

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NOVOZYMES A/S, )  
 )  
 Plaintiff, )  
 )  
 v. ) Civil Action No. 05-160-KAJ  
 )  
 GENENCOR INTERNATIONAL, INC. and )  
 ENZYME DEVELOPMENT CORPORATION, )  
 )  
 Defendants. )

**MEMORANDUM ORDER**

**I. INTRODUCTION**

Plaintiff, Novozymes A/S ("Novozyymes"), brought this patent infringement suit against defendants, Genencor International, Inc. ("Genencor") and Enzyme Development Corporation ("EDC"). Subject matter jurisdiction is proper under 28 U.S.C. § 1338. The patent-in-suit, U.S. Patent No. 6,867,031 (the "'031 patent"), was issued on March 15, 2005 and is entitled "Amylase Variants." (Docket Item ["D.I."] 1, Ex. A.) The named inventors of the '031 patent are Henrik Bisgård-Frantzen, Allan Svendsen, and Torben Vedel Borchert; Novozymes is the sole assignee. (*Id.*)

On June 22, 2005, Novozymes filed a motion for a preliminary injunction to halt the sales of Genencor's allegedly infringing product. (D.I. 16; the "Motion".) Having reviewed the parties' submissions and heard the parties at oral argument, I conclude that Genencor and EDC have raised a substantial question concerning the validity of the '031 patent. Therefore, Novozymes has not carried its burden of showing a

likelihood of success on the merits, and its motion for a preliminary injunction must be denied.

## II. BACKGROUND<sup>1</sup>

Novozymes and Genencor sell enzymes used in industrial processes. (D.I. 17 at 1; D.I. 40 at 3.) The '031 patent claims variant  $\alpha$ -amylases, which are enzymes that, among other things, are useful in the conversion of starch to fuel ethanol. (See D.I. 17 at 1; D.I. 40 at 3-4.) Due to the requirements of the relevant industrial processes,  $\alpha$ -amylases capable of maintaining activity at high temperatures are desirable. (See D.I. 17 at 5; D.I. 40 at 4.) Claims 1 and 3 of the '031 patent, which are asserted here, relate to variant  $\alpha$ -amylases which are thermostable (i.e., able to withstand high temperatures). (D.I. 1 at Ex. A, col. 4, lines 1-3.) The thermostability is achieved by deleting two specific amino acid residues from the  $\alpha$ -amylase.<sup>2</sup>

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<sup>1</sup>The following background information is drawn from the parties' submissions and does not constitute findings of fact.

<sup>2</sup>Claim 1 reads as follows:

A variant of a parent *Bacillus stearothermophilus* alpha-amylase, wherein the variant has an amino acid sequence which has at least 95% homology to the parent *Bacillus stearothermophilus* alpha-amylase and comprises a deletion of amino acids 179 and 180, using SEQ ID NO:3 for numbering, and wherein the variant has alpha-amylase activity.  
'031 patent, col. 65, lines 11-17.

Claim 3 reads as follows:

A variant alpha-amylase, wherein the variant has at least 95% homology to SEQ ID NO:3 and comprises a deletion of amino acids 179 and 180, using SEQ ID NO:3 for numbering and wherein the variant has alpha-amylase activity.  
*Id.* at col. 65, line 21-col. 66, line 12.

In April 2004, Genencor began selling a product that is now accused of infringing the '031 patent. (D.I. 46 at 1514.) EDC is a distributor of the accused product. (*Id.*)

In support of its motion for a preliminary injunction, Novozymes contends that it has shown a likelihood of success on the merits because the accused product literally infringes the '031 patent and the '031 patent is valid and enforceable. Novozymes also asserts that irreparable harm to its business will result if Genecor and EDC continue to sell the accused product, and that the balance of hardships and harm to the public interest support the grant of preliminary relief. (D.I. 17, D.I. 59.) Genencor and EDC argue that the accused product does not infringe the '031 patent, that claims 1 and 3 are invalid and unenforceable, that Novozymes has failed to make a sufficient showing of irreparable harm, and that the balance of hardships and public interest weigh in their favor. (D.I. 40.)

### **III. STANDARD OF REVIEW**

A preliminary injunction is “a drastic and extraordinary remedy that is not to be routinely granted.” *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993). As the moving party, Novozymes is entitled to a preliminary injunction only if it shows the following: (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) (citing *Reebok Int’l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994)). “The burden is always on the movant to show entitlement to a preliminary injunction.” *Reebok*, 32 F.3d at 1555.

