UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

MOMENTA PHARMACEUTICALS, INC. and SANDOZ INC., Plaintiffs,	)	
v.	)	Civil Action No. Jury Trial Demanded
TEVA PHARMACEUTICALS INDUSTRIES LTD and TEVA PHARMACEUTICALS USA, INC., Defendants.	)	

COMPLAINT

INTRODUCTION

Plaintiffs Momenta Pharmaceuticals, Inc. ("Momenta") and Sandoz Inc. ("Sandoz"), bring this action for patent infringement and declaratory judgment against defendants Teva Pharmaceuticals Industries, Ltd and Teva Pharmaceuticals USA, Inc. (collectively, "Teva"). Plaintiffs seek judgment that certain methods used by the defendants when making an enoxaparin drug product have infringed and/or will infringe United States Patent Nos. 7,575,886 (the "'886 patent") and 7,790,466 (the "'466 patent").

PARTIES

1. Plaintiff Momenta is a Delaware corporation with a principal place of business at 675 West Kendall Street, Cambridge, Massachusetts 02142. Momenta is a bio-technology company specializing in the identification, design, and evaluation of complex drugs and biologics.

2. Plaintiff Sandoz is a Colorado corporation with a principal place of business at 506 Carnegie Center, Princeton, New Jersey 08540. Sandoz is engaged in the business of, *inter alia*, developing, manufacturing and selling generic drug products and biologics.

3. On information and belief, defendant Teva Pharmaceuticals Industries, Ltd is a Israeli corporation with a principal place of business at 5 Basel St., Petach Tikva 49131, Israel.

4. On information and belief, defendant Teva Pharmaceuticals USA, Inc., is a Delaware corporation with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva Pharmaceuticals USA, Inc., is a wholly-owned subsidiary of Teva Pharmaceuticals Industries, Ltd.

5. Teva is in the business of developing and manufacturing pharmaceutical drug products and biologics and selling them in the United States and throughout the world.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action, pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, because it arises under the patent laws of the United States and the Federal Declaratory Judgment Act.

7. This Court has personal jurisdiction over the defendants because the defendants (a) knowingly transact a large volume of business in Massachusetts, (b) on information and belief, have engaged in, and made meaningful preparations to engage in, infringing conduct in Massachusetts, and (c) have caused, and are causing, injury to the plaintiffs in Massachusetts.

8. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), (d) and 1400(b), because the defendants transact a large volume of business in this District and, on information and belief, have committed, or made meaningful preparations to commit, acts of infringement in this District.

THE MOMENTA PATENTS

9. On August 18, 2009, the United States Patent and Trademark Office (the "PTO") lawfully issued the '886 patent, entitled "Analysis of Sulfated Polysaccharides." A true copy of the '886 patent is attached hereto as **Exhibit A**.

10. Momenta is the assignee and owner of the '886 patent, which generally relates to the identification of a structural signature of a low molecular weight heparin known as "enoxaparin sodium."

11. Sandoz is an exclusive licensee under the '886 patent.

12. On September 7, 2010, the PTO lawfully issued the '466 patent, entitled "Evaluating Mixtures of Low Molecular Weight Heparins By Chain Profiles Or Chain Mapping." A true copy of the '466 patent is attached hereto as **Exhibit B**.

13. Momenta is the assignee and owner of the '466 patent, which relates to methods of processing an enoxaparin preparation using chain sequencing methods to determine the presence of certain defined carbohydrate structures in defined ranges.

14. Sandoz is an exclusive licensee under the '466 patent.

MOMENTA AND SANDOZ'S GENERIC ENOXAPARIN PRODUCT

15. On August 26, 2005, Momenta entered into a collaboration and licensing agreement with Sandoz to develop a generic version of enoxaparin sodium. That collaboration led to the filing of ANDA No. 77-857, by which Sandoz sought FDA approval to market enoxaparin sodium in the United States.

16. One of the key hurdles in developing a generic enoxaparin product was finding a way to manufacture enoxaparin that matched the unique structural profile of the branded enoxaparin drug product which is known by the trade name "Lovenox®." To solve this problem,

Momenta developed novel methods of processing an enoxaparin preparation that would match the structural profile of Lovenox®.

17. On July 23, 2010, the FDA approved the ANDA allowing Sandoz to market the first generic enoxaparin sodium product.

18. The claims of the '886 patent are directed to, *inter alia*, methods "for analyzing an enoxaparin sample for the presence or amount of a non naturally occurring sugar associated with peak 9 of FIG. 1 [of the '886 patent] that results from a method of making enoxaparin that included β-eliminative cleavage with a benzyl ester and depolymerization." The "non naturally occurring sugar associated with peak 9 of FIG. 1" is a 1,6-anhydro derivative structure.

19. In order to sell a generic enoxaparin sodium product, a generic manufacturer, like Teva, must determine as part of its manufacturing process, that 1,6-anhydro derivative structures are present in each batch of enoxaparin sodium that it produces.

20. The claims of the '466 patent are directed to, *inter alia*, methods of processing an enoxaparin preparation by determining that one or more defined tetrasaccharide sequences is present in a defined relative amount.

