

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK A/S)
and NOVO NORDISK)
PHARMACEUTICALS, INC.,)
)
Plaintiffs,)
)
v.) Civil Action No. 02-332-SLR
)
BIO-TECHNOLOGY GENERAL)
CORP., LTD. and TEVA)
PHARMACEUTICALS USA, INC.,)
)
Defendants.)

Frederick L. Cottrell, III, Esquire, of Richards, Layton & Finger, Wilmington, Delaware. Counsel for Plaintiffs. Of Counsel: Albert L. Jacobs, Jr., Esquire; Daniel A. Ladow, Esquire; Gerard F. Diebner, Esquire; Brad S. Needleman, Esquire; Joseph M. Manak, Esquire; and Elizabeth Lapadula, Esquire, of Greenberg Traurig, LLP, New York, New York.

Josy W. Ingersoll, Esquire of Young Conaway Stargatt & Taylor, LLP, Wilmington, Delaware. Counsel for Defendants. Of Counsel: Richard L. DeLucia, Esquire, Steven J. Lee, Esquire and Charles A. Weiss, Esquire of Kenyon & Kenyon, New York, New York.

MEMORANDUM OPINION

Dated: June 7, 2002
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

In this patent infringement suit, plaintiffs Novo Nordisk Pharmaceuticals, Inc. and Novo Nordisk A/S (collectively, "Novo") have accused defendants Bio-Technology General Corp. ("BTG") and Teva Pharmaceuticals USA, Inc. ("Teva") of infringing United States Patent No. 5,633,352 ("the '352 patent") through their activities involving Tev-Tropin™ brand human growth hormone ("hGH"). This court has jurisdiction over these proceedings pursuant to 28 U.S.C. § 1338(a). Presently pending before the court is Novo's motion for injunctive relief (D.I. 5), which has been fully briefed and heard by the court. For the reasons that follow, the court shall grant Novo's motion for a preliminary injunction.

II. STANDARD OF REVIEW

The standard of review governing the matter at bar is well known. A party seeking the extraordinary relief of a preliminary injunction has the burden to demonstrate: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest." Amazon.com, Inc. v. BarnesandNoble.com Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001). No one of these factors is dispositive; "rather, the district court must weigh and measure each factor against the other factors and against the

form and magnitude of the relief requested." Id. (citing Hybritech, Inc. v. Abbott Labs., 849 F.2d 1446, 1451 (Fed. Cir. 1988)). In order to prevail, a movant must establish the first two factors, i.e., likelihood of success on the merits and irreparable harm. To demonstrate a likelihood of success on the merits, the movant must show that, in light of the presumptions and burdens that will inhere at trial on the merits, (1) it will likely prove that its patent is infringed, and (2) any challenges to the validity and enforceability of its patent "lack[] substantial merit." Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1366 (Fed. Cir. 2001). "Irreparable harm is presumed when a clear showing of patent validity and infringement has been made." Amazon.com, 239 F.3d at 1350 (citing Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 708 (Fed. Cir. 1997)). In the absence of a presumption of irreparable harm, the court is directed to "consider, weigh, and balance all of the equitable circumstances" in order to determine whether monetary damages can sufficiently compensate the patent holder for infringement occurring during the course of the litigation. Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 683 (Fed. Cir. 1990). Therefore, the extent of a patentee's commercial activities (including its licensing practices) is one of many factors to consider in this equitable

undertaking. See High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1556-57 (Fed. Cir. 1995).

III. DISCUSSION

A. Likelihood of Success on the Merits

1. Infringement

"It is well settled that an infringement analysis involves two steps: the claim scope is first determined, and then the properly construed claim is compared with the accused device to determine whether all of the claim limitations are present either literally or by a substantial equivalent."

Amazon.com, 239 F.3d at 1351. The only claim at issue is claim 1 of the '352 patent:

Biosynthetic ripe human growth hormone free of contaminants from pituitary derived human growth hormone.

