup>&</sup>lt;sup>53</sup> *Id.* at 9.

enactment of H.R. 1249. Indeed, Congress did so as intentionally as it did comprehensively.

In this regard, Congress ended well over a century of patent law that made the prior inventions of other inventors prior art. It prevented the use of an inventor's invention date from being used to antedate disclosures that otherwise would have constituted prior art. It repealed the bar to non-U.S.based use/on-sale activities constituting prior art. It eliminated abandonment as a loss of right to patent provision. It did the same for premature foreign patenting. It eliminated prior art for obviousness purposes arising from private communications from other inventors. It similarly eliminated prior art arising from commonly assigned patent filings used for novelty-defeating purposes—and did the same for patent filings arising through joint research agreements. It permitted correction of misjoinder and non-joinder of inventors under all circumstances, repealing an entire body of law that defined when such inventor changes would be barred on the ground of deceptive intention. It similarly removed the deceptive intention limitations on other remedial actions, including access to reissue procedures and retroactive foreign filing licenses. It rendered the "best mode" disclosure

requirement irrelevant to patent validity—mooting a huge body of patent law on when and how this requirement was to apply.<sup>54</sup>

It was in the context of these remarkable changes to the U.S. patent law that H.R. 1249 extended the established definition of "in public use or on sale" activities to inventor-related activities. Under any calculus, this modest reform measure was not among the most consequential changes to the patent law wrought under H.R. 1249.<sup>55</sup>

Moreover, the policy justification for eliminating inventor-related, non-public use/on-sale activities from 102(a)(1) is profound; doing so is

<sup>&</sup>lt;sup>54</sup> For an overview of the changes H.R. 1249 made to the patent statute, see Robert A. Armitage. Understanding the America Invents Act and Its Implications for Patenting, 40 AIPLA Q.J. 1, 10-14 (2012)

<sup>&</sup>lt;sup>55</sup> The IPP Brief warns that H.R. 1249, by overruling forfeiture cases such as *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829), *Egbert v. Lippmann*, 104 U.S. 333 (1881), *Pfaff v. Wells Elec., Inc.*, 525 U.S. 55 (1998), and *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), "opens the door to revisiting [anticipation by] inherency," the "experimental use exception," and the requirement that prior art be enabled to constitute an anticipation—not to mention double patenting. *Id.*, pp. 17-18. The H.R. 1249 House Report addressed "inherency," "enablement," and other prior art issues through its citation to the Senate colloquies, explaining that "inherency" as an anticipation doctrine would not be disturbed and "enablement" would remain a requirement for anticipation. For a detailed account of this legislative explanation, see Matal, at 21 FED. CIR. B.J. 467-469.

important for the proper functioning of the patent system now that the firstinventor-to-file principle is at the heart of U.S. patent law.

While the first-inventor-to-file principle operates to encourage promptly filing for patents, the repeal of the forfeiture doctrine affords the inventor a *continuing incentive to disclose*. The old patent statute had the unfortunate effect of encouraging continued secret commercial exploitation of inventions once the one-year forfeiture deadline had passed—which is at odds with the fundamental purpose of the patent system to encourage disclosure.

Self-evidently, Congress did all these things to make the patent law more transparent and objective and to make patentability and patent validity assessments more certain. Under the new patent law, patentability was to be ascertainable based solely on publicly available information. A patent law with such a degree of relative simplicity and predictability is hardly unknown and its policy implications are certainly not untenable. Such is the hallmark of patent laws throughout the industrialized world.

#### C. The Lack of Any Serious Controversy Over The Repeal Of Old § 102(b)'s Forfeiture Provision Eliminated Any Need For More Congressional Deliberations Before Proceeding With H.R. 1249.

The IPP Brief urges the court to ignore the words "available to the public" in § 102(a)(1) because there were "no legislative hearings on this radical move"<sup>56</sup> and because there was no "legislative history describing why the definition of prior art is being changed so radically."<sup>57</sup> The brief then contends that it is unlikely that "Congress just decided on a major sea change in this very old and very much relied upon body of law." <sup>58</sup>

<sup>56</sup> *Id.* at 9.