21. In order to sell a generic enoxaparin sodium product, a generic manufacturer, like Teva must include, as part of its manufacturing process, a method for determining that the tetrasaccharide chains in each batch of enoxaparin sodium have certain defined chain sequences in particular relative amounts.

TEVA'S INFRINGING CONDUCT

22. On information and belief, Teva intends to market imminently an enoxaparin product in the United States. In order to manufacture commercial quantities of generic

enoxaparin in preparation for launch, Teva has engaged in, and/or is engaging in, activities that infringed, or are infringing, the claims of the '886 and '466 patents.

23. In accordance with its announced plans to market a generic enoxaparin product in the United States, Teva filed an ANDA and amendments thereto with the FDA.

24. Teva has stated that it intends, and is prepared, to sell its enoxaparin immediately following FDA approval. In February 2010, the President and CEO of Teva North America Pharmaceuticals, Bill Marth, stated: "[A]ll I can say is that when that approval [of generic enoxaparin] comes, we'll be ready." A true copy of Teva's Q4 2009 Earnings Conference Transcript, dated February 16, 2010, is attached hereto as **Exhibit C**.

25. In May 2010, Teva stated its belief that FDA approval of its enoxaparin product would occur shortly thereafter. Teva's President and CEO, Shlomo Yanai, stated: "Again you know, all the questioning we get from the FDA leads us to be fairly confident that [approval] will come .... We're just hopeful that it comes soon as we see the questioning. It just leads us to believe that it is that we're far down the path." A true copy of Teva's Q1 2010 Earnings Call, dated May 4, 2010, is attached hereto as **Exhibit D**.

26. On July 23, 2010, the day that the FDA approved Sandoz and Momenta's generic enoxaparin sodium for commercial sale, Teva announced that "[it] believes it has demonstrated to the FDA that its version of generic Lovenox® meets their criteria and that Teva's pending ANDA is approvable." A true copy of Teva's press release, dated July 23, 2010, is attached hereto as **Exhibit E**. Later, in July 2010, Teva's Mr. Marth stated: "As far as launch quantities with respect to enoxaparin, the answer is yes we're in good shape. So we just will need the approval ...." A true copy of Teva's Q2 2010 Earnings Conference Transcript, dated July 27, 2010, is attached hereto as **Exhibit F**.

27. In August 2010, Teva stated its belief that its enoxaparin product would be approved by the FDA. Teva's Research and Development Officer, Benzion Weiner, stated to Israel's Calcalist financial newspaper: "We are waiting to receive the approval soon and the chances of receiving it is high." A true copy of the article entitled, "Teva Copy of Lovenox® May Be Close," Reuters, dated August 5, 2010, is attached hereto as **Exhibit G**.

28. During an earnings call held on November 2, 2010, Teva's President and CEO, Mr. Yanai, reported that during a recent meeting with the FDA "we confirmed that our version of generic Lovenox® meets the FDA's criteria to demonstrate chemical sameness." On the same call, Teva's Mr. Marth stated that Teva is "still hopeful" that it will obtain FDA approval this year. A true copy of Teva's Q3 2010 Earnings Conference Transcript, dated November 2, 2010, is attached hereto as **Exhibit H**.

29. On information and belief, in order for Teva to have had a reasonable basis for its statements that it believes that the FDA will approve its manufacture of generic enoxaparin, Teva has included in its manufacturing process for each batch of enoxaparin sodium that it has prepared, and will prepare, for commercial sale:

(a) a method for determining that its oligosaccharides contain the 1,6-anhydro derivative. The use of such a method infringes the '886 patent; and

(b) a method for determining the presence, in the tetrasaccharide chains of its enoxaparin, of particular chain sequences in particular relative amounts that infringes the '466 patent.

30. On information and belief, in order to be prepared for immediate commercial launch in the United States, Teva has manufactured and/or is in the process of manufacturing commercial quantities of generic enoxaparin sodium using the methods claimed in the '886 and '466 patents.

COUNT I
(Infringement of U.S. Patent No. 7,575,886)

31. Plaintiffs re-allege, and incorporate herein by reference, the allegations of Paragraph 1-30 of this Complaint as if fully set forth herein.

32. Teva has infringed, and continues to infringe, or has induced others to infringe, the '886 patent, either literally or under the doctrine of equivalents, by, *inter alia*, manufacturing generic enoxaparin for commercial sale using the methods claimed in the '886 patent and offering those products for sale in the United States.

33. Teva has not obtained a license to use the methods claimed in the '886 patent or to offer for sale in the United States products made by that process.

34. Unless Teva is preliminarily and permanently enjoined by this Court from offering to sell, and selling, its generic enoxaparin product made using methods that infringe the '886 patent, Momenta and Sandoz will be substantially and irreparably harmed by Teva's infringing conduct.

35. Upon information and belief, Teva's direct or indirect infringement of the '886 patent has been, and continues to be, willful, deliberate, and objectively reckless. Teva's conduct provides a basis for this Court to award enhanced damages pursuant to 35 U.S.C. § 284, and makes this an exceptional case within the meaning of 35 U.S.C. § 285.

