

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA**

DANISCO US INC.)	
)	CASE NO. 1:12-cv-85
Plaintiff,)	
)	
v.)	
)	COMPLAINT FOR
NOVOZYMES A/S, and)	DECLARATORY JUDGMENT OF
NOVOZYMES NORTH AMERICA, INC.,)	NON-INFRINGEMENT,
)	INVALIDITY AND PRIORITY OF
Defendants.)	INVENTION

Danisco US Inc. (“Danisco”) for its Complaint against Novozymes A/S and Novozymes North America, Inc. (collectively “Novozymes”), on knowledge as to itself and its own actions, and on information and belief as to all other matters, alleges the following:

INTRODUCTION

1. Danisco seeks a declaratory judgment that its Rapid Starch Liquefaction alpha-amylase products (“the RSL Products”) do not infringe Novozymes’s U.S. Patent No. 8,252,573 (“Novozymes’s New Patent”).¹ Alternatively, Danisco seeks a determination under 35 U.S.C. § 291 that Danisco’s U.S. Patent No. 8,084,240 (“Danisco’s Patent”), attached hereto as Exhibit 2, has priority over Defendant Novozymes’s New Patent, which claims interfering subject matter. Danisco also seeks a declaratory judgment that Novozymes’s New Patent is invalid under 35 U.S.C. §§ 101, 102, 103 and/or 112.

¹Novozymes New Patent No. 8,252,573 issued from United States Patent Application Serial Number 13/020,545, on August 28, 2012, at 12:01 a.m., Eastern time, as shown on the Issue Notification attached as Exhibit 1. A copy of the issued patent was not available at the time this complaint was filed.

THE PARTIES

2. Danisco is a Delaware corporation having a principal place of business at 925 Page Mill Road, Palo Alto, CA 94304.

3. Danisco manufactures and sells food ingredients and enzyme products, including alpha-amylases, in this District and elsewhere throughout the United States.

4. Alpha-amylases are a type of enzyme and are used in the production of ethanol from corn and other plant-based sources. Danisco sells a number of alpha-amylase products, including its RSL Products. The RSL Products consist of Spezyme® CL, Spezyme® CL WB, Spezyme® RSL, and Spezyme® RSL WB. Spezyme® RSL has been on sale in the United States since at least June 2010. Danisco's RSL products are primarily made in and sold from this District.

5. On information and belief, Novozymes A/S ("Novozymes A/S") is a Danish corporation with its principal place of business at Krogshoejvej 36, DK-2880 Bagsvaerd, Denmark.

6. On information and belief, Novozymes North America, Inc. ("Novozymes N.A.") is a 100%-owned subsidiary of Novozymes A/S, and a New York Corporation with its principal place of business at 77 Perry Chapel Church Road, Franklinton, North Carolina.

7. On information and belief, Novozymes N.A. is the North American Division of Novozymes A/S, with its principal place of business at 77 Perry Chapel Church Road, Franklinton, North Carolina.

8. Novozymes A/S and Novozymes NA are collectively referred to herein as "Novozymes."

9. On information and belief, Novozymes exercises a high degree of control over its United States divisions and subsidiaries, including those doing business in Iowa. Novozymes has published the statement that all of its strategy is led by Denmark.² On information and belief, all of Novozymes's divisions and subsidiaries' Intellectual Property strategy is led by Novozymes A/S in Denmark.

10. On information and belief, the structure of Novozymes A/S is divided into five areas by function, rather than by entity, region, or country,³ and Novozymes A/S provides consolidated financial reports that integrate the financial performance of its related entities, including divisions and subsidiaries, including Novozymes N.A. This structure and financial reporting system further reflects that Novozymes A/S in Denmark functions together with its related divisions and subsidiaries, including Novozymes N.A., to operate in concert and for a common purpose, including to do so in Iowa.

11. Novozymes A/S, directly and through its divisions and subsidiaries, such as Novozymes N.A., develops and sells enzyme products, including alpha-amylases, in direct competition with Danisco in the United States and abroad, including to customers in Iowa, and otherwise maintains continuous and systematic contacts with Iowa, such that the exercise of jurisdiction over Novozymes A/S and Novozymes N.A. would not offend traditional notions of fair play and substantial justice.

