United States Court of Appeals for the Federal Circuit

00-1272

APOTEX USA, INC.,

Plaintiff-Appellant,

v.

MERCK & CO., INC.,

Defendant-Appellee.

Alan H. Bernstein, Caesar, Rivise, Bernstein, Cohen & Pokotilow, LTD., of Philadelphia, Pennsylvania, argued for plaintiff-appellant. With him on the brief were Robert S. Silver and William Joseph Castillo.

Nicolas G. Barzoukas, Howrey Simon Arnold & White, LLP, of Houston, Texas, argued for defendant-appellee. With him on the brief were John F. Lynch, Gerard M. Devlin, Jr., and Peter J. Chassman, Howrey Simon Arnold & White, LLP, and Paul D. Matukaitis, Merck & Company, of White Station, New Jersey.

Appealed from: U.S. District Court for the Northern District of Illinois

Judge Matthew F. Kennelly

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DECIDED: June 8, 2001

Before LOURIE, CLEVENGER, and LINN, Circuit Judges.

LOURIE, Circuit Judge.

Apotex USA, Inc. appeals from the decision of the United States District Court for the Northern District of Illinois granting Merck & Co., Inc.'s motion for summary judgment that the claims of U.S. Patents 5,573,780 and 5,690,962 are invalid under 35 U.S.C. § 102(g). Apotex Corp. v. Merck & Co., No. 96-C-7375, 2000 WL 97,582 (N.D. Ill. Jan. 25, 2000) ("Apotex I"). Because the district court did not err in granting summary judgment that the '780 and '962 patents are invalid under 35 U.S.C. § 102(g), we affirm.

BACKGROUND

Apotex is the assignee of the '780 and '962 patents, which relate to a process for making a stable solid formulation of enalapril sodium for use in the treatment of high blood pressure. Apotex I at *1. Claim 1 of the '780 patent, which is representative of the claims at issue, reads as follows:

> 1. A process of manufacture of a pharmaceutical solid composition comprising enalapril sodium, which process comprises the steps of:
>
> i) a) mixing enalapril maleate with an alkaline sodium compound and at least one other excipient, adding water sufficient to moisten, and mixing to achieve a wet mass, or
> b) mixing enalapril maleate with at least one excipient other than an alkaline sodium compound, adding a solution of an alkaline sodium compound in water, sufficient to moisten and mixing to achieve a wet mass; thereby to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water,
> ii) drying the wet mass, and
> iii) further processing the dried material into tablets.

'780 patent, col. 5, l. 34 to col. 6, l. 15. The claims of the '962 patent, which is a continuation of the application that led to the '780 patent, are identical to those found in the '780 patent except that they are not restricted to tablet form, but rather encompass any solid pharmaceutical dosage form of enalapril sodium. '962 patent, col. 5, l. 22 to col. 6, l. 11. This distinction is not material to the resolution of this appeal.

Merck manufactures enalapril sodium under the trade name VASOTEC®, and has been continuously manufacturing and commercially selling VASOTEC® tablets since 1983. Apotex I at *7. Merck owns both U.S. and Canadian patents covering the enalapril sodium compound, but does not own a patent covering its process of manufacturing VASOTEC®. Id. at *1. However, in 1992, Merck

disclosed the ingredients utilized in its VASOTEC® manufacturing process in a Canadian product monograph, and more than 30,000 copies of the monograph were distributed in 1993 alone. Id. at *7. Merck also disclosed the ingredients used in manufacturing RENITEC® (the trademark used for its enalapril sodium product sold in various foreign countries) in the 1988 edition of the Dictionnaire Vidal, a French pharmaceutical dictionary. Id.

In 1991, Merck and its Canadian subsidiary, Merck Frosst Canada, Inc., sued Apotex's Canadian affiliate, Apotex Canada, for infringement of Merck's Canadian patent covering the enalapril sodium compound. Id. at *1. During the 1994 trial ("the Canadian trial"), Brian McLeod, Merck's then-vice president of marketing, performed a step-by-step narration of a videotape demonstrating Merck's process of manufacturing VASOTEC®. Id. Within days of hearing this testimony, Dr. Bernard Sherman, an Apotex official, allegedly conceived the patented process at issue. Id.

Apotex filed the present action against Merck, alleging that Merck's process of manufacturing VASOTEC® infringes all of the claims of both the '780 and '962 patents. Id. Both parties filed cross-motions for summary judgment on the issue of infringement, and Merck cross-moved for summary judgment of invalidity under § 102(g). Id. The district court granted Apotex's motion for summary judgment of infringement, but also granted Merck's cross-motion for summary judgment of invalidity because it found that Merck invented the process claimed in the '780 and '962 patents within the United States before Apotex, and did not abandon, suppress, or conceal that invention within the meaning of § 102(g). Id. at *9.

