Helsinn Healthcare S.A. v. Teva Pharma. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017)

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BACKGROUND

Plaintiff Helsinn Healthcare S.A. ("Helsinn") owned four patents, U.S. Patent Nos. 7,947,724 (''724 patent''), 7,947,725 (''725 patent''), 7,960,424 (''424 patent''), and 8,598,219 (''219 patent'') (collectively, ''the patents-in-suit'') covering intravenous solution for treating chemotherapy-induced nausea and vomiting ("CINV") using palonosetron. The effective application date for all four of the patents-in-suit was January 30, 2003, which was the date Helsinn filed a provisional patent application and claimed it as a priority date for the patents-in-suit.

Helsinn brought a patent infringement suit against the defendant Teva Pharmaceuticals USA, Inc. ("Teva") in the district court alleging that Teva's Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic version of the palonosetron product would infringe several claims of its patents-in-suit. Even though there were various claims under each patent that Helsinn alleged as infringed, Claim 2 of the '725 patent was taken as a representative of the asserted claims of the '724, '725, and '424 patents. This Claim 2 of the '725 patent was governed by the pre-Leahy-Smith American Invents Act ("pre-AIA") version of 35 U.S.C. § 102. On the other hand, Claim 1 was representative of the asserted claims of the '219 patent, and this claim was governed by the AIA version of 35 U.S.C. § 102.

In response to Helsinn's allegation, Teva brought the on-sale bar defense in counter-claiming that Helsinn's four patents-in-suit were all invalid and hence not infringed. Teva argued that two contracts that Helsinn signed with a marketing and distributing company called MGI Pharma, Inc. ("MGI") should constitute as an invalidating sale because they were signed more than a year before the effective application date for the patents-in-suit. The two agreements regarding the invention associated with the patents-in-suit that Teva was referencing were the License Agreement and the Supply and Purchase Agreement, which were both signed on April 6, 2001.

PROCEDURAL HISTORY

The district court at a bench trial didn't accept Teva's on-sale bar defense, and it held that Teva's ANDA infringed Helsinn's four patents-in-suit. It used the Pfaff two-prong test which requires that an invention be

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ready to be patented and also be sold or be offered for sale before the critical date for the on-sale bar defense to apply.[1] The district court found that the agreement that Helsinn signed with MGI constituted an invalidating sale in regard to the Claim 2 of the '725 patent, which was governed by the pre-AIA provision. However, it held that the agreement didn't constitute a sale in regard to Claim 1 of the '219 patent which was governed by the AIA provision because the court believed that the AIA changed the meaning of the on-sale bar under 35 U.S.C. § 102.

Furthermore, the district court held that both Claim 1 of the '219 patent and Claim 2 of the '725 patent, which was a representative of the three patents, were not ready to be patented before the critical date of January 30, 2002, which was one year before the provisional application date. Since Teva's defense didn't pass the Pfaff two-prong test, the district court found its ANDA application to be infringing on Helsinn's patents-in-suit. Consequently, Teva filed an appeal with the Federal Circuit.

ISSUES

On appeal, the Federal Circuit addressed three different issues: (1) whether the invention associated with the representative Claim 2 of the '725 patent that was governed by the pre-AIA provision was subject to a sale or offer for sale prior to the critical date, (2) whether the AIA provision of 35 U.S.C. § 102 has changed the meaning of the on-sale bar so that there was no invalidating sale associated with Claim 1 of the '219 patent, and (3) whether the invention associated with both Claim 2 of the '725 patent and Claim 1 of the '219 patent was ready to be patented before the critical date based on the priority date from the provisional application.

DECISION

The Federal Circuit reversed the district court decision and held that (1) the Supply and Purchase Agreement constituted as an invalidating sale on Claim 2 of the '725 patent that was governed by the pre-AIA provision, (2) the AIA hasn't changed the meaning of the on-sale bar, and hence the Supply and Purchase Agreement constituted an invalidating sale also on Claim 1 of the '219 patent that was governed by the AIA provision, and (3) the invention associated with both Claim 2 of the '725 patent and Claim 1 of the '219 patent was ready to be patented before the critical date because it was already reduced to practice, and hence Helsinn's four patents-in-suit were invalid under the on-sale bar.

