NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

2008-1436

(Re-examination No. 90/007,785)

IN RE NATURES REMEDIES, LTD.

John J. Marshall, Drinker Biddle & Reath LLP, of Berwyn, Pennsylvania, argued for appellant. With him on the brief was Kathryn R. Doyle, of Philadelphia, Pennsylvania.

Robert J. McManus, Associate Solicitor, Office of the Solicitor, United States Patent and Trademark Office, of Arlington, Virginia, argued for the Director of the United States Patent and Trademark Office. With him on the brief was Shannon M. Hansen, Associate Solicitor. Of counsel was Raymond T. Chen, Solicitor.

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

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Appeal from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences.

DECIDED: March 12, 2009

Before MICHEL, Chief Judge, MAYER and DYK, Circuit Judges.

PER CURIAM.

Natures Remedies, Ltd. ("Remedies") appeals a decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office affirming the rejection of claim 2 of U.S. Patent No. 5,945,107 (the "'107 patent") as unpatentable under 35 U.S.C. § 102(b). We affirm.

I.

Remedies manufactures and distributes herbal products. In 1999, it obtained the '107 Patent, entitled "Compositions and Methods for Weight Reduction." Claim 2, as amended, provides:

> 2. A composition which produces weight loss in a patient comprising a combination of selected herbal extracts wherein said combination comprises at least one herbal extract capable of inhibiting gastric emptying and one herbal extract which increases metabolic rate in a patient, wherein the combination of selected herbal extracts comprises Guarana, Damiana and Paraguay.

The board affirmed the rejection of claim 2 as anticipated by a reference entitled "The Effect of Medi-Tab Capsules on the Ventricular Emptying Time" (the "Medi-Tab Application"). The Medi-Tab Application, which was submitted to the Scientific-Ethical Committee of Copenhagen in Denmark (the "Copenhagen Committee"), sought approval for clinical testing of Medi-Tab capsules on the emptying time of the human stomach, and was dated April 10, 1996, more than a year prior to the December 8, 1997, priority date of the '107 patent. Appendix I to the Medi-Tab Application states that Medi-Tab capsules contain three herbal extracts: Guarana, Damiana and (Yerbe) Maté, which is another term for the herb Paraguay.

In determining that claim 2 of the '107 patent was anticipated by the Medi-Tab Application, the board relied upon the declaration of Unna Scherer, who served as Secretary for the Copenhagen Committee. Scherer explained that the task of the Copenhagen Committee "is to ensure the protection of trial patients in biomedical clinical trials" and that all clinical trials were required to obtain committee approval prior to their start. Scherer further stated, based upon her "personal knowledge," that:

> 3. The Notification of the Scientific Ethical Committee for the project Effect of Medi-Tab Capsules on Gastric Emptying, with the attached Study Protocol and Project Description ("Notification and Study Protocol"), has been kept in the files of the Scientific Ethical Committee of Copenhagen County since 10 April 1996. . . .
>
> 4. As required by the Danish Open Files Act, the Notification and Study Protocol is a public record, and has been open to inspection by the

> public since 10 April 1996 in accordance with the rules in the Danish Open Files Act. . . .
>
> 5. The Scientific Ethical Committee of Copenhagen County maintains an index of the notifications of clinical trials that are submitted. The index is also open to inspection by the public. In April 1996, the Notification and Study Protocol was assigned reference no. KA 96085g, and listed in this index.

The board determined that the Scherer declaration was "impartial evidence" sufficient to establish a prima facie case that the Medi-Tab Application was "publically available" and therefore a "printed publication" under 35 U.S.C. § 102(b). In an effort to rebut this prima facie showing, Remedies submitted the declaration of Henrik B. Sanders, a Danish attorney. Sanders stated:

> The purpose of article 12(1), 2° in The Danish Open File Act is to prevent companies from suffering significant economical losses as a result of the right of access to documents. Since the formulation for the Slimming Product disclosed in the [Medi-Tab] Application would be regarded as information on technical plan or processes or on operation or business procedures or the like, the [Medi-Tab] Application is covered by the exception in article 12(1), 2° of The Danish Open File Act, and would not have been available to the public before the effective filing date of [the] U.S. Patent Application.