12. On information and belief, Novozymes has several sales and technical service personnel located in Iowa, including Cam Fowler, Mitchell Marine, and Zackery Hall.⁴

² See *Novozymes A/S v. Genencor Intern., Inc.*, 474 F.Supp.2d 592, 603 (D. Del. 2007).

³ See <http://www.novozymes.com/en/about-us/organization/Pages/The-Novozymes-structure-.aspx> (last visited August 27, 2012).

⁴ See <http://www.linkedin.com/pub/cam-fowler/7/a56/364>; <http://www.linkedin.com/pub/mitchell-marine/7/ab8/1a5>; <http://www.linkedin.com/pub/zackery-hall/7/9a3/44b> (last visited August 27, 2012).

13. On information and belief, Novozymes has its Customer Solutions Office and Lab in Ames, Iowa, which was started to support fuel ethanol customers, including those in Iowa, in 2007.⁵ Novozymes published a statement that “[t]he focus of the site [is] to provide regionally-based know-how and services to Novozymes’s customer base in the Midwest, with an emphasis on support and training to plants using enzyme products to convert starches into fuel ethanol.”⁶ At issue in this declaratory judgment action are enzyme products referred to as liquefaction amylases. Liquefaction amylases are a type of enzyme used in the conversion of starches into fuel ethanol.

14. On information and belief, Novozymes’s total sales in Iowa exceeded \$50 million in 2011. Additionally, on information and belief, Novozymes’s sales of liquefaction amylases exceeded \$15 million in 2011 in Iowa alone.

15. On information and belief, Novozymes supplies the enzymes for a \$25 million facility in Blairstown, Iowa for the production of fuel from municipal waste. Novozymes has published a statement on this supply, through Adam Monroe.⁷ On information and belief, Adam Monroe acts as both a Regional Vice President of Novozymes A/S and as the President of Novozymes North America.

JURISDICTION AND VENUE

16. This is an action for declaratory judgment pursuant to 28 U.S.C. §§ 2201(a) and 2202. The action arises under the patent laws of the United States.

17. This Court has subject matter jurisdiction over Danisco’s claims under 28 U.S.C. §§ 1331 and 1338(a), 28 U.S.C. § 2201 and 35 U.S.C. § 291.

⁵ See <http://www.novozymes.com/en/Pages/worldwide.aspx> (last visited August 27, 2012).

⁶ See <http://www.novozymes.com/en/news/news-archive/Pages/42982.aspx> (last visited August 27, 2012).

⁷ See <http://www.novozymes.com/en/news-archive/Pages/Novozymes-partner-Fiberight-to-build-commercial-scale-plant-in-US.aspx> (last visited August 27, 2012).

18. Venue is proper in this District pursuant to 28 U.S.C. §1391 and 35 U.S.C. § 291.

BACKGROUND

Danisco's Patent

19. Danisco's Patent is entitled "*Geobacillus Stearotherophilus* Alpha-Amylase (AMYS) Variants With Improved Properties." The United States Patent and Trademark Office ("USPTO") awarded Danisco the patent on December 27, 2011. Danisco's Patent lists William A. Cuevas, Sang Kyu Lee, Sandra W. Ramer, Andrew Shaw, Amr R. Topozada, David E. Estell, and Sura H. Hadi (collectively "Danisco's named inventors") as its inventors. Danisco is the assignee of Danisco's Patent.

20. The Danisco Patent claims priority to U.S. Provisional Patent Application No. 61/059,423, which was filed on June 6, 2008.

21. The only claim of Danisco's Patent is directed to "an isolated variant" of a truncated *Geobacillus stearotherophilus* (also known as *Bacillus stearotherophilus*) alpha amylase enzyme, at least 99% identical to the parent amino acid sequence (SEQ ID NO: 2), containing a substitution of glutamic acid for proline at position 188, and "exhibiting increased viscosity reduction in a starch liquefaction assay" compared to the parental enzyme. The USPTO issued a notice of allowance for this claim on October 20, 2011.

22. Each of the RSL Products contains a genetically modified variant alpha amylase that includes an amino acid substitution, from glutamic acid to proline, at position 188 of the truncated alpha amylase identified by "SEQ ID NO: 2" in Danisco's Patent.

Novozymes's New Patent

23. Novozymes's New Patent issued at 12:01 a.m. Eastern time, August 28, 2012, to named inventors Allan Svendsen, Carsten Anderson, Thomas Thisted, and Claus Von der Osten

(collectively “Novozymes’s named inventors”). It is entitled “Alpha-Amylase Variant With Altered Properties.” Novozymes A/S is listed on the face of Novozymes’s New Patent as the assignee.