#### IV. DISCUSSION

To carry its burden of showing a likelihood of success on the merits, Novozymes must show that, “in light of the presumptions and burdens that will inhere at trial on the merits,” Novozymes will likely prove that the defendants infringe the ‘031 patent, and that the ‘031 patent will likely withstand the defendants’ challenges to validity and enforcement. *Amazon.com*, 239 F.3d at 1350. If the defendants raise “a substantial question concerning either infringement or validity, i.e., assert[] an infringement or invalidity defense that the patentee cannot prove lacks substantial merit, the preliminary injunction should not issue.” *Id.* at 1350-51 (internal quotations omitted). In particular, since the moving party bears the burden of showing entitlement to a preliminary injunction, “[v]alidity challenges during preliminary injunction proceedings can be successful . . . on evidence that would not suffice to support a judgment of invalidity at trial.” *Id.* at 1358. “Vulnerability is the issue at the preliminary injunction stage . . . [and] [t]he showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself.” *Id.* at 1359.

Here, the defendants have successfully raised a substantial question as to invalidity. They argue that the asserted claims of the ‘031 patent are obvious in light of a prior art reference not disclosed to the patent examiner, the Machius reference (D.I. 44 at 804-805M). During prosecution, the examiner decided there was prima facie obviousness based on the Suzuki reference (D.I. 45 at 980-85), which taught that deleting two amino acid residues from a particular  $\alpha$ -amylase would increase thermostability, and the Bisgård-Frantzen reference (D.I. 44 at 666-771), which taught

that the *B. stearothermophilus*  $\alpha$ -amylase was homologous to the  $\alpha$ -amylase studied in Suzuki. The examiner concluded that these two references showed that making the claimed deletion in the *B. stearothermophilus*  $\alpha$ -amylase would be expected to increase thermostability, thus making the claims obvious. (D.I. 45 at 950.) Novozymes overcame this obviousness rejection by claiming that the deletion achieved unexpected results. (D.I. 18 at Ex. H, ¶¶8-9.)

The examiner, however, never considered the Machius reference, which contains the following additional information. First, the reference discloses the three-dimensional structure of an  $\alpha$ -amylase, and, based on a sequence alignment in the context of secondary structure information revealed by the new three-dimensional structure (D.I. 44, 805J), the reference states that the three-dimensional structure of the *B. stearothermophilus*  $\alpha$ -amylase “can be expected to be very similar” to the  $\alpha$ -amylase structure disclosed in the reference (*id.* at 805H). Second, the reference discloses that the Suzuki deletion was located in a loop region and that having two extra residues there “could cause increased mobility of this region and a decreased thermostability of the whole protein.” (*Id.*) By showing the location of the Suzuki deletion and predicting the structural similarity of the relevant  $\alpha$ -amylases, the Machius reference raises a substantial question concerning the nonobviousness of claims 1 and 3.<sup>3</sup> While a trial

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<sup>3</sup>After preliminary review, it appears that, contrary to Novozymes’s argument, the Machius reference does not teach away from the claimed invention. While the reference concedes that the reasons for the increased thermostability in Suzuki “cannot be completely judged by our study,” and that “[n]one of the above mentioned theories is able to explain satisfactorily the enhanced thermostability,” (D.I. 44, 805H), these statements only reflect an incomplete theoretical understanding of why the deletions cause increased thermostability.

may eventually show that this evidence is not sufficient to prove obviousness by clear and convincing evidence, it suffices to show vulnerability. Novozymes has thus failed to carry the burden of showing that the defendants' validity challenge lacks substantial merit and, as a consequence, has failed to show a reasonable likelihood of success on the merits. *Amazon.com*, 239 F.3d at 1350.

Since that critical factor has not been established, I need not consider the other three factors associated with the granting of preliminary injunctive relief. See *Reebok*, at 1556 (“[T]he district court may deny a preliminary injunction based on the movant’s failure to establish either of [the first] two crucial factors without making additional findings respecting the other factors.”); *New England Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882-84 (Fed. Cir. 1992) (affirming the denial of a preliminary injunction based on a failure to show a likelihood of success on the merits, even though no findings were made concerning irreparable harm).

**V. CONCLUSION**

Accordingly, it is hereby ORDERED that the Motion for a Preliminary Injunction is DENIED.

  
UNITED STATES DISTRICT JUDGE

October 24, 2005  
Wilmington, Delaware