United States Court of Appeals for the Federal Circuit

04-1191, -1192
(Interference No. 104,646)

GARY H. RASMUSSON and GLENN F. REYNOLDS,

Appellants,

v.

SMITHKLINE BEECHAM CORPORATION,

Cross Appellant.

Robert L. Baechtold, Fitzpatrick, Cella, Harper & Scinto, of New York, New York, argued for appellants. With him on the brief were Daniel S. Glueck and Stephen E. Belisle, of Washington, DC.

Herbert H. Mintz, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for cross appellant. With him on the brief was Lara C. Kelley.

Appealed from: United States Patent and Trademark Office, Board of Patent Appeals and Interferences

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Cross-Appellant.

DECIDED: June 27, 2005

Before BRYSON, Circuit Judge, PLAGER, Senior Circuit Judge, and PROST, Circuit Judge.

BRYSON, Circuit Judge.

This is an appeal from an interference proceeding before the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office ("PTO"). At issue in the interference proceeding were a set of claims from U.S. Patent Application Serial No. 08/460,296 ("the '296 application"), and another set of claims from U.S. Patent Nos. 5,637,310 ("the '310 patent") and 5,496,556 ("the '556 patent") and their corresponding reissue applications, U.S. Patent Application Serial Nos. 09/964,383 ("the '310 reissue patent application") and 09/984,083 ("the '556 reissue patent application"). Gary H. Rasmusson and Glenn F. Reynolds (collectively, "Rasmusson") are the inventors named on the '296 application. SmithKline Beecham

Corporation is the assignee of the ’310 and ’556 patents and the corresponding reissue patent applications. The Board of Patent Appeals and Interferences held that Rasmusson was not entitled to the benefit of a priority date based on certain previous applications and that Rasmusson could not defeat the priority date accorded to SmithKline’s patents and reissue applications. Because that decision is supported by substantial evidence and is not contrary to law, we affirm. The Board also held that SmithKline’s patents and reissue patent applications were not anticipated by a European patent application, EP No. 285383 (“EP ’383”). The Board based that ruling on its conclusion that EP ’383 was not enabled. We reverse that aspect of the Board’s decision and find that EP ’383 was enabled for purposes of anticipation. We therefore remand this case to the Board for a determination of the effect of that application on the claims of SmithKline’s patents and reissue patent applications and Rasmusson’s ’296 application.

I

A

This case relates to a method of treating a type of prostate cancer by administering a chemical compound called finasteride. Finasteride inhibits the production of an enzyme known as 5-α-reductase (“5αR”), which is responsible for converting the hormone testosterone to dihydrotestosterone (“DHT”). Both testosterone and DHT are in the class of hormones known as androgens, which bind to receptors on certain target cells and initiate a chain of biological events that are important in the expression of male sex characteristics. DHT is known to be a more potent androgen than testosterone, and high levels of DHT are associated with prostate cancer. As a

result, numerous attempts have been made to decrease DHT levels by seeking out inhibitors of the 5αR enzyme.

There are two main categories of 5αR inhibitors: "selective" (or "pure") and "multi-active." Multi-active inhibitors not only inhibit the 5αR enzyme, but also reduce the effects of testosterone by competing with testosterone for the same target receptor sites. Selective 5αR inhibitors decrease the level of DHT solely by inhibiting the production of the 5αR enzyme, thereby eliminating any side effects associated with blocking testosterone. The parties agree that finasteride acts as a selective 5αR inhibitor.

B

Rasmusson's '296 application was filed on June 2, 1995. It is the ninth in a series of applications stemming from U.S. Patent Application No. 07/034,808, which was filed on April 3, 1987. The '296 application is directed to "Methods of treating Prostatic Carcinoma with 17-Beta-N-monosubstituted-carbamoyl-4-aza-5α-androst-1-en-3-ones." SmithKline's '310 and '556 patents and the corresponding reissue applications were previously accorded the benefit of a filing date of another issued patent, U.S. Patent No. 5,300,294 ("the '294 patent"). That filing date is June 27, 1990. Those patents and their corresponding reissue applications cover a "Method of Treating Prostatic Adenocarcinoma by employing a steroid 5-α-reductase inhibiting compound or a combination of steroid 5-α-reductase inhibiting compounds."