24. On information and belief, and consistent with past practice, Novozymes North America has obtained all substantial rights in Novozymes’s New Patent, either by license, assignment, or similar agreement.

25. Novozymes’s New Patent issued from Application No. 13/020,545 (“the ’545 Application”), which was filed on February 3, 2011. The ’545 Application claims priority to several other applications, the earliest of which is U.S. Provisional Patent Application No. 60/296,631, filed on June 7, 2001.

26. The only claim of Novozymes’s New Patent is directed to “an isolated variant polypeptide having alpha amylase activity,” the variant “having at least 99% amino acid sequence identity to the parental” full-length *Geobacillus stearothermophilus* amino acid sequence identified as SEQ ID NO: 6, and containing a substitution of glutamic acid for proline at position 188.

27. The claim that issued in Novozymes’s New Patent was added by amendment to the ’545 Application on November 11, 2011. Prior to that date, neither the ’545 Application, nor any of the other applications to which Novozymes’s New Patent claims priority, included a claim requiring a mutation at position 188 in a *Geobacillus stearothermophilus* alpha-amylase enzyme amino acid sequence.

28. During prosecution of Novozymes’s New Patent, Novozymes asserted to the USPTO that then-pending claim 1 of Danisco’s U.S. Patent Application No. 12/447,028 (which later issued as Danisco’s Patent) and the claim that has now issued in Novozymes’s New Patent

were directed to interfering subject matter. In other words, Novozymes contended that Novozymes's New Patent covers the same invention as Danisco's Patent. Specifically, Novozymes asserted that the claim in Novozymes's New Patent encompassed the same alpha-amylase variant recited by Danisco's Patent claim.

29. The USPTO, however, declined to declare an interference. Rather, the USPTO determined that the parties' claims were not directed to the same subject matter. In particular, the Examiner stated that the truncated *Geobacillus stearothermophilus* alpha-amylase variant in Danisco's claim "does not fall within the scope of the genus of variants [in Novozymes's claim]" because it does not meet the "at least 99% amino acid sequence identity to the parental polypeptide of SEQ ID NO: 6" limitation. *See* Notice of Allowance for '545 Application, dated Dec. 21, 2011, at 5 (emphasis in original), attached hereto as Exhibit 3.

30. Following the USPTO's decision to not declare an interference, Novozymes filed a Request for Continuing Examination. Novozymes then asserted that the Examiner had "mistakenly concluded" that the truncated *Geobacillus stearothermophilus* alpha-amylase variant in Danisco's claim did not fall within the scope of Novozymes's then-pending claim, because the Examiner had not correctly interpreted the percent identity limitation in Novozymes's claim. *See* Comments on Statement of Reasons for Allowance, dated March 27, 2012, at 2, attached hereto as Exhibit 4.

31. In response, the USPTO again rejected Novozymes's assertions. In particular, the Examiner stated that the calculation of percent identity in Novozymes's claim "require[s] taking into consideration the length of the reference sequence, which in this case is SEQ ID NO: 6. Otherwise, recitation of a reference sequence (in this case SEQ ID NO: 6) would be meaningless." As a result, the Examiner determined, for a second time, that the truncated

Geobacillus stearothermophilus alpha-amylase variant in Danisco's claim "does not fall within the scope of the genus of variants [in Novozymes's claim]." See Notice of Allowance for the '545 Application, dated June 28, 2012, at 4 (emphasis in original), attached hereto as Exhibit 5.

The Events Giving Rise to this Suit

32. As stated above, Novozymes repeatedly told the USPTO that Novozymes's New Patent claim encompasses the variant in Danisco's Patent. On information and belief, Novozymes's decision to pursue this claim was based on Novozymes's belief that Danisco's RSL Products would infringe the claim in Novozymes's New Patent once that claim was issued.

33. Novozymes is the world's largest producer of alpha amylase enzymes; Danisco is its primary competitor in what is largely a two-competitor market. Novozymes has sued Danisco, or its predecessors, for infringement of different alpha-amylase patents on three prior and separate occasions. Two of the suits were filed on the same day that the asserted patents issued. The most recent example of this is a suit filed by Novozymes against Danisco in May 2010, which concluded with the invalidation of the Novozymes patent asserted in that case. Novozymes is currently appealing that ruling.

