IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

For its complaint, Plaintiff Merck Sharp & Dohme Corp. ("Merck") 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 Teva Pharmaceuticals USA, Inc. ("Teva"). This action relates to Abbreviated New Drug Application ("ANDA") No. 205149 filed by Teva with the U.S. Food and Drug Administration ("FDA") for approval to market mometasone furoate nasal spray, a generic version of 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 08889-0111.

3. On information and belief, Teva is a Delaware corporation with its principal place of business at 425 Privet Road, Horsham, Pennsylvania 19044.

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 Teva because, upon information and belief, Teva is a Delaware corporation.

7. This Court also has jurisdiction over Teva because, inter alia, this action arises from actions of Teva directed toward Delaware, and Teva 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, Teva 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, Teva 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.

8. Teva 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.

BACKGROUND

9. 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. The '353 patent discloses and claims novel form(s) of mometasone furoate monohydrate (also designated 9α,21-dichloro-16α-methyl-1,4-pregnadiene-11β,17α-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.

10. 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.

11. 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.

12. 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.

13. On information and belief, Teva has filed an ANDA with the FDA for generic mometasone furoate nasal spray, 0.05 mg base/spray (ANDA No. 205149). Teva's ANDA No. 205149 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 "invalid, unenforceable, or will not be infringed." Notice of that certification, but not the certification, was transmitted to Merck on or after May 21, 2014, and received by Merck on or after May 22, 2014.

14. Teva has refused to make ANDA No. 205149 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.

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

16. On information and belief, Teva filed ANDA No. 205149 because Teva 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, before the expiration of the '353 patent.

COUNT I

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

18. On information and belief, Teva filed ANDA No. 205149 to obtain approval under the FFDCA 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 Teva has committed an act of infringement under 35 U.S.C. § 271 (e)(2)(A), and Teva 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.

19. On information and belief, when Teva filed ANDA No. 205149 seeking approval to market generic mometasone furoate nasal spray before the expiration of the '353 patent, Teva was aware of the existence of the '353 patent and that the filing of ANDA No. 205149 constituted an act of infringement of that patent.

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

21. If Teva'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

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

23. On information and belief, Teva filed ANDA No. 205149 to obtain approval under the FFDCA 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 Teva has committed an act of infringement under 35 U.S.C. § 271 (e)(2)(A), and Teva will further contribute to the infringement of others of at least one claim of the '353 patent by marketing and selling its generic copies of Nasonex® nasal spray in the United States.

24. Teva 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. 205149.

25. On information and belief, Teva has or will have knowledge that if it were to receive approval from the FDA to market the product described in ANDA No. 205149 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.

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

27. If Teva'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 Teva has infringed the '353 patent by submitting ANDA No. 205194 to the FDA;

b) That a permanent injunction be issued under 35 U.S.C. § 271(e) restraining or enjoining Defendant Teva, 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;

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. 205194 be a date which is not earlier than the expiration date of the '353 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

Jack B. Blumenfeld (#1014)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com

Attorneys for Plaintiff

OF COUNSEL:

Nicolas Barzoukas
Joshua Davis
BAKER BOTTS L.L.P.
One Shell Plaza
910 Louisiana Street
Houston, TX 77002-4995
(713) 229-1234

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