Apotex thereafter filed a motion asking the court to reconsider its grant of summary judgment of invalidity, which the district court denied. Apotex Corp. v. Merck & Co., No. 96-C-7375, 2000 WL 656,670 (N.D. Ill. Mar. 17, 2000). Apotex appeals from the district court's grant of summary judgment of invalidity. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (1994).

DISCUSSION

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). For purposes of the motion, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). We review a district court's grant of a motion for summary judgment de novo. Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 149 F.3d 1309, 1315, 47 USPQ2d 1272, 1275 (Fed. Cir. 1998).

Apotex argues that the district court improperly invalidated the '780 and '962 patents because Merck failed to prove by clear and convincing evidence that it did not suppress or conceal the patented process. Apotex contends that proof of invalidity under § 102(g) requires Merck to prove that it did not suppress or conceal the process of manufacturing VASOTEC® tablets based on its activities within the United States, and that Merck's foreign disclosures therefore cannot be used to satisfy its burden of proof. Apotex also contends that, in any event, Merck's foreign disclosures fail to prove that it did not suppress or conceal the process because

nothing in the testimony from the Canadian trial, the product monograph, or the French dictionary disclosed the use of water, the occurrence of an acid-base chemical reaction between enalapril maleate and sodium bicarbonate, or the resultant enalapril sodium product. Finally, Apotex argues that the evidence demonstrates that Merck in fact suppressed or concealed its invention by failing to file a patent application on the process, by submitting misleading information in its New Drug Application ("NDA") that only disclosed the starting ingredients used to make VASOTEC®, and by preventing the details of its process from circulating outside of the company.

Merck responds that § 102(g) only requires proof that the prior invention was made in the United States, and that evidence of lack of suppression or concealment can be proven by both foreign and domestic activities. Merck further argues that it did not suppress or conceal the process because it used it commercially, disclosed it in open court directly to its competitor, and published the ingredients used to make VASOTEC® tablets in both the product monograph and the French dictionary. Merck also argues that the submissions it made with respect to its NDA were proper and in any event could not constitute suppression or concealment because it was the Food and Drug Administration that never made those submissions public. Finally, Merck contends that the process was not suppressed or concealed because it was obvious and Dr. Sherman admitted that VASOTEC® tablets could be reverse-engineered to reveal the details of the process.

Section 102(g) operates to ensure that a patent is awarded only to the "first" inventor in law. In addition to governing priority determinations in interference

proceedings in the United States Patent and Trademark Office, § 102(g) may be asserted as a basis for invalidating a patent in defense to an infringement suit. New Idea Farm Equip. Corp. v. Sperry Corp., 916 F.2d 1561, 1566, 16 USPQ2d 1424, 1428 (Fed. Cir. 1990) (citation omitted). That section provides in relevant part that: "A person shall be entitled to a patent unless . . . before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C.A. §102(g) (West Supp. 2000). Therefore, if a patentee's invention has been made by another, prior inventor who has not abandoned, suppressed, or concealed the invention, § 102(g) will invalidate that patent. New Idea, 916 F.2d at 1566, 16 USPQ2d at 1428.

Apotex does not dispute that Merck invented the patented process in the United States well before Dr. Sherman's alleged date of conception. Apotex also concedes that Merck did not abandon its process of manufacturing VASOTEC® tablets as shown by its continuous commercial use of the process since 1983. The sole issue on appeal, therefore, is whether Merck "suppressed" or "concealed" the process within the meaning of § 102(g). Whether suppression or concealment has occurred is a question of law, which we review de novo. Brokaw v. Vogel, 429 F.2d 476, 480, 166 USPQ 428, 431 (CCPA 1970).

As an initial matter, we disagree with Apotex's interpretation of § 102(g) as requiring proof negating suppression or concealment to arise from activities occurring within the United States. The plain language of § 102(g) clearly requires that the prior invention be made "in this country." However, in light of the grammatical structure of § 102(g), it would be a strained reading of that provision to

interpret the language "in this country" to also modify the requirement that the prior invention was "not . . . abandoned, suppressed, or concealed." A more reasonable interpretation is that it only modifies the antecedent verb "made," but not the "abandoned, suppressed, or concealed" clause that follows it. Had Congress intended the phrase "in this country" to modify "abandoned, suppressed, or concealed," it would have inserted language to that effect.