34. Novozymes has previously amended patent applications, like the one leading to Novozymes's New Patent, to add new claims specifically calculated to encompass alpha-amylase products that Danisco itself invented, and that were already being manufactured and sold by Danisco to customers in the United States. On information and belief, the only *Geobacillus stearothermophilus* alpha-amylase enzymes with a mutation at position 188 that are on the market are the patented RSL products invented, developed and sold by Danisco.

35. Now that Novozymes's New Patent has issued, and based on Novozymes's past actions, Danisco has a reasonable apprehension that Novozymes will assert Novozymes's New

Patent against Danisco claiming infringement based on Danisco's manufacture and sale of the RSL Products, and will seek to substantially deprive customers the choice of a competitive alpha amylase enzyme

CLAIMS FOR RELIEF

**Count 1
Declaratory Judgment of Non-Infringement**

36. Danisco incorporates by reference and repeats the allegations in paragraphs 1-35 above.

37. The alpha-amylase variant in Danisco's RSL Products does not infringe the claim in Novozymes's New Patent.

38. An actual and justiciable controversy exists between Danisco and Novozymes as to whether Novozymes's New Patent is infringed by Danisco's RSL Products. As a result, there exists a substantial controversy between Novozymes and Danisco, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

39. Pursuant to 28 U.S.C. § 2201, Danisco requests a declaration of the Court that Danisco has not and does not currently infringe, either directly, indirectly, literally or under the doctrine of equivalents, the claim of Novozymes's New Patent.

**Count 2
Declaratory Judgment of Invalidity**

40. Danisco incorporates by reference and repeats the allegations in paragraphs 1-39 above.

41. Novozymes's New Patent relates to isolated variants of parent alpha-amylases.

42. The specification of Novozymes's New Patent, and the applications to which it claims priority, states that possible parent alpha-amylases include SEQ ID NOS: 2 (SP690), 4

(SP722), 6 (*Bacillus stearothermophilus*), 8 (*Bacillus licheniformis*), 10 (*Bacillus amyloliquefaciens*), 12 (AA560) and 13 (#707). The specification further states that alpha-amylases which display at least 60% homology to any of those amino acid sequences, as well as hybrid alpha-amylases including combinations of parts of those sequences, may also be parent alpha-amylases.

43. The specification of Novozymes's New Patent, and the applications to which it claims priority, lists over 450 different amino acid positions, using the numbering in SEQ ID NO: 8, as possible positions in a parent alpha-amylase to alter.

44. The specification of Novozymes's New Patent, and the applications to which it claims priority, does not identify or otherwise suggest to one of skill in the art that making alterations at position 188 in SEQ ID NO: 6, is any more or less likely to result in a useful variant than making alterations at any of the other more than 450 positions listed therein.

45. Additional research, beyond the disclosure in the specification of Novozymes's New Patent, and the applications to which it claims priority, is required to identify useful variants from among the possible variants contemplated in that specification.

46. The specification of Novozymes's New Patent, and the applications to which it claims priority, do not contain a single example involving a mutation of glutamic acid to proline at position 188 in SEQ ID NO: 6.

47. The specification of Novozymes's New Patent, and the applications to which it claims priority, do not contain a single example involving a *Geobacillus sterothermophilus* alpha-amylase enzyme.

48. The claim in Novozymes's New Patent fails to meet the requirements of 35 U.S.C. § 112, first paragraph. Neither Novozymes's New Patent, nor any of the patent

applications to which it claims priority, contains a written description that adequately describes an isolated variant of a *Geobacillus stearothermophilus* alpha-amylase enzyme having alpha amylase activity, containing a mutation of glutamic acid to proline at position 188. Nor does that specification enable a person of ordinary skill in the art to make and use such a variant without undue experimentation. Likewise that specification does not disclose the utility of making the claimed variant as opposed to any one of the trillions upon trillions of possible variants that could be made from introducing alterations at one or more of the over 450 listed positions.

49. As stated above, the first time Novozymes filed a claim specifically directed to an isolated variant of a *Geobacillus stearothermophilus* alpha-amylase enzyme containing a substitution of proline (abbreviated “P”) for glutamic acid (abbreviated “E”) at position 188 was on November 11, 2011, well after such a variant was invented, made, used and sold by Danisco.

50. The patent application leading to Danisco’s Patent discloses such an alpha-amylase variant and was published almost two years before November 11, 2011.