On January 22, 2001, the PTO declared an interference between the claims of Rasmusson's '296 application and SmithKline's '310, '556, and '294 patents, although the Board later dismissed the '294 patent from the interference. Before the Board,

Rasmusson moved to have SmithKline's claims rejected, and SmithKline moved to deny Rasmusson the benefit of its eight earlier applications and to add claims to the interference from the reissue patent applications corresponding to the '310 and '556 patents.

After considering preliminary motions from both sides, the Board granted SmithKline's motion to deny Rasmusson the benefit of its eight earlier applications and to add the '310 and '556 reissue patent applications to the interference. The Board also granted Rasmusson's motion to hold the relevant claims from SmithKline's '310 and '556 patents invalid, but denied Rasmusson's motion to hold the claims of the '310 and '556 reissue patent applications invalid based on anticipation by the European counterpart to Rasmusson's first application.

As a result of its rulings on invalidity, the Board issued an Order Redeclaring Interference, which substituted a new count for the count previously declared in the interference.[1] The replacement count reads as follows:

> The method of claim 4 of the Rasmusson 08/460,296 application wherein the animal is human[;] or [t]he method of claim 3 of the [SmithKline] 09/964,383 application[;] or [t]he method of claim 2 of the [SmithKline] 09/984,083 application.

[1] The replacement count corresponds to claims 1-8 of the '296 patent, claim 1 of the '310 patent, claim 1 of the '556 patent, claims 1 and 3 of '310 reissue patent application, and claims 1 and 2 of the '556 reissue patent application. Because the Board held claim 1 of the '310 and claim 1 of the '556 patents to be invalid, and because claim 1 of the '310 reissue application and claim 1 of the '556 reissue application were based on those invalidated claims, the only SmithKline claims incorporated in the replacement count were claim 3 of the '310 reissue application and claim 2 of the '556 reissue application.

Claim 4 of Rasmusson's '296 application depends on claim 3, which, in turn, depends on claim 1. Taking the language of all three claims into account, the Board summarized claim 4 as follows:

> A method of treating prostatic carcinoma in animals including humans which comprises administering a therapeutically effective amount of the compound 17β-(N-tertbutylcarbamoyl)-4-aza-5α-androst-1-en-3-one.

The chemical compound recited in claim 4 is a formula for finasteride.

Claim 3 of SmithKline's '383 application reads as follows:

> A method of treating human prostatic adenocarcinoma which comprises administering to a subject in need thereof an oral dosage unit containing about 1 mg. to about 500 mg. of a steroid 5-α-reductase inhibiting compound from 1-6 times during a twenty four hour period.

Claim 2 of SmithKline's '083 application reads as follows:

> A method of treating human prostatic adenocarcinoma which comprises administering in a human subject in need thereof, a dosage unit containing about 0.1 mg/kg to about 100 mg/kg of 17β-(N-tertbutylcarboxamide)-5-α-androst-1-ene-4-aza-3-one from one to six times daily.

The chemical formula recited in claim 2 is a representation of finasteride.

After the Board issued its decision on the parties' preliminary motions and its Order Redeclaring Interference, Rasmusson requested reconsideration of the Board's motion decision. The Board reaffirmed its earlier decision. Rasmusson appeals from aspects of the Board's ruling; SmithKline has filed a conditional cross-appeal.

II

The June 27, 1990, filing date accorded to SmithKline's patents and reissue applications falls between the filing dates of Rasmusson's third and fourth applications. In order to overcome the June 27, 1990, filing date, Rasmusson therefore sought priority on the basis of his first, second, and third applications, which were filed on April

3, 1987; May 19, 1988; and June 21, 1989, respectively. The Board found that Rasmusson was not entitled to priority based on any of those filing dates because the corresponding applications failed to satisfy the written description and enablement requirements of 35 U.S.C. § 112.

With respect to enablement, the Board found that none of the applications filed before the ninth application "would have enabled a person of ordinary skill in the art as of each of the respective filing date[s] to treat human prostate cancer by administering a therapeutically effective amount of finasteride to a human in need thereof without undue experimentation." The Board based that finding on its determination that a person of ordinary skill in the art would have had no basis as of the filing date of the eighth application for believing that finasteride could be used to treat prostate cancer in light of the state of the art and in light of Rasmusson's failure to provide any data to demonstrate the effects of finasteride in treating prostate cancer.