Indeed, if there were any doubt, the legislative history of § 102(g) demonstrates that Congress contemplated that precise modification, as it applied to another clause in §102(g), and failed to adopt it. An earlier version of that provision considered in the House read as follows:

> [B]efore the applicant's invention thereof the invention was in fact made in this country by another who had not abandoned it and who was using reasonable diligence in this country in reducing it to practice or had reduced it to practice.

H.R. 3760, 82nd Cong. (1951) (emphasis added). The fact that the drafters found it desirable to emphasize that the language "in this country" applies to "using reasonable diligence" as well as to the word "made" supports the conclusion that it only modifies the verb that precedes it and not any subordinate clause that follows it. Accordingly, based upon the plain language of § 102(g) and the relevant legislative history of that provision, we conclude that the language "in this country" only applies to the country where "the invention was made," and that proof negating suppression or concealment is not limited to activities occurring within the United States.

We next turn to an issue that has not been squarely addressed by this court in considering suppression or concealment as negating prior invention in a defense

to an infringement suit under § 102(g) — the burdens of proof governing such a determination. Section 282 of the Patent Act provides that "[a] patent shall be presumed valid." 35 U.S.C.A. § 282 (West Supp. 2000). In order to overcome the presumption of validity, the party challenging a patent must prove facts supporting a determination of invalidity by clear and convincing evidence. Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed. Cir. 1984). Section 282 applies with full force to a § 102(g) defense, and thus a party asserting invalidity under § 102(g) must prove facts by clear and convincing evidence establishing a prior invention that was not abandoned, suppressed, or concealed. See Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., 973 F.2d 911, 915, 23 USPQ2d 1921, 1924 (Fed. Cir. 1992).

In Young v. Dworkin, one of our predecessor courts set forth the relevant burdens of proof governing a determination whether a prior invention was suppressed or concealed, in the context of an interference between co-pending applications, as follows:

> The sole remaining question is whether the board correctly held that junior party-appellant suppressed or concealed his invention within the meaning of 35 U.S.C. § 102(g). Here, the senior party-appellee bears the burden of proof by a preponderance of the evidence, notwithstanding junior party-appellant's burden on the issue of priority of invention which he has sustained.

Young v. Dworkin, 489 F.2d 1277, 1279, 180 USPQ 388, 390 (CCPA 1974) (citing Gallagher v. Smith, 206 F.2d 939, 99 USPQ 132 (CCPA 1953)). Thus, under § 102(g) interference law involving co-pending applications, once the first party to invent has established priority of invention, the second party to conceive and reduce

the invention to practice has the burden of proving that the first party suppressed or concealed the invention. In such an interference, the first party to invent does not bear any burden of proof regarding suppression or concealment once it has established an earlier date of invention.

A § 102(g) prior invention defense is governed by the identical "suppressed or concealed" language applicable to priority determinations in interference proceedings. 35 U.S.C. § 102(g). We must therefore interpret the § 102(g) defense provision consistently with established interference law. However, infringement actions implicating a § 102(g) defense differ from interferences in that a patent has been granted on the invention at issue, and therefore the presumption of validity under § 282 applies.[1] Because the patentee (analogous to the second-to-invent in the interference context) has the benefit of the presumption of validity, that party should only be held to bear a burden of producing evidence indicating that the prior inventor may have suppressed or concealed the invention once the challenger (analogous to the first-to-invent in the interference context) has

[1] Generally speaking, the presumption of validity does not apply to patents involved in interference proceedings, and thus the invalidity of a patent involved in an interference under § 102(g) need only be proven by preponderant evidence. See Bruning v. Hirose, 161 F.3d 681, 686, 48 USPQ2d 1934, 1938 (Fed. Cir. 1998) (holding that, in an interference involving a patent issued from an application that was co-pending with the interfering application, the appropriate standard of proof for validity challenges is the preponderance of the evidence standard because the presumption of validity is inapplicable). However, the presumption may effectively be implicated in the case of a priority contest between an issued patent and an application that was filed after the issuance of the patent. In such a situation, the junior party must establish priority of invention by clear and convincing evidence. Price v. Symsek, 988 F.2d 1187, 1194, 26 USPQ2d 1031, 1036 (Fed. Cir. 1993). Such a factual scenario is not before us.

established prior invention by clear and convincing evidence. That burden bears a rough similarity to placing the burden of proving suppression or concealment on the second-to-invent under interference law, but at the same time is appropriately limited to one of production, not persuasion, giving due regard to the presumption of validity.