51. The alpha-amylase variant included in the RSL Products has been on sale in the United States since at least June 2010, more than a year before November 11, 2011.

52. On information and belief, Novozymes did not seek a claim directed to an isolated variant of a *Geobacillus stearothermophilus* alpha-amylase enzyme containing a substitution of proline for glutamic acid at position 188 until after it learned that the USPTO had issued a notice of allowance for Danisco’s Patent.

53. In addition, the claim in Novozymes’s New Patent is invalid because it fails to meet the requirements of 35 U.S.C. § 112, paragraph 2. For example, the term “an amino acid sequence having at least 99% amino acid sequence identity to the parental polypeptide of SEQ

ID NO: 6” is indefinite in light of the specification and prosecution history of Novozymes’s New Patent.

54. Moreover, the claim in Novozymes’s New Patent is invalid under 35 U.S.C. §§ 102 and/or 103 in light of at least the following prior art references: Gregory L. Gray et al., *Structural Genes Encoding the Thermophilic α -Amylases of Bacillus stearothermophilus and Bacillus licheniformis*, 166 J. BACTERIOLOGY 635 (1986) and U.S. Pat. No. 7,432,099.

55. The claim in Novozymes’s New Patent is also invalid under 35 U.S.C. § 102 because it does not reflect the proper inventors of the claimed invention, the invention claimed was first invented by another, and the inventors that are listed derived the invention from others.

56. Based on the above facts, Novozymes’s New Patent is invalid under 35 U.S.C §§ 101, 102, 103, and 112.

57. An actual and justiciable controversy exists between Danisco and Novozymes concerning the validity of Novozymes’s New Patent. As a result, there exists a substantial controversy between Novozymes and Danisco, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

58. Pursuant to 28 U.S.C. § 2201, Danisco requests a declaration that the claim in Novozymes’s New Patent is invalid because it fails to satisfy one or more of the conditions for patentability specified in 35 U.S.C. §§ 101, 102, 103 and/or 112.

Count 3

Determination of Priority of Invention under 35 § U.S.C. 291

59. Danisco incorporates by reference and repeats the allegations in paragraphs 1-58 above.

60. As stated above, the USPTO concluded that the claim in Novozymes’s New Patent does not encompass a truncated *Geobacillus stearothermophilus* alpha-amylase variant as

claimed in Danisco's Patent and found in Danisco's RSL products. Accordingly, Danisco's RSL products do not infringe Novozymes's New Patent.

61. Alternatively, if the claim in Novozymes's New Patent claim is construed to encompass the truncated *Geobacillus stearothermophilus* alpha amylase enzyme claimed in the Danisco's Patent, there is an interference-in-fact between the claims of Danisco's Patent and Novozymes's New Patent because each parties' respective claim anticipates and/or renders obvious the other.

62. Danisco's Patent claim has priority over the claim in Novozymes's New Patent. Danisco's named inventors conceived of and reduced to practice the invention claimed in the Danisco Patent at least by June 2, 2009.

63. Prior to June 2, 2009, Novozymes's named inventors had not conceived of, nor reduced to practice, either actually or constructively, the invention claimed in Novozymes's New Patent.

64. Accordingly, if the claim in Novozymes's New Patent is construed to encompass the truncated *Geobacillus stearothermophilus* alpha amylase enzyme claimed in Danisco's Patent, Danisco's Patent and Novozyme's New Patent are interfering patents, and Danisco seeks an adjudication that Danisco's Patent has priority, and therefore that Novozymes's New Patent is invalid, pursuant to 35 U.S.C. § 291, as well as 35 U.S.C. § 102.

PRAYER FOR RELIEF

Wherefore, Danisco respectfully requests that the Court enter judgment as follows:

- a) That Danisco has not infringed and is not infringing, either directly, indirectly, literally or under the doctrine of equivalents, any valid claim of Novozyme's New Patent;

- b) That the claim of Novozymes's New Patent is invalid;
- c) That Danisco is the prevailing party and that this is an exceptional case under 35 U.S.C. § 285 and awarding Danisco its reasonable attorneys' fees, expenses, and costs in this action;
- d) An award of priority of invention of the interfering subject matter between the Danisco Patent and Novozymes's New Patent to Danisco; and
- e) Such other and further relief as the Court may deem appropriate.

Dated: August 27, 2012

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