UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

MOMENTA PHARMACEUTICALS, INC. and SANDOZ INC., Plaintiffs, v. AMPHASTAR PHARMACEUTICALS, INC., INTERNATIONAL MEDICATION SYSTEMS, LTD., WATSON PHARMACEUTICALS, INC., and WATSON PHARMA, INC. Defendants.	Civil Action No. 11-11681 Jury Trial Demanded

AMENDED COMPLAINT

INTRODUCTION

Plaintiffs Momenta Pharmaceuticals, Inc. ("Momenta") and Sandoz Inc. ("Sandoz"), bring this action for patent infringement and declaratory judgment against defendants Amphastar Pharmaceuticals, Inc. ("Amphastar"), International Medication Systems, Ltd. ("IMS"), Watson Pharmaceuticals, Inc. ("Watson") and Watson Pharma, Inc. ("Watson Pharma") (collectively, "Defendants"). Plaintiffs seek judgment that certain methods used by Amphastar and IMS when making an enoxaparin drug product and the sale of that product by Amphastar, Watson and Watson Pharma 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 Amphastar is a Delaware corporation with a principal place of business at 11570 Sixth Street, Rancho Cucamonga, California 91730. Amphastar has two wholly-owned manufacturing subsidiaries: (1) defendant IMS, whose manufacturing facilities are located in South El Monte, California; and (2) Armstrong Pharmaceuticals, whose manufacturing facilities and employees are located in West Roxbury and Canton, Massachusetts.

4. On information and belief, defendant IMS is a Delaware corporation with a principal place of business at 11570 Sixth Street, Rancho Cucamonga, California 91730. On information and belief, IMS is a wholly-owned subsidiary of defendant Amphastar.

5. On information and belief: (i) defendant Watson is a Nevada corporation with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054; and (ii) defendant Watson Pharma, which is a subsidiary of Watson, is a Delaware corporation with a principal place of business also at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Watson Pharma's registered agent in Massachusetts is CT Corporation System, 155 Federal Street Suite 700, Boston, Massachusetts 02110.

6. On information and belief, Amphastar is in the business of developing and manufacturing specialty and generic pharmaceutical products and selling them in the United States, including in this district, and throughout the world.

7. On information and belief, IMS is in the business of manufacturing sterile injectable pharmaceutical products for sale in the United States, including this district, and throughout the world.

8. On information and belief, Watson and Watson Pharma are in the business of developing and manufacturing generic, brand, and biologic pharmaceutical products and selling those products in the United States, including in this district, and throughout the world.

JURISDICTION AND VENUE

9. 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 Declaratory Judgment Act.

10. 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 in Massachusetts by reason of their conduct within and outside of the Commonwealth.

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because (a) this Court has personal jurisdiction over Defendants and (b) on information and belief, Defendants have committed, or made meaningful preparations to commit, acts of infringement in this District.

THE MOMENTA PATENTS

12. 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**.

13. 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."

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

15. 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**.

16. 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, or the presence and relative amount of, certain defined oligosaccharide structures.

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

MOMENTA AND SANDOZ'S GENERIC ENOXAPARIN PRODUCT

18. 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 approval from the U.S. Food and Drug Administration ("FDA") to market enoxaparin sodium in the United States.

19. One of the key hurdles in developing a generic enoxaparin product was finding a way to manufacture an 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®.

20. On July 23, 2010, the FDA approved the ANDA and allowed Sandoz to market the first generic enoxaparin sodium product.

21. 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 sugar that includes a 1,6-anhydro ring structure.

22. The FDA requires a generic manufacturer to include in its manufacturing process the analysis of each batch of its enoxaparin drug substance to confirm that its manufacturing process results in the production of oligosaccharides that include defined relative amounts of a non-naturally occurring sugar that includes a 1,6-anhydro ring structure. Accordingly, in order to sell a generic enoxaparin sodium product, generic manufacturers, like defendants Amphastar and IMS, must determine as part of their manufacturing processes, that sugars including 1,6-anhydro ring structures are present in defined relative amounts in each batch of enoxaparin sodium that they produce.

23. 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 or is present in a defined relative amount.

24. The FDA requires a generic manufacturer to include in its manufacturing process the analysis of each batch of its enoxaparin drug substance to confirm that its generic enoxaparin

has a distribution of oligosaccharide chain lengths equivalent to that of Lovenox® and that, within the subset of shorter chain oligosaccharides (including tetrasaccharides), its generic enoxaparin has a distribution of chain sequences that is the equivalent to that of Lovenox®. Accordingly, in order to sell a generic enoxaparin sodium product, generic manufacturers, like defendants Amphastar and IMS, must include, as part of their manufacturing processes, a method for determining that the tetrasaccharide chains in each batch of enoxaparin sodium have certain defined chain sequences in particular relative amounts.

DEFENDANTS' INFRINGING CONDUCT

25. On September 19, 2011, Watson announced in a press release that the FDA has approved Amphastar's ANDA for its generic enoxaparin product. A true copy of Watson Pharmaceuticals, Inc.'s September 19, 2011 Press Release entitled "Watson Pharmaceuticals Announces Approval of Amphastar's Generic Lovenox®" is attached hereto as **Exhibit C**.