1. Helsinn Healthcare S.A. v. Teva Pharma. USA, Inc., 855 F.3d 1356, 1363 (Fed. Cir. 2017).

REASONING

The Federal Circuit reviewed the on-sale bar question in this case de novo, and used the Pfaff two-prong test that the district court applied. The Pfaff test requires that an invention must be the subject of a commercial offer for sale and that it must be ready to be patented in order for the on-sale bar to apply.[2]

In regard to the Claim 2 of the '725 patent, the court looked into contract law and the UCC to determine the definition of sale and offer to sale in addition to factors that would advise against the application of the on-sale bar which they didn't find in this case. On the contrary, the court found factors that would favor application of the on-sale bar, including the fact that the Supply and Purchase Agreement expressly contemplated a transfer of title and that the agreement was publicly disclosed even if there were some details redacted.

Another major factor the court looked into was that Helsinn commercially marketed its invention and sought partners like MGI to market and distribute its invention. The court stated that the Supply and Purchase Agreement "bears all the hallmarks of a commercial contract for sale"[3] since it included terms like the price, method of payment and delivery, etc. and hence the on-sale bar is applicable on the Claim 2 of the '725 patent. It further clarified that a contract for a sale of invention contingent on regulatory approval such as FDA approval was still a commercial sale as the commercial community would understand it,[4] and it would not prevent the application of the on-sale bar per se unless there were additional reasons.[5]

In addressing the second issue of whether the AIA changed the meaning of the on-sale bar, the court rejected Helsinn's argument that AIA required that a sale discloses an invention to the public in order for the on-sale bar to apply. Helsinn referenced the language in the AIA provision "otherwise available to the public",[6] and floor discussions to show that Congress had the intent to change the application of the on-sale bar in order to allow secret sales, but the court said that confidentiality was only a factor to consider but that it was not determinative. The court also stated that the cases that Congress considered in the discussions were about "public use" not "public sale"[7] and it would not broaden the issue more than what was necessary in this case.

The court further noted that requiring disclosure of the actual invention in order for the on-sale bar to apply or failing to find public sales, which withhold the invention purposely, as invalidating the patent would materially

2. *Id.*
3. *Id.* at 1364.
4. *Id.* at 1365.
5. *Id.* at 1366.
6. *Id.* at 1369.
7. *Id.*

retard the progress of invention.[8] It also expected Congress to make its intent clearer if it intended to make such a sweeping change on the on-sale bar. The court interpreted Congress' language of "available to the public" as putting the invention in the "public domain."[9] It decided that a sale that is disclosed publicly, even if it doesn't reveal the invention, would put the invention in the public domain which meant that it would be barred from being patented. Therefore, the court concluded that there was no difference between the pre-AIA and the AIA provision of the on-sale bar and hence Claim 1 of the '219 patent was also invalid under the on-sale bar.

Finally, the court determined whether the invention as it relates to all the patents-in-suit was ready to be patented or not by the critical date of January 30, 2002. Under the second prong of the Pfaff test, there are at least two ways to show whether an invention is ready to be patented.[10] The first way is by showing that the inventor had reduced the invention to practice, which is what the district court had looked into. The second way is by showing that the inventor had prepared sufficient drawings and descriptions that would allow a person having ordinary skill in the art to practice the invention. Since this Court already found the invention to have been ready to be patented under the first option, it didn't look into the second option.

This court relied on the definition of reduction to practice as construction of an embodiment of an invention that met all the limitations and worked for its intended purpose[11], putting particular emphasis on the invention achieving its intended purpose. Since the parties stipulated on the intended purpose of the invention as reducing emesis or reducing the likelihood of CINV, the court also narrowed its determination on this purpose. The Court from the outset clarified that FDA standards and patent law standards in determining whether an invention has achieved its intended purpose are very different and criticized the district court for using the more demanding and strict FDA standard.

In looking into the more flexible standard of patent law, the court said that the test varies on a number of factors including uncertainty level, and it is a very case-specific analysis. However, the general test is that the invention must work for its intended purpose "beyond a probability of failure" but not "beyond a possibility of failure,"[12] and the fact that further tests are required doesn't necessarily mean it is not reduced to practice. In this case, the court said that it looked into an overwhelming amount of evidence including reports, declarations and testimonies from some of the inventors, and prosecution history on the patents-in-suit, which showed the intended purpose of the invention had already been achieved. The fact that the palonosetron product had already helped some patients in reducing CINV as of the critical date showed that the invention had already achieved its

8. *Id.*
9. *Id.* at 1370.
10. *Id.* at 1371.
11. *Id.* at 1371-72.
12. *Id.* at 1372.

intended purpose, which meant that it was reduced to practice. Therefore, the court concluded that the invention was ready to be patented.