On appeal, Rasmusson asserts that the specifications of the respective applications are enabling because a person of ordinary skill in the art could perform the steps of the disclosed method without the need for any experimentation. Rasmusson argues that the Board's finding regarding efficacy does not support its finding of lack of enablement. According to Rasmusson, efficacy is not relevant to enablement, but pertains only to the issue of utility under 35 U.S.C. § 101. Because the Board did not make a determination based on section 101, Rasmusson asserts that the Board erred.

We disagree. In order to satisfy the enablement requirement of section 112, an applicant must describe the manner of making and using the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make

and use the same . . . ." 35 U.S.C. § 112, para. 1. As this court has explained, "the how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention." In re Cortright, 165 F.3d 1353, 1356 (Fed. Cir. 1999), quoting In re Ziegler, 992 F.2d 1197, 1200 (Fed. Cir. 1993); see also In re Schoenwald, 964 F.2d 1122, 1124 (Fed. Cir. 1992) (stating that utility must be disclosed to satisfy the section 112 enablement requirement). In explaining what constitutes a sufficient showing of utility in the context of the enablement requirement, this court has stated that an applicant's failure to disclose how to use an invention may support a rejection under either section 112, paragraph 1 for lack of enablement, or "section 101 for lack of utility 'when there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention.'" Cortright, 165 F.3d at 1356, quoting Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 762 (Fed. Cir. 1984).

In the context of determining whether sufficient "utility as a drug, medicant, and the like in human therapy" has been alleged, "it is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the allegations as obviously correct." In re Jolles, 628 F.2d 1327, 1332 (Fed. Cir. 1980), citing In re Novak, 306 F.2d 924 (CCPA 1962); see Application of Irons, 340 F.2d 974, 977-78 (CCPA 1965). Indeed, in In re Brana, 51 F.3d 1560 (Fed. Cir. 1995), we stated that "a specification disclosure which contains a teaching of the manner and process of making and using the invention . . . must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support."

Id. at 1566, quoting Marzocchi, 439 F.2d 220, 223 (CCPA 1971); Fiers v. Revel, 984 F.2d 1164, 1171-72 (Fed. Cir. 1993), quoting Marzocchi, 439 F.2d at 223; see also Application of Armbruster, 512 F.2d 676, 677 (CCPA 1975); Application of Knowlton, 500 F.2d 566, 571 (CCPA 1974); Application of Bowen, 492 F.2d 859 (CCPA 1974); Application of Hawkins, 486 F.2d 569, 576 (CCPA 1973). However, where there is "no indication that one skilled in [the] art would accept without question statements [as to the effects of the claimed drug products] and no evidence has been presented to demonstrate that the claimed products do have those effects," an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement. Novak, 306 F.2d at 928.

In the applications at issue in this case, Rasmusson claimed a method of treating prostate cancer by using finasteride as a selective 5αR inhibitor. While both parties agree that a person of ordinary skill in the art at the time of Rasmusson's applications would have recognized that finasteride was a selective 5αR inhibitor, the parties disagree as to whether a person of ordinary skill in the art would have believed, before June 27, 1990, that finasteride would be effective in treating prostate cancer. Relying on articles demonstrating that various multi-active 5αR inhibitors were effective in treating prostate cancer, Rasmusson argues that a person of ordinary skill in the art at the time of his applications would have believed that administering a therapeutically effective amount of finasteride could be used for treating human prostate cancer. For that reason, Rasmusson asserts that he did not need to provide any data to demonstrate the efficacy of finasteride.

The Board found that a person of ordinary skill in the art would not have believed that finasteride was effective in treating prostate cancer simply because finasteride was known to be a selective 5αR inhibitor. That finding is supported by substantial evidence. Based on scientific articles and expert testimony from both parties, the Board found that a person of ordinary skill in the art as of August 10, 1993, the filing date of the eighth application, would not have concluded that a selective 5αR inhibitor would have any anti-tumor effects, because the anti-tumor effects shown by published experiments involving multi-active 5αR inhibitors could be attributable to contaminating activities having no relation to 5αR inhibition. In particular, the Board referred to articles and testimony to show that a person of ordinary skill in the art as of the filing date of the eighth application would not know that 5αR inhibition contributed to any anti-tumor effects, because it was not clear whether DHT or testosterone caused prostate cancer. If testosterone, and not DHT, caused the disease, then the anti-tumor effects resulting from multi-active 5αR inhibitors were not due to 5αR inhibition, but rather to anti-testosterone mechanisms such as the inhibition of testosterone receptor binding.

