IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 3:15-cv-2384-PGS-TJB
	)	
APOTEX INC. and APOTEX CORP.,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

For its Second Amended Complaint, Plaintiff Merck Sharp & Dohme Corp. ("Merck") alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement and for declaratory judgment of patent infringement of United States Patent No. 6,127,353 (the "'353 patent"). This action arises out of Defendants', Apotex Inc.'s and Apotex Corp.'s (collectively, "Defendants") current and/or imminent manufacture, use, sale, importation, and/or offer to sell and/or encouragement of others to do any of the foregoing, within the United States, of a generic version of Nasonex® mometasone furoate nasal spray before expiration of the '353 patent; and/or Defendants' filing of Abbreviated New Drug Application ("ANDA") No. 91-161 with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Nasonex® mometasone furoate nasal spray in the United States before expiration of 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, Apotex Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9.

4. On information and belief, Apotex Corp. ("Apotex USA") regularly transacts business in New Jersey and is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

5. On information and belief, Apotex USA is the United States subsidiary of Apotex.

6. On information and belief, Apotex conducts business operations in the United States, including in the state of New Jersey, through Apotex USA.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. Jurisdiction is founded on Title 28, United States Code §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Apotex because Apotex has maintained continuous and systematic contacts with the state of New Jersey.

9. Apotex has previously submitted to the jurisdiction of this Court in several cases and has previously availed itself of the District of New Jersey by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. On information and belief, generic drug products developed and manufactured by Apotex, including Defendants' mometasone furoate nasal spray at issue in this case and approved by the FDA are offered for sale, sold, and/or imported in the state of New Jersey and in this District.

11. This Court has personal jurisdiction over Apotex USA because Apotex USA has maintained continuous and systematic contacts with the state of New Jersey, including,

upon information and belief, by the offer for sale, sale, and or importation of Defendants' mometasone furoate nasal spray at issue in this case.

12. Apotex USA has previously submitted to the jurisdiction of this Court in several cases and has previously availed itself of the District of New Jersey by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

13. On information and belief, Apotex USA markets and sells drug products in the United States manufactured by Apotex, following any FDA approval. Apotex USA markets and sells such drug products, including Defendants' mometasone furoate nasal spray, in this judicial District and has registered as a wholesaler with the New Jersey Department of Health and Senior Services.

14. Apotex USA's acts and continuous contacts with the state of New Jersey, as an agent for Apotex, are also attributable to Apotex for jurisdictional purposes.

15. This Court also has specific jurisdiction over this matter. Apotex filed an ANDA with the FDA with a certification under Title 21, United States Code § 355(j)(2)(A)(vii)(IV) ("paragraph IV") and sent notification of its paragraph IV certification to Merck in New Jersey. Apotex's act of filing its ANDA with a paragraph IV notification and, alternatively, Apotex's sales and/or offers for sale of the accused product sufficient minimum contacts with the state of New Jersey under a specific jurisdiction analysis. Therefore, this cause of action arises out of Apotex's contacts with the state of New Jersey.

16. This Court further has supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) over the claims for tortious interference and unjust enrichment under New Jersey

common law stated herein, because those claims form part of the same case or controversy as the other claims stated herein.

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

BACKGROUND

18. 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 Yuen, 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 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 Second Amended Complaint as Exhibit 1.

19. 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.

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

21. 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.

22. Apotex has filed an ANDA with the FDA for generic mometasone furoate nasal spray, 0.05 mg base/spray (ANDA No. 91-161). Apotex's ANDA No. 91-161 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, originally was transmitted to Merck and Schering-Plough Corporation on or after November 6, 2009, and received by Merck on or after November 9, 2009.

23. On information and belief, Apotex filed ANDA No. 91-161 because Apotex sought 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.

24. On December 18, 2009, Merck filed a complaint against Defendants for infringement of the '353 patent based on ANDA No. 91-161 in this District in a case that was assigned Civil Action No. 3:09-cv-06373 (the "Previous Litigation"). That case was tried before United States District Court Judge Peter G. Sheridan in April 2012 and resulted in an opinion and order that the '353 patent was not invalid, but that Merck had not met its burden with respect to demonstrating infringement by the product allegedly submitted by Apotex for FDA approval at that time. *See Schering Corp. v. Apotex Inc. and Apotex Corp.* (hereinafter, "*Schering v. Apotex*"), 3:09-cv-06373, D.I. 443 (attached as Exhibit 2), *aff'd* 517 F. App'x. 939 (Fed. Cir. 2013).

25. In connection with the Previous Litigation, and despite numerous efforts from Merck to obtain samples of Defendants' mometasone furoate nasal spray from as many batches as possible, Defendants only provided Merck with samples from one batch, HW9234.

26. Defendants represented to the Court that batch HW9234 was the "exhibit batch" and that any other batches "would be irrelevant to the question of infringement because the [other] batches are not the exhibit batch and would not have received FDA approval nor been placed on the market!" *Schering v. Apotex*, 3:09-cv-06373, D.I. 467-1 (April 2, 2012 Letter from A. Calmann to Hon. T.J. Bongiovanni, U.S.M.J.) at 15 (exclamation point in original) (attached as Exhibit 3).

