

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
AMNEAL PHARMACEUTICALS LLC,	)	
	)	
Defendant.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

For its complaint, Plaintiff Merck Sharp & Dohme Corp. alleges as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the patent laws of the United States of America, Title 35, United States Code, against Defendant Amneal Pharmaceuticals LLC (“Amneal”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 207989 filed by Amneal with the U.S. Food and Drug Administration (“FDA”) for approval to market mometasone furoate nasal spray, a generic version of Plaintiff Merck Sharp & Dohme Corp.’s (Merck’s) Nasonex® drug product, prior to expiration of U.S. Patent No. 6,127,353 (the ’353 patent).

**PARTIES**

2. Merck is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100.

3. On information and belief, Amneal is a limited liability company organized and existing under the laws of Delaware with a principal place of business at 400 Crossing Blvd., Bridgewater, New Jersey 08807.

**JURISDICTION AND VENUE**

4. This action arises under the patent laws of the United States of America, Title 35, United States Code, and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

5. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

6. This Court has jurisdiction over Amneal because, upon information and belief, Amneal is a limited liability company organized and existing under the laws of Delaware.

7. Upon information and belief, Amneal is registered to conduct business with the State of Delaware and maintains as a registered agent The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, Delaware 19801.

8. Upon information and belief, Amneal is registered pursuant to Del. Code Ann. Tit. 24, § 2540 to distribute its generic pharmaceutical products in Delaware.

9. This Court also has jurisdiction over Amneal because, inter alia, this action arises from actions of Amneal directed toward Delaware, and Amneal has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Amneal regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through affiliates. Upon information and belief, Amneal derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

10. Amneal has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertion of counterclaims and by filing suits in Delaware.

11. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Amneal.

**BACKGROUND**

12. On October 3, 2000, the '353 patent, entitled MOMETASONE FUROATE MONOHYDRATE, PROCESS FOR MAKING SAME AND PHARMACEUTICAL COMPOSITIONS, duly and legally issued to Pui-Ho Yen, Charles Eckhart, Teresa Etlinger, and Nancy Levine. The '353 patent is currently scheduled to expire on October 3, 2017, with pediatric exclusivity through April 3, 2018. The '353 patent discloses and claims novel form(s) of mometasone furoate monohydrate (also designated  $9\alpha,21$ -dichloro- $16\alpha$ -methyl- $1,4$ -pregnadiene- $11\beta,17\alpha$ -diol- $3,20$ -dione- $17$ -( $2'$ -furoate) monohydrate) and novel pharmaceutical compositions thereof. A copy of the '353 patent is attached to this Complaint as Exhibit 1.

13. Merck is the owner through assignment of the '353 patent, and is the owner of approved New Drug Application No. 20762, covering mometasone furoate monohydrate metered nasal spray that is sold under the Nasonex® trademark.

14. Merck's Nasonex® nasal spray is extremely successful and is widely used in Delaware, the United States, and throughout the world to treat diseases of the upper airways, including allergic and nonallergic rhinitis.

15. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA). Merck has listed the '353 patent in the Orange Book as covering its Nasonex® nasal spray.

16. On information and belief, Amneal has filed an ANDA with the FDA for generic mometasone furoate nasal spray, 50 mcg (ANDA No. 207989). Amneal's ANDA No. 207989 allegedly contains a certification under Title 21, United States Code § 355(j)(2)(A)(vii)(IV) and Title 21, Code of Federal Regulations, § 314.95, that the '353 patent is "unenforceable, invalid, and/or not infringed." Notice of that certification, but not the certification, was transmitted to Merck on or after February 3, 2015, and received by Merck on or after February 4, 2015.

17. Amneal has refused to make ANDA No. 207989 or samples of its proposed generic copy of Nasonex® nasal spray available to Merck under reasonable conditions that would allow evaluation of the ANDA and/or samples before the filing this Complaint.

18. Upon information and belief, Amneal's proposed generic copy would contain mometasone furoate in such a form that would infringe the '353 patent.

19. On information and belief, Amneal filed ANDA No. 207989 because Amneal seeks to enter the lucrative intranasal mometasone furoate market that Nasonex® nasal spray has created with its beneficial and advantageous treatments for diseases of the upper airways, including allergic and nonallergic rhinitis.

### **COUNT I**

20. Each of the preceding paragraphs is incorporated as if fully set forth herein.

21. On information and belief, Amneal filed ANDA No. 207989 to obtain approval under the FDCA to engage in the commercial manufacture, use, or sale of a drug product which is claimed in the '353 patent, before the expiration of the '353 patent. On information and belief, Amneal has committed an act of infringement under 35 U.S.C. § 271

(e)(2)(A), and Amneal will further infringe at least one claim of the '353 patent by making, using, offering to sell, and selling its generic copies of Nasonex® nasal spray in the United States and/or importing such copies into the United States unless enjoined by the Court.

22. On information and belief, when Amneal filed ANDA No. 207989 seeking approval to market generic mometasone furoate nasal spray before the expiration of the '353 patent, Amneal was aware of the existence of the '353 patent and that the filing of ANDA No. 207989 constituted an act of infringement of that patent.

23. On information and belief, Amneal acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '353 patent.

24. If Amneal's marketing and sale of generic mometasone furoate nasal spray prior to expiration of the '353 patent and all other relevant exclusivities is not enjoined, Merck will suffer substantial and irreparable harm for which there is no remedy at law.

## **COUNT II**

25. Each of the preceding paragraphs is incorporated as if fully set forth herein.

26. On information and belief, Amneal filed ANDA No. 207989 to obtain approval under the FDCA to engage in the commercial manufacture, use, or sale of a drug product which is claimed in the '353 patent, before the expiration of the '353 patent. On information and belief, Amneal has committed an act of infringement under 35 U.S.C. § 271 (e)(2)(A), and Amneal will further contribute to the infringement of others of at least one claim of the '353 patent.

27. Amneal has knowledge of the '353 patent, as evidenced by at least its identification of the '353 patent in connection with its filing of ANDA No. 207989.

28. On information and belief, Amneal has or will have knowledge that if it were to receive approval from the FDA to market the product described in ANDA No. 207989 and made said product available for sale and/or use during the proposed shelf life of the product, such activities would result in the sale and/or use of an infringing article that is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '353 patent by another.

29. On information and belief, Amneal acted without a reasonable basis for a good faith belief that it would not be liable for contributing to the infringement the '353 patent.

30. If Amneal's marketing and sale of generic mometasone furoate nasal spray prior to expiration of the '353 patent and all other relevant exclusivities is not enjoined, Merck will suffer substantial and irreparable harm for which there is no remedy at law.

**REQUESTED RELIEF**

WHEREFORE, Plaintiff Merck respectfully seeks the following relief:

- a) That judgment be entered that Defendant Amneal has directly infringed and/or contributed to the infringement of the '353 patent by submitting ANDA No. 207989;
- b) That a permanent injunction be issued under 35 U.S.C. § 271(e) restraining or enjoining Defendant Amneal, its officers, agents or attorneys or employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any chemical entity and/or therapeutic composition, covered by the '353 patent for the full term thereof, including the applicable pediatric exclusivity, and from contributing to such activities;

c) That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 207989 be a date which is not earlier than the expiration date of the asserted patent, including the applicable pediatric exclusivity;

d) That this is an exceptional case under 35 U.S.C. § 285 and that judgment be entered for costs and reasonable attorney fees to be awarded to Merck; and

e) That this Court award such other and further relief as the Court may deem proper and just under the circumstances.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Jack B. Blumenfeld*

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