The Board referred to evidence pertinent to each of the relevant Rasmusson application filing dates, from the mid-1980s to the mid-1990s. In particular, the Board referred to a 1991 article by Dr. Glenn Gormley stating that "the concept that androgen-dependent prostate cancer is exclusively dependent on DHT and not testosterone has yet to be definitively established." Likewise, the Board referred to a 1992 article by Dr. Joseph Presti stating that "[w]hether prostatic cancer cells are dependent upon [DHT] rather than testosterone is not well defined." The Board concluded, however, that as of the filing date of the ninth application, June 2, 1995, a person of ordinary skill in the art

would have believed that 5αR inhibition could play a role in treating prostate cancer in light of a presentation made by Dr. Ruben Gittes at the American Urological Association in August 1994, in which he reported successful results from treating prostate cancer with finasteride. Therefore, the Board determined that Rasmusson could claim priority as of the filing date of his most recent continuation application, which is June 2, 1995. While Rasmusson submitted articles supporting the use of multi-active inhibitors for treating prostate cancer, the Board found that those articles were not sufficient, because Rasmusson was claiming that the efficacy of finasteride was based on 5αR inhibition, as opposed to other effects.

Rasmusson did not make any contrary showing that a person of ordinary skill in the art as of the filing date of the third application would have recognized that a selective 5αR inhibitor in general, or finasteride in particular, would be effective in treating prostate cancer. In particular, the evidence cited by Rasmusson on appeal does not contravene the Board's finding, because that evidence is either dated too late with respect to the respective filing dates of the applications or pertains only to the use of multi-active inhibitors to treat prostate cancer. In order to obtain a priority date earlier than June 27, 1990, Rasmusson needed to provide experimental proof that his invention could be effective in treating cancer. Because Rasmusson failed to do so and obtained a priority date only as of the filing date of his '296 application, the Board was correct to find that all applications prior to that application were not enabled, and that Rasmusson is not entitled to a priority date earlier than the priority date of SmithKline's '310 and '553 patents and the corresponding reissue applications.

Rasmusson argues that the enablement requirement of section 112 does not mandate a showing of utility or, if it does, it mandates only a showing that it is "not implausible" that the invention will work for its intended purpose. As we have explained, we have required a greater measure of proof, and for good reason. If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis. Because we have upheld the Board's determination of priority due to lack of enablement, it is unnecessary for us to address the Board's ruling regarding lack of adequate written description.

III

Rasmusson next argues that the pertinent claims of SmithKline's patents and reissue applications are invalid in light of the European application, EP '383.

In conjunction with filing his first application in the United States for finasteride, Rasmusson also filed EP '383. That application was published on October 5, 1988, between the filing dates of Rasmusson's second and third applications, and more than one year before the priority date assigned to SmithKline's patents and reissue patent applications. Before the Board, Rasmusson argued that EP '383 anticipated and rendered obvious all of SmithKline's claims at issue in this interference. The Board found, however, that EP '383 does not anticipate those claims because EP '383 lacks

an enabling disclosure inasmuch as it fails to demonstrate that finasteride is effective in treating prostate cancer. The Board also found that EP '383 does not render the claims of the SmithKline patents and reissue applications invalid for obviousness, because it provides no reasonable expectation of success for treating prostate cancer with a 5αR inhibitor.

A patent claim "cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051, 1054 (Fed. Cir. 2003). The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102, however, differs from the enablement standard under section 112. In In re Hafner, 410 F.2d 1403 (CCPA 1969), the court stated that "a disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or of how to use for such purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim." Id. at 1405; see Schoenwald, 964 F.2d at 1124; In re Samour, 571 F.2d 559, 563-64 (CCPA 1978). The reason is that section 112 "provides that the specification must enable one skilled in the art to 'use' the invention whereas [section] 102 makes no such requirement as to an anticipatory disclosure." Hafner, 410 F.2d at 1405; see 1 Donald S. Chisum, Chisum on Patents § 3.04[1][c] (2002); see also In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349-52 (Fed. Cir. 2001) (finding anticipation where applicant sought a patent based on a new use for a previously disclosed method).