- <sup>57</sup> *Id.* at 10.
- <sup>58</sup> *Ibid.* Among the legislative deliberations overlooked in the IPP Brief is Sen. Kyl's explanation of what the imposition of the "available to the public" standard was designed to accomplish: "By eliminating confidential sales and other secret activities as grounds for invalidity and imposing a general standard of public availability, this change will make the patent system simpler and more transparent. Whether a patent is valid or not will be determined exclusively on the basis of information that is available to the public. As a result, at the outset of any dispute over a patent, the patentee and potential infringer can develop a full and complete understanding of the information that will determine the novelty and nonobviousness of the claimed invention. This change not only will provide greater certainty and predictability-it should also substantially reduce the need for discovery in patent litigation, since defendants will no longer need to uncover evidence of private sales or offers for sale or other nonpublic information in order to determine whether the patent is valid." 154 CONG. REC. S9992.

As discussed above, the IPP Brief seems oblivious to the fact that H.R. 1249 was all about far more radical changes to the U.S. patent law than extending the definition of "in public use or on sale" that applied to noninventor activities to inventor activities. Moreover, extending the existing definition for "public use or on sale" activities in this manner was a matter of broad consensus, not serious controversy. It was a consensus element in H.R. 1249 supported by a broad spectrum of U.S. interests that had advocated for adoption of a first-inventor-to-file system and supported repealing the old § 102(b)'s forfeiture bar as a harmonization measure, *e.g.*, the National Association of Manufacturers, the Biotechnology Industry Association, the Intellectual Property Owners Association, the American Intellectual Property Law Association, and Intellectual Property Law Section of the American Bar Association.<sup>59</sup>

<sup>&</sup>lt;sup>59</sup> See Comments Regarding the International Effort to Harmonize the Substantive Requirements of Patent Laws at http://www.uspto.gov/patent/laws-and-regulations/commentspublic/comments-regarding-international-effort-harmonize-0, in response to Request for Comments on the International Effort to Harmonize the Substantive Requirements of Patent Laws, 66 FED. REG. 15409 (March 19, 2001), in which public comments were sought on the issue of secret commercial use/on-sale activities constituting prior art under old 102(b) and ABA IPL Section Response to the Recommendations of the National Research Council of the National Academies on "A 21st Century Patent System" (Appendix), available at

As to the IPP Brief's specific concern on the supposed lack of congressional hearings, Congress rarely focuses hearings where there is a widespread consensus on broadly supported changes to the law.

http://www.americanbar.org/content/dam/aba/migrated/intelprop/reports/ NAS\_Report\_Appendix.authcheckdam.pdf, p. 18.

#### CONCLUSION

Congress enacted H.R. 1249 to broadly reform the patent laws, make them simpler and more objective, and make determinations of patentability and patent validity more certain by focusing such determinations on information available to the public. Failing to give effect to the limitation that § 102(a)(1) prior art must be available to the public not only contravenes the plain meaning of the statute, and contradicts the entirety of the legislative history of H.R. 1249, but would spoil an important component of the most significant reforms to the U.S. patent system in more than a century.

Respectfully submitted,

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# United States Court of Appeals for the Federal Circuit

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, 16-1284

## **CERTIFICATE OF SERVICE**

I hereby certify that on the date indicated below, I caused the foregoing **BRIEF OF AMICUS CURIAE CONGRESSMAN LAMAR SMITH IN SUPPORT OF APPELLEES** to be filed via CM/ECF with the Clerk of the Court, thereby electronically serving it on all counsel of record in this matter.

Date: April 21, 2016

/s/ Robert A. Armitage Robert A. Armitage COUNSEL FOR AMICUS CURIAE 320 Seaview Court #1811 Marco Island, FL 34145 (703) 801-6334 raarmitage@aol.com

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