27. Additionally, Defendants represented to the Court that their ANDA "product" must be considered as a whole for the purposes of infringement, arguing that:

> However, the liquid contents of the accused ANDA product, by themselves, are not a "product." The packaging is an integral part of the accused product for two reasons. First, the packaging serves to protect and dispense the liquid contents, and is subject to FDA review and approval. Without the packaging, Apotex would not have a "product" that can be approved by the FDA or used by anyone as a nasal spray. Moreover, Schering's infringement theory is based on alleged "conversion" that starts in the actuator assembly, which is part of the packaging of the liquid contents.

Jan. 30, 2012 Letter from A. Calmann to Hon. Peter G. Sheridan, U.S.D.J., at 3-4 (attached as Exhibit 4).

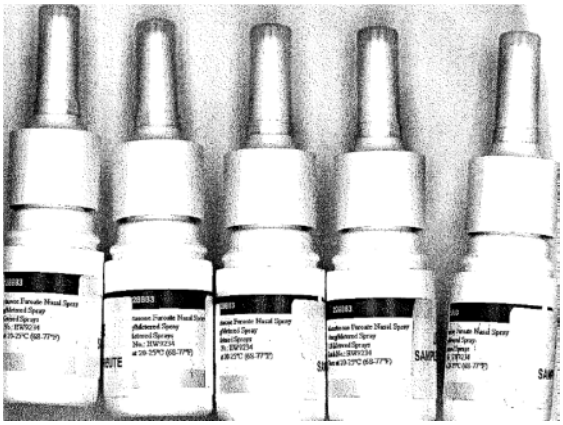
28. Thus, Defendants recognized both that the bottle (i.e., "packaging") that contains their mometasone furoate nasal spray is an inseparable and integral part of their ANDA "product" and that the particulars of the bottle can affect infringement.

29. On information and belief, Apotex began offering for sale a generic version of mometasone furoate nasal spray in Canada on or about March 25, 2013.

30. On information and belief, at least since the time Defendants made the foregoing representations to the Court in the Previous Litigation, Apotex amended its ANDA and/or changed its ANDA "product" before the FDA approved its ANDA "product."

31. The mometasone furoate nasal spray product that Apotex sells in Canada is packaged in bottles that differ from the HW9234 samples provided to Merck in the Previous Litigation. For example, Defendants represented to the Court in the Previous Litigation that although changes had been made to the size, configuration, and composition of bottles for their mometasone furoate nasal spray product, those changes were made for submissions to the Canadian regulatory authorities only: "For Canada, [Apotex] also committed to submit data for JK7465 & JK7468, which contain 140 metered doses as suppose [sic] to 120 metered doses (for US). These batches also packaged with the new shorter bottle and pump with addilene change, but not with the nitrile change." Exhibit 3 at 14-15.

32. Merck has confirmed that the generic mometasone furoate nasal spray product offered for sale and sold by Apotex in Canada differs from what was provided to Merck for testing in the Previous Litigation, as illustrated in the differences in respective bottles below:



Bottles from HW9234, Provided to Merck in Previous Litigation. *See* Exhibit 3 at 4.

Bottle Sold by Apotex in Canada, attached as Exhibit 5.

33. On information and belief, at least as early as the time of Merck's original complaint in this case and despite Defendants' representations to the Court in the Previous Litigation, Defendants planned to conform (and now have since conformed) their U.S.

mometasone furoate nasal spray product to Apotex's Canadian mometasone furoate nasal spray product, in an effort to leverage lower production costs and maintain profits while offering their product at a substantially reduced price. Therefore, upon approval by the FDA, Defendants planned to manufacture, use, offer for sale, and/or sell a product in the United States (the "New Product") that would be different than the product that was the subject of the Previous Litigation (represented by HW9234).

34. On December 11, 2014, Merck wrote to Defendants seeking "confirmation from Apotex that it has not modified the mometasone furoate nasal spray for which it was seeking FDA approval in any respect (including, but not limited to, changes to the container, actuator assembly, and/or bottle materials)." Exhibit 7. In the event that Apotex had proposed modifications to its mometasone furoate nasal spray, Merck requested samples of the New Product. *Id.* Merck raised its concerns in the December 11 letter, and Defendants were well aware that changes to the packaging of their proposed mometasone furoate nasal spray may affect infringement of the '353 patent (as evidenced by their many representations to the Court in the Previous Litigation). Defendants did not respond to Merck's December 11, 2014 letter or deny that Defendants had changed or planned to change their product.

35. Merck also wrote to Defendants on March 27, 2015, raising the same issues as in its December 11, 2014 letter and informing Defendants of Merck's filing of the complaint in this matter. Again, Merck emphasized that it was "seeking confirmation that the mometasone furoate nasal spray product for which Apotex is seeking FDA approval had not been modified and is not expected to be modified." Exhibit 8. Again, Defendants did not respond or deny that Defendants had changed or planned to change their product.