COUNT II
(Infringement of U.S. Patent No. 7,790,466)

36. Plaintiffs re-allege, and incorporate herein by reference, the allegations of Paragraph 1-35 of this Complaint as if fully set forth herein.

37. Teva has infringed, and continues to infringe, or has induced others to infringe, the '466 patent, either literally or under the doctrine of equivalents, by, *inter alia*, manufacturing

generic enoxaparin for commercial sale using the methods claimed in the '466 patent and offering those products for sale in the United States.

38. Teva has not obtained a license to use the methods claimed in the '466 patent or to offer for sale in the United States products made by that process.

39. Unless Teva is preliminarily and permanently enjoined by this Court from offering to sell, and selling, its generic enoxaparin product made using methods that infringe the '466 patent, Momenta and Sandoz will be substantially and irreparably harmed by Teva's infringing conduct.

40. Upon information and belief, Teva's direct or indirect infringement of the '466 patent has been, and continues to be, willful, deliberate, and objectively reckless. Teva's conduct provides a basis for this Court to award enhanced damages pursuant to 35 U.S.C. § 284 and makes this an exceptional case within the meaning of 35 U.S.C. § 285.

COUNT III
(Declaratory Judgment of Infringement of the '886 Patent)

41. Plaintiffs re-allege, and incorporate herein by reference, the allegations of Paragraphs 1-40 of this Complaint as if fully set forth herein.

42. An actual and justiciable controversy of sufficient immediacy exists between Momenta and Sandoz, on the one hand, and Teva, on the other, as to whether Teva's activities regarding the manufacture of a generic enoxaparin product for commercial sale in the United States infringes, or will infringe, the '886 patent.

43. Teva has made meaningful preparations to infringe the '866 patent, including the development of a manufacturing process that infringes one or more claims of the '886 patent and the making of material preparations for the commercial launch of a generic enoxaparin product that has been, and will be, manufactured using methods that infringe the '866 patent.

44. Teva has not obtained a license to use the methods claimed in the '886 patent.

45. Unless Teva is preliminarily and permanently enjoined by this Court from offering for sale or selling its generic enoxaparin product that has been made using methods that infringe the '886 patent, Momenta and Sandoz will be substantially and irreparably harmed by Teva's conduct.

COUNT IV
(Declaratory Judgment of Infringement of the '466 Patent)

46. Plaintiffs re-allege, and incorporate herein by reference, the allegations of Paragraphs 1-45 of this Complaint as if fully set forth herein.

47. An actual and justiciable controversy of sufficient immediacy exists between Momenta and Sandoz, on the one hand, and Teva, on the other, as to whether Teva's activities regarding the manufacture of a generic enoxaparin product for commercial sale in the United States infringes, or will infringe, the '466 patent.

48. Teva has made meaningful preparations to infringe the '466 patent, including the development of a manufacturing process that infringes one or more claims of the '466 patent and the making of material preparations for the commercial launch of a generic enoxaparin product that has been, and will be, manufactured using methods that infringe the '466 patent.

49. Teva has not obtained a license to use the methods claimed in the '466 patent.

50. Unless Teva is preliminarily and permanently enjoined by this Court from offering for sale or selling its generic enoxaparin product that has been made using methods that infringe the '466 patent, Momenta and Sandoz will be substantially and irreparably harmed by Teva's conduct.

PRAYER FOR RELIEF

WHEREFORE, the plaintiffs respectfully request:

(a) That the Court determine that Teva has infringed, is infringing, or will infringe, one or more claims of United States Patent No. 7,575,886;

(b) That the Court determine that Teva has infringed, is infringing, or will infringe, one or more claims of United States Patent No. 7,790,466;

(c) That the Court enter a preliminary injunction restraining Teva, its officers, agents, attorneys, servants, employees, and all persons in active concert or participation with them, from selling, offering to sell, or importing into the United States an enoxaparin product made using a method that infringes one or more claims of either United States Patent No. 7,575,886 or U.S. Patent No. 7,790,466;

(d) That the Court enter a permanent injunction precluding Teva, its officers, agents, attorneys, servants, employees, and all persons in active concert or participation with them, from selling, offering to sell, or importing into the United States an enoxaparin product made using a method that infringes one or more claims of either United States Patent No. 7,575,886 or U.S. Patent No. 7,790,466;

(e) That the Court determine the amount of damage caused to Momenta and Sandoz by Teva's infringing conduct and enter judgment for Momenta and Sandoz in the amount of their damages, plus interest and the costs of this action;

(f) That the Court determine that Teva's infringement has been willful and deliberate and award up to treble damages to Momenta and Sandoz pursuant to 35 U.S.C. § 284;

(g) That the Court determine that this case is exceptional, within the meaning of 35 U.S.C. § 285, and order Teva to pay plaintiffs' reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

(h) That the Court grant such other and further relief as it deems appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38, the plaintiffs hereby respectfully request a jury trial on all issues triable of right by a jury.

MOMENTA PHARMACEUTICALS, INC.,

By their attorneys,

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Dated: December 2, 2010

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and that paper copies will be sent to those non-registered participants (if any) on December 2, 2010.

/s/ Michael E. Murawski