Consistent with the specification of the '352 patent, "biosynthetic" requires that the human growth hormone be made by recombinant DNA techniques, and "ripe" indicates that it has the 191 amino acid sequence identical to that of the hormone produced by the human pituitary gland, as well as the full biological activity of the human pituitary gland. ('352 patent, col. 1, lns. 20-25, 30-36; col. 5, lns. 36-38; see also D.I. 30, Ex. 4 at 2-4)

The accused product, Tev-Tropin™, is described in product literature as "a polypeptide of recombinant DNA origin

[that] has 191 amino acid residues. . . . It has an amino acid sequence identical to that of human growth hormone of pituitary origin." (D.I. 39, Ex. 3 at 20; see also D.I. 36, Ex. FF) Defendants' expert, Dr. Wajnrajch, admitted that Tev-Tropin™ is 191 amino acid hGH, and is free of contaminants from pituitary derived human growth hormone. (D.I. 41, Ex. 1 at 81) Defendants have produced no persuasive evidence in response to the above. The court concludes, therefore, that Novo has carried its burden to demonstrate its likely success in proving that Tev-Tropin™ infringes claim 1 of the '352 patent.

2. Validity

Defendants contend that claim 1 of the '352 patent is anticipated by "several different prior art Genentech patents," including United States Patent Nos. 4,601,980 ("the '980 patent"), 4,755,465 ("the '465 patent"), and 4,859,600 ("the '600 patent"). The court has reviewed the cited references, the prosecution history of the '352 patent, and the Federal Circuit's decisions in Bio-Technology General v. Genentech, Inc., 267 F.3d 1325 (Fed. Cir. 2001) and other relevant litigation.¹ The court finds that defendants' challenge to the validity of the '352 patent lacks substantial merit. First, all of the references

¹Bio-Technology General, Inc. v. Genentech, Inc., 80 F.3d 1553 (Fed. Cir. 1996); Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361 (Fed. Cir. 1997); Novo Nordisk of North Am., Inc. v. Genentech, Inc., 77 F.3d 1364 (Fed. Cir. 1996).

cited by defendants have been considered by the PTO during the prosecution and reexamination of the '352 patent. (See D.I. 9, Exs. 2, 5) The Federal Circuit's decision in Bio-Technology General v. Genentech, Inc. does not demonstrate, as argued by BTG, that the '980 patent is enabled, but only that BTG failed to carry its burden to prove by clear and convincing evidence that the '980 patent is not enabled. See 267 F.3d at 1331-32. Finally, although the court declines to reach the issue of judicial estoppel in the context of this preliminary injunction proceeding, the fact that BTG initiated an interference in order to take claim 1 of the '352 patent from Novo tends to support the fact that claim 1 is valid over the prior art.²

B. Irreparable Harm

Having concluded that a clear showing of patent validity and infringement has been made by Novo, irreparable harm is presumed. The court rejects defendants' argument the Novo's licensing history rebuts the presumption. As stated above, the extent of a patentee's commercial activities is a factor to consider in determining whether money damages will suffice to

²The Manual of Patent Examining Procedure, ¶ 2306, provides that "[a]n interference may be declared between an applicant and a patent if the application and patent are claiming the **same patentable subject matter**" (D.I. 30, Ex. 5) Section 1.606 of Title 37 of the Code of Federal Regulations provides that "[a]ll claims in the application and patent which define the **same patentable invention** as a count shall be designated to correspond to the count." (Id.)

make the patentee whole. Nevertheless, the court finds that the circumstances of this case weigh in favor of an injunction. Specifically, Novo has licensed research-based competitors, all of whom were already on the market, in connection with settling infringement litigation; Novo has not issued licenses in the ordinary course of business. Defendants have failed to present any other evidence sufficient to rebut the presumption of irreparable harm.

C. Public Interest

Although the court is not persuaded that patients will be harmed physically if compelled to change brands of human growth hormone due to litigation, there is no reason to question the evidence demonstrating that compliance problems among patients on growth hormone therapy are reduced by a stable treatment regimen. Therefore, the court finds that the public interest factor weighs in favor (albeit not to a significant degree) of an injunction.

D. Balance of the Equities

Given the history of litigation between the competitors in the hGH market (indeed, the prior litigation between the parties to these proceedings), defendants were well aware of the risks of market entry. The fact that defendants chose to go forward and incurred expenses in that endeavor does not compel a

finding that defendants are entitled to market a likely infringing product in the face of a valid patent.

IV. CONCLUSION

For the reasons stated above, the court finds that plaintiffs are entitled to injunctive relief.

An appropriate order shall issue.

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BIO-TECHNOLOGY GENERAL)	
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O R D E R

At Wilmington this 7th day of June, 2002, for the reasons stated in the memorandum opinion issued this same date,

IT IS ORDERED that plaintiffs' motion for a preliminary injunction (D.I. 5) is granted.

Sue L. Robinson
United States District Judge