Since Hafner, this court has continued to recognize that a prior art reference need not demonstrate utility in order to serve as an anticipating reference under section 102. See Schoenwald, 964 F.2d at 1124 ("it is beyond argument that no utility need be disclosed for a reference to be anticipatory of a claim"); In re Donohue, 632 F.2d 123, 126 n.6 (CCPA 1980) ("proof of utility is not a prerequisite to availability of a prior art reference under 35 U.S.C. § 102(b)"), citing In re Samour, 571 F.2d at 563-64; see also Application of Lukach, 442 F.2d 967, 969 (CCPA 1971) (recognizing that there are "anomalies between the requirements for claim-anticipating disclosures and for claim-supporting disclosures" and citing Hafner as an example).

The parties disagree about the significance of Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc., 246 F.3d 1368 (Fed. Cir. 2001), in which this court held that a scientific article anticipated claims to a method for treating cancer by administering a particular drug. SmithKline argues that the case merely stands for the proposition that a reference must be enabling in order to anticipate under 35 U.S.C. § 102. Rasmusson, however, asserts that the case stands for the broader proposition that proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation.

We agree with Rasmusson. In the Bristol-Myers Squibb case, the article and the patent disclosed the same method for administering the drug. The article, however, presented data purporting to show that the method was not effective in providing anti-tumor effects, while the patent contained data purporting to show the opposite. The court decided that the negative results reported in the article did not prevent the article from anticipating the patent given that "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent."

236 F.3d at 1376. The court explained that "a reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. Thus, the question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis." Id. at 1378., quoting Celeritas Techs., Ltd. v. Rockwell Int'l Group, 150 F.3d 1354, 1361 (Fed. Cir. 1998). The court added that "anticipation does not require actual performance of suggestions in a disclosure." 246 F.3d at 1379.

In this case, the Board found (1) that in light of the state of the art at the time of the publication of EP '383 in 1988, there was no reasonable scientific basis for a person of ordinary skill in the art to conclude that the claimed method would be effective in treating prostate cancer, and (2) that given the lack of proof provided in the publication itself, a person of ordinary skill in the art as of the publication date of EP '383 would not have believed that the method described in EP '383 would be effective. Under the legal standard set forth in Hafner and the cases that have followed it, those findings are insufficient to support the Board's conclusion that EP '383 is not an enabling reference for purposes of anticipation. Because the Board erred in ruling that EP '383 was not enabled for purposes of anticipation, we reverse the Board on that issue. Rasmusson argues that EP '383 discloses every limitation of SmithKline's claims at issue in the interference. SmithKline does not expressly challenge that contention, and Rasmusson accordingly urges us to rule that SmithKline's claims are anticipated. However, we consider that the preferable course is to allow the Board to resolve the anticipation question in the first instance. We therefore remand the case for the Board to rule on anticipation in light of our enablement decision. In light of our decision on anticipation,

we do not address Rasmusson's argument that the Board erred in finding that SmithKline's claims were not shown to have been obvious in light of EP '383.

IV

Our determination that EP '383 is an enabling reference has significant ramifications for Rasmusson's '296 patent application. Under section 102, an invention is not patentable if it was "described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). EP '383 was published on October 5, 1988, and we have determined that the '296 application is entitled to priority only as of June 2, 1995, the filing date of the ninth application. EP '383 was therefore published more than one year before that filing date. In view of the versions of the applications submitted to this court on appeal, EP '383 and the '296 application appear to share the same disclosure. We leave it to the Board, however, to make the factual determination of whether EP '383 and the '296 application disclose the same invention, and we therefore remand to the Board to determine whether EP '383 invalidates the '296 application under section 102(b). Finally, because we are upholding the Board's priority determination, we need not address SmithKline's conditional cross-appeal, in which SmithKline challenges the Board's denial of SmithKline's motion seeking to broaden the count in interference to include the use of selective 5αR inhibitors as a class.

Each party shall bear its own costs for this appeal.

AFFIRMED-IN-PART, REVERSED-IN-PART, and REMANDED.