We therefore interpret §102(g) as requiring that once a challenger of a patent has proven by clear and convincing evidence that "the invention was made in this country by another inventor," 35 U.S.C. § 102(g), the burden of production shifts to the patentee to produce evidence sufficient to create a genuine issue of material fact as to whether the prior inventor has suppressed or concealed the invention. However, in accordance with the statutory presumption in 35 U.S.C. §282, the ultimate burden of persuasion remains with the party challenging the validity of the patent. See Innovative Scuba Concepts, Inc. v. Feder Indus., Inc., 26 F.3d 1112, 1115, 31 USPQ2d 1132, 1134 (Fed. Cir. 1994) ("While a patentee may have the burden of going forward with rebuttal evidence once a challenger presented a prima facie case of invalidity, the presumption of validity remains intact and the ultimate burden of proving invalidity remains with the challenger throughout the litigation." (citing Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986))). Once the patentee has satisfied its burden of production, the party alleging invalidity under §102(g) must rebut any alleged suppression or concealment with clear and convincing evidence to the contrary.

Our case law distinguishes between two types of suppression or concealment. The first is implicated in a situation in which an inventor actively

suppresses or conceals his invention from the public. Fujikawa v. Wattanasin, 93 F.3d 1559, 1567, 39 USPQ2d 1895, 1901 (Fed. Cir. 1996) (citing Kendall v. Winsor, 62 U.S. (21 How.) 322, 328 (1858)). The second involves a legal inference of suppression or concealment based upon an unreasonable delay in filing a patent application.[2] Peeler v. Miller, 535 F.2d 647, 655, 190 USPQ 117, 122 (1976) (holding that a four-year delay in filing a patent application after the invention was perfected was unreasonably long); Shindelar v. Holdeman, 628 F.2d 1337, 1342, 207 USPQ 112, 116 (1980) (finding suppression or concealment because no reasonable explanation was given for the two-year and five-month delay between reduction to practice and the filing of a patent application). The latter type is involved here.

Although a prior inventor implicated in a § 102(g) infringement defense may not have filed a patent application, in contrast to an interference contestant, that party's delay in otherwise bringing the knowledge of the invention to the public may nevertheless raise a similar inference of suppression or concealment. See Int'l Glass Co. v. United States, 408 F.2d 395, 403, 159 USPQ 434, 441 (Ct. Cl. 1969) (holding that the prior invention of a process did not invalidate a patent on the same process under § 102(g) because the prior inventor did nothing to make the invention known to the public). Even though there is no explicit disclosure requirement in

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[2] A subset of the category of "inferred" suppression or concealment arises in a situation in which the first inventor is "spurred" into filing a patent application by another application, Mason v. Hepburn, 13 App.D.C. 86 (D.C. Cir. 1898), or by the commercial activity of another, Woofter v. Carlson, 367 F.2d 436, 445-446, 151 USPQ 407, 416 (CCPA 1967). This case does not involve "spurring."

§ 102(g), the spirit and policy of the patent laws encourage an inventor to take steps to ensure that "the public has gained knowledge of the invention which will insure its preservation in the public domain" or else run the risk of being dominated by the patent of another. Palmer v. Dudzik, 481 F.2d 1377, 1387, 178 USPQ 608, 616 (CCPA 1973); see also Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1446, 1453, 223 USPQ 603, 607, 614 (Fed. Cir. 1984) (defining § 102 "prior art" to be "technology already available to the public," and stating that "secret prior art" may not be used to invalidate a patent under § 102(g)); Oddzon Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396, 1402, 43 USPQ2d 1641, 1645 (Fed. Cir. 1997) ("[W]hen the possessor of secret prior art (art that has been abandoned, suppressed, or concealed) that predates the critical date is faced with a later-filed patent, the later-filed patent should not be invalidated in the face of this 'prior' art, which has not been made available to the public. Thus, prior, but non-public, inventors yield to later inventors who utilize the patent system."). Absent a satisfactory explanation for the delay or the presence of other mitigating facts, a prior invention will therefore be deemed suppressed or concealed within the meaning of § 102(g) "if, within a reasonable time after completion, no steps are taken to make the invention publicly known." Int'l Glass, 408 F.2d at 403, 161 USPQ at 441.

In the case at hand, we find that Apotex has satisfied its burden of producing evidence sufficient to create a genuine issue of material fact that Merck suppressed or concealed its process of manufacturing enalapril sodium tablets. We emphasize

at the outset that although § 102(g) prior art must be somehow made available to the public in order to defeat another patent, a § 102(g) prior inventor is under no obligation to file a patent application. Checkpoint Sys., Inc. v. United States Int'l Trade Comm'n, 54 F.3d 756, 763, 35 USPQ2d 1042, 1048 (Fed. Cir. 1995). Thus, while Merck's failure to file a patent application may be relevant to a determination whether it suppressed or concealed its process, especially if there were evidence that such failure was based on a decision to retain the invention as a trade secret, that failure alone does not satisfy the patentee's burden of producing evidence sufficient to create a genuine issue of material fact of suppression or concealment. See E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1437, 7 USPQ2d 1129, 1135 (Fed. Cir. 1988) (explaining that a patent application need not be filed on an invention for it to be considered § 102(g) prior art as long as the invention is found not to have been abandoned, suppressed, or concealed).