The board concluded that Sanders' declaration failed to establish that the Medi-Tab Application would have qualified for exemption from disclosure under Article 12(1) of the Danish Open Files Act. In order to be exempt from disclosure under that provision, information must be of such "material importance to the economy of the person or enterprise" that a request for access to the information will be refused. Sanders, however, failed to demonstrate that the information in the Medi-Tab Application was of "material importance" to Remedies' "economy." The board noted, moreover, that the Medi-Tab Application stated that the results of the Medi-Tab study would be "published in an international gastro-enterological medical publication," and

that this undercut Remedies' assertion that information in the application was intended to be kept confidential. Because it concluded that "the evidence of public accessibility . . . outweigh[ed] . . . evidence that [the Medi-Tab Application] would not have been accessible to the interested public," the board affirmed the examiner's rejection of claim 2 under 35 U.S.C. § 102(b).

Remedies then timely appealed to this court. We have jurisdiction under 28 U.S.C. § 1295 and 35 U.S.C. § 141.

II.

35 U.S.C. § 102 "serves as a limiting provision, both excluding ideas that are in the public domain from patent protection and confining the duration of the monopoly to the statutory term." Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 64 (1998). It provides that: "A person shall be entitled to a patent unless . . . the invention was patented or 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." This statutory "bar is grounded on the principle that once an invention is in the public domain, it is no longer patentable by anyone." SRI Int'l, Inc. v. Internet Sec. Sys., 511 F.3d 1186, 1194 (Fed. Cir. 2008) (citation and internal quotation marks omitted).

The parties do not dispute that the Medi-Tab Application teaches every element of claim 2. Nor do they dispute that it was submitted to the Copenhagen Committee on April 10, 1996, more than one year before the December 8, 1997, priority date of the '107 patent. Rather, the narrow issue on appeal is whether the Medi-Tab Application was accessible to the public and therefore a "printed publication" under 35 U.S.C. § 102(b).

"Accessibility goes to the issue of whether interested members of the relevant public could obtain the information if they wanted to." Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1568 (Fed. Cir. 1988). Thus, a reference will be deemed "publicly accessible" if it:

> has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation.

In re Wyer, 655 F.2d 221, 226 (C.C.P.A. 1981); see Bruckelmyer v. Ground Heaters, Inc., 445 F.3d 1374, 1378 (Fed. Cir. 2006).

As the board correctly determined, the declaration of Unna Scherer, the Secretary for the Copenhagen Committee, was sufficient to establish a prima facie case that the Medi-Tab Application was publicly accessible more than one year prior to the '107 patent's critical date. Scherer stated, based upon her "personal knowledge" that the Medi-Tab Application was a "public record" that had "been open to inspection by the public" since April 10, 1996 "in accordance with the rules in the Danish Open Files Act." The public accessibility of the Medi-Tab Application was further supported by the Copenhagen Committee's indexing protocol. Scherer explained that the Committee maintained "an index of the notifications of clinical trials" that was "open to inspection by the public" and asserted that the Medi-Tab Application had been listed in this index since April, 1996.

Because Scherer's declaration established a prima facie case of public availability, the onus was on Remedies to demonstrate that the Medi-Tab Application was not accessible to interested members of the public. Remedies, however, failed to

carry its burden. The only piece of evidence it submitted to demonstrate lack of accessibility was a declaration from Henrik Sanders, a Danish attorney. Sanders attempted to establish that the information in the Medi-Tab Application would have been exempt from disclosure under Article 12(1) of the Danish Open Files Act. That provision states:

> Exempt Information
>
> 12.-(1) The right of access to administration files shall not apply to . . . .
>
> 2° information on technical plant or processes or on operating or business procedures or the like, provided it is of material importance to the economy of the person or enterprise that grant of the request be refused.

Under Article 12(1), information is exempt from disclosure only if it is of "material importance" to a company's "economy." Sanders, however, did not establish that the information in the Medi-Tab Application was "of material importance" to Remedies' financial interests. Thus, as the board correctly concluded, his declaration was inadequate to demonstrate that the Medi-Tab Application would have been exempt from disclosure under Article 12(1).