26. In its press release, Watson stated that "Amphastar is currently preparing for launch and anticipates launching its Enoxaparin Sodium Injection product in the fourth quarter of 2011" and that Watson would be selling that product to retail pharmacies throughout the United States. *See* **Exhibit C**, Watson Press Release.

27. On information and belief, in order for the FDA to have approved Defendants' manufacture of generic enoxaparin, defendants Amphastar and IMS will have included in their process for manufacturing batches of enoxaparin sodium for commercial sale:

(a) a method for determining that a defined percentage of the oligosaccharide chains that make up enoxaparin include, at their reducing ends, a non-naturally occurring sugar that includes a 1,6-anhydro ring structure, which method infringes the '886 patent; and

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

28. On information and belief, in order to be prepared to launch their generic enoxaparin product in the fourth quarter of 2011, Amphastar and IMS have manufactured, and/or are in the process of manufacturing, commercial quantities of generic enoxaparin sodium using the methods claimed in the '886 and '466 patents.

29. By offering for sale or selling Amphastar's generic enoxaparin, Amphastar, Watson and Watson Pharma are infringing or shortly will infringe the '886 and '466 patents.

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

30. Plaintiffs re-allege, and incorporate herein by reference, the allegations of Paragraph 1-29 of this Complaint as if fully set forth herein.

31. Defendants Amphastar and IMS have infringed, and are continuing to infringe, and have 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. Defendants Amphastar, Watson and Watson Pharma have infringed, and are continuing to infringe, and have induced others to infringe, the '886 patent, either literally or under the doctrine of equivalents, by, *inter alia*, offering those products for sale in the United States.

32. Defendants have not obtained a license to use the processes claimed in the '886 patent or to offer for sale in the United States products made by those processes.

33. Unless Defendants are preliminarily and permanently enjoined by this Court from making their generic enoxaparin using a process that infringes the '886 patent, and from offering for sale, and selling, that generic enoxaparin product, Momenta and Sandoz will be substantially and irreparably injured.

34. Upon information and belief, Defendants' direct or indirect infringement of the '886 patent has been, and continues to be, willful, deliberate, or objectively reckless. Defendants' 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)

35. Plaintiffs re-allege, and incorporate herein by reference, the allegations of Paragraph 1-34 of this Complaint as if fully set forth herein.

36. Defendants Amphastar and IMS have infringed, and are continuing to infringe, and have 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. Defendants Amphastar, Watson and Watson Pharma have infringed, and are continuing to infringe, and have induced others to infringe, the '466 patent, either literally or under the doctrine of equivalents, by, *inter alia*, offering those products for sale in the United States.

37. Defendants have not obtained a license to use the processes claimed in the '466 patent or to offer for sale in the United States products made by those processes.

38. Unless Defendants are preliminarily and permanently enjoined by this Court from making their generic enoxaparin using a process that infringes the '466 patent, and from offering for sale, and selling, that generic enoxaparin product, Momenta and Sandoz will be substantially and irreparably injured.

39. Upon information and belief, Defendants' direct or indirect infringement of the '466 patent has been, and continues to be, willful, deliberate, and objectively reckless.

Defendants' 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)

40. Plaintiffs re-allege, and incorporate herein by reference, the allegations of Paragraphs 1-39 of this Complaint as if fully set forth herein.

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

42. Defendants are infringing, or have 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.

43. Unless Defendants are preliminarily and permanently enjoined by this Court from manufacturing their generic enoxaparin using a process that infringes the '886 patent, and from offering for sale, and selling, that enoxaparin product, Momenta and Sandoz will be substantially and irreparably injured by Defendants' conduct.

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

44. Plaintiffs re-allege, and incorporate herein by reference, the allegations of Paragraphs 1-43 of this Complaint as if fully set forth herein.

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

46. Defendants are infringing, or have 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.

47. Unless Defendants are preliminarily and permanently enjoined by this Court from manufacturing their generic enoxaparin using a process that infringes the '466 patent, and from offering for sale, and selling, that enoxaparin product, Momenta and Sandoz will be substantially and irreparably injured by Defendants' conduct.

PRAYER FOR RELIEF

WHEREFORE, the plaintiffs respectfully request:

(a) That the Court determine that Amphastar, IMS, Watson, and Watson Pharma have infringed, are infringing, or will infringe, one or more claims of United States Patent No. 7,575,886;

(b) That the Court determine that Amphastar, IMS, Watson, and Watson Pharma have infringed, are 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 Amphastar, IMS, Watson, and Watson Pharma, their officers, agents, attorneys, servants, employees, subsidiaries and all persons in active concert or participation with them, from 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, and from offering for sale and selling an enoxaparin product that has been

made by a method that infringes one or more of the claims of either U.S. Patent No. 7,575,886 or U.S. Patent No. 7,790,466;

(d) That the Court enter a permanent injunction precluding Amphastar, IMS, Watson, and Watson Pharma, their officers, agents, attorneys, servants, employees, subsidiaries and all persons in active concert or participation with them, from 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, and from offering for sale and selling an enoxaparin product that has been made by a method that infringes one or more of the claims of either U.S. 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 Amphastar, IMS, Watson, and Watson Pharma'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 Amphastar, IMS, Watson, and Watson Pharma'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 Amphastar, IMS, Watson, and Watson Pharma 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. and SANDOZ INC.,

By their attorneys,

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Dated: October 17, 2011

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 October 17, 2011.

/s/ Courtney M. Schou