However, Apotex did allege that Merck failed to make its invention publicly known. Merck perfected its process and began commercially using the process to manufacture VASOTEC® tablets no later than 1983. Although Merck argues that its process was disclosed to the public because its VASOTEC® tablets could have been reverse-engineered, that argument is based on the admissions of Dr. Sherman, who drew upon the information provided in Merck's subsequent disclosures to determine the details of the process.[3] Thus, it appears that Merck

[3] It is worth noting that if it were clear that Merck's process could be reverse-engineered by one of ordinary skill through an inspection of VASOTEC® tablets, Apotex could not benefit from the inference of suppression or concealment because Merck could not be said to have delayed in making the benefits of its

took no steps to make the invention publicly known for nearly five years, when it first published the ingredients used in its process in the 1988 edition of the Dictionnaire Vidal. We find that such a delay raises an inference that Merck suppressed or concealed its invention. Accordingly, because Apotex has successfully discharged its burden of going forward with evidence creating a genuine issue of material fact of suppression or concealment, the burden shifts to Merck to rebut that showing by clear and convincing evidence to the contrary.

We conclude that Merck has succeeded in rebutting the inference of suppression or concealment created by its period of inactivity by clear and convincing evidence. In Paulik v. Rizkalla, we stated the rule that "the first inventor will not be barred from relying on later, resumed activity antedating an opponent's entry into the field, merely because the work done before the delay was sufficient to amount to a reduction to practice." 760 F.2d 1270, 1275, 226 USPQ 224, 228 (Fed. Cir. 1985) (holding that the inference of suppression or concealment from a four-year delay between reduction to practice and the filing of a patent application was overcome by the first inventor's resumption of activity before the second inventor's date of conception). Thus, even though Merck may have suppressed or concealed the process for a period of time after it reduced it to practice in 1983, as long as it "resumed activity" (i.e., made the benefits of its invention known to the

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invention known to the public. See Palmer, 481 F.2d at 1386-87, 178 USPQ at 615 (stating that a commercial use of an invention will preclude a finding of suppression or concealment only when such use enables the public to learn of the invention).

public) before Apotex's entry into the field, it cannot be deemed to have suppressed or concealed the invention within the meaning of § 102(g).

Merck made several disclosures following its period of suppression or concealment that made the invention publicly known, all of which took place before Apotex's entry into the field (here, Dr. Sherman's alleged œonception in April of 1994). First, Merck disclosed the ingredients used in manufacturing VASOTEC® tablets in the 1988 edition of the Dictionnaire Vidal. It also widely distributed the product monograph in Canada from October 1992 through 1994, which similarly disclosed the ingredients it used in its manufacturing process. Merck also provided a step-by-step description of the process through the testimony given by Brian McLeod at the Canadian trial on March 28, 1994.

Apotex argues that these disclosures inadequately described Merck's process of manufacturing VASOTEC® tablets, and therefore that the public never received the benefit of the invention. However, Dr. Sherman admitted both in his deposition in this case and in his 1994 Statement of Facts prepared for the Canadian trial that his inspection of the VASOTEC® tablets that Merck sold commercially revealed that they were made using a wet granulation process. He also admitted that, after learning of the disclosed starting ingredients from the Canadian product monograph (which included sodium bicarbonate), it "immediately occurred" to him and was "obvious to any knowledgeable formulator or chemist" that the final enalapril sodium product in the VASOTEC® tablets was the result of an acid-base chemical reaction between enalapril maleate and sodium bicarbonate in water. Merck's various disclosures, in conjunction with Apotex's admissions,

therefore clearly and convincingly prove that Merck made the knowledge of its invention available to the public, thereby satisfying its burden of rebutting Apotex's evidence of suppression or concealment.

Moreover, Apotex's argument that Merck suppressed or concealed the process by submitting misleading information to the FDA in 1983 is irrelevant because any suppression that was implicated was overcome by Merck's subsequent activity. We therefore conclude that the district court did not err in granting summary judgment that the '780 and '962 patents are invalid under § 102(g).

We have considered Apotex's remaining arguments and find them to be unpersuasive.

CONCLUSION

Because the district court did not err in granting summary judgment that the '780 and '962 patents are invalid under 35 U.S.C. § 102(g), we

AFFIRM.