On appeal, Remedies argues that the board misinterpreted the Sanders declaration. It contends that "[a]ny fair reading of the Sanders Declaration shows that he is offering his opinion that the [Copenhagen] Committee would have regarded the information on Remedies 'Slimming Product' to be of material importance, the disclosure of which could cause significant economic loss." Contrary to Remedies' assertions, however, the Sanders declaration says nothing about the economic importance to Remedies of the information contained in the Medi-Tab Application. Instead, the only mention of "economic loss" in the Sanders declaration is his statement

that the purpose of the Article 12(1) exemption was "to prevent companies from suffering significant economical losses as a result of the right of access to documents." The evidence of record simply does not establish that the disclosure of information contained in the Medi-Tab Application would have caused economic loss sufficient to warrant exemption from disclosure under Article 12(1).

Remedies also challenges the board's determination that the Scherer declaration was sufficient to establish a prima facie case of public accessibility. In Remedies' view, Scherer's declaration only describes the procedure for obtaining documents under the Danish Open Files Act, but does not establish "which, if any, of the contents of the [Medi-Tab Application] would have been made available to a requestor before the critical date." We agree with Remedies that the Scherer declaration could have been clearer and more comprehensive. Scherer did not discuss the Article 12(1) disclosure exemption, or indicate whether it might have been possible for Remedies to use this provision to block access to information regarding the formulation of the Medi-Tab capsules.

We must accept the board's factual determinations, however, if they are supported by substantial evidence. See Kyocera Wireless Corp. v. Int'l Trade Comm'n, 545 F.3d 1340, 1350 (Fed. Cir. 2008) (This court must accord "substantial evidence deference to the factual components of the determination" as to whether a reference qualifies as a printed publication under 35 U.S.C. § 102(b)). Scherer stated: (1) that the Medi-Tab application was a "public record," (2) that it "ha[d] been open to inspection by the public since 10 April 1996 in accordance with the rules in the Danish Open Files Act," and (3) that it was listed in an index of clinical trials which was "open to inspection

by the public." Given these explicit statements as to the public availability of the Medi-Tab Application, we conclude that substantial evidence supports the board's interpretation of the Scherer declaration as sufficient to establish a prima facie case of public accessibility. See Bruckelmyer, 445 F.3d at 1379 (concluding that a reference was publically available where it was "classified and indexed . . . providing the roadmap that would [allow] one skilled in the art to locate [it]"); In re Hall, 781 F.2d 897, 899-900 (Fed. Cir. 1986) (holding that a single catalogued thesis in a German university library was sufficiently accessible to the public).

The board's determination as to public accessibility, moreover, is supported by the fact that the Medi-Tab Application itself contains no restrictions on public dissemination. To the contrary, the application states the results of the study would be "published in an international gastro-enterological medical publication." Furthermore, the application indicates that volunteers participating in the study will be provided with the project number of the clinical trial notification—presumably so that they could access information about the study in the Copenhagen Committee's index. The fact that there is nothing in the Medi-Tab Application evidencing an intent to keep its contents confidential serves to buttress the board's determination that it was publically available prior to the '107 patent's critical date. See Mass. Inst. of Tech. v. AB Fortia, 774 F.2d 1104, 1109 (Fed. Cir. 1985) (concluding that a paper orally presented at a scientific meeting was publically accessible where written copies were distributed "without any restrictions" to those requesting them); Garrett Corp. v. United States, 422 F.2d 874, 878 (Ct. Cl. 1970) (distributing documents "without restriction on use" constitutes publication).

At oral argument, Remedies' counsel asserted that his client did not intend to disseminate information about the Medi-Tab study until after the study had been completed and "all patent obligations had been satisfied." Attorney argument, however, cannot take the place of record evidence. See In re Geisler, 116 F.3d 1465, 1470 (Fed. Cir. 1997); Johnston v. IVAC Corp., 885 F.2d 1574, 1581 (Fed. Cir. 1989). Here, the evidence of record does not establish that Remedies intended to keep the formulation of the Medi-Tab capsule confidential until after the study had been completed and a patent application had been filed.