36. The only response that Merck received from Defendants occurred after Merck instituted this action in the form of a request for documents and/or data underlying Merck's allegations in Paragraph 37 of Merck's original complaint. *See* Exhibit 9. Yet again, Defendants did not deny that Defendants had changed their product. When Merck responded that it was willing to engage in expedited discovery for this case—provided that the parties agreed to abide by the Confidentiality Order from the Previous Litigation, and importantly, that such discovery would involve a mutual exchange of information—Defendants refused to engage in any substantive communication. *See* Exhibit 10.

37. Additionally, Merck informed Defendants that Merck viewed Defendants' continued non-response as to whether or not Defendants had changed their product as confirmation that "Apotex has, indeed, changed its bottle, as alleged in Merck's complaint." *See id*.; Exhibit 11. Defendants still have not denied that they have changed their product.

38. On information and belief, no reasonable and rational actor would risk or engage in needless litigation. Therefore, on information and belief, Merck previously concluded from Defendants' failure to respond to Merck's multiple inquiries that, if approved by the FDA, Defendants would manufacture, use, market, offer for sale, import, and/or sell their New Product in the United States. Defendants' actions and other information set forth herein have further confirmed that the product that was the subject of the Previous Litigation was not the product for which Apotex ultimately sought regulatory approval in the United States.

39. Upon information and belief, the generic mometasone furoate nasal spray sold by Apotex in Canada contains mometasone furoate monohydrate. Dr. Peter Müller, Director of the Diffraction Facility of the Massachusetts Institute of Technology Department of

Chemistry, performed a study ("Müller Study") and published a peer-reviewed article entitled "Mometasone furoate revisited, or how did the hydrate get in the bottle?" Acta Crystallographica (2015) C71, 1080-1084. *See* http://journals.iucr.org/c/issues/2015/12/00/ov3071/index.html. In that article, Dr. Müller analyzed the contents of a bottle of the mometasone furoate nasal spray sold by Apotex in Canada and concluded that the Canadian product contained mometasone furoate monohydrate crystals. Therefore, the mometasone furoate nasal spray sold by Apotex in Canada would infringe at least claim 1 of the '353 patent if manufactured, used, imported, sold, and/or offered for sale in the United States.

40. On information and belief, Defendants sought approval from the FDA to manufacture, use, and/or sell a version of generic mometasone furoate nasal spray product in the United States that corresponds to the product that Apotex has sold in Canada, containing mometasone furoate monohydrate, and which would infringe at least claim 1 of the '353 patent if manufactured, used, imported, sold, and/or offered for sale in the United States.

41. Since the time of Merck's First Amended Complaint in this action, Apotex has announced that it received FDA approval to market its generic version of Merck's Nasonex® product in the United States. Specifically, Apotex announced that it launched its generic version of Merck's Nasonex® product in the United States on or around March 22, 2016. Apotex's website posts a press release dated March 24, 2016 and entitled "Apotex Launches First Generic Version of Merck's Nasonex®," which states, "Apotex Inc. announced today that it has launched the first generic version of Merck's Nasonex® nasal spray (mometasone furoate monohydrate) in the United States" and that Apotex had received FDA approval for its generic version of Nasonex®. *See* http://www.apotex.com/global/about/press/20160324.asp.

However, a PR Newswire press release dated March 22, 2016 included similar content, indicating that Apotex had made the announcement two days earlier. *See* http://www.prnewswire.com/news-releases/apotex-launches-first-generic-version-of-mercks-nasonex-573064911.html.

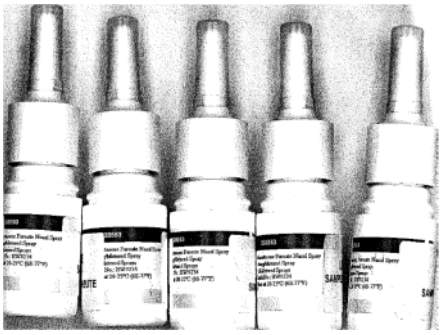
42. After the launch of Defendants' New Product, Merck acquired a sample of the New Product and tested the New Product. Merck obtained a sample of Defendants' New Product marketed in the United States, pictured below:

Apotex U.S. New Product Bottle (Exhibit 12)

43. The packaging for Defendants' New Product identifies the same active ingredient, mometasone furoate, as in Apotex's Canadian product. An inspection of the New Product confirmed Merck's previous allegation that Defendants' New Product in the United States would differ from the product samples that Defendants provided in the Previous Litigation. The appearance of the New Product's bottle does not appear to differ in any material way from the bottle for Apotex's Canadian product and is different from the bottles that Defendants provided to Merck for testing in the Previous Litigation, as shown below:

Apotex Canadian Bottle (Exhibit 5)

Apotex U.S. New Product Bottle (Exhibit 12)



Bottles from HW9234, Provided to Merck in Previous Litigation. (Exhibit 3 at 4)

44. Upon review of the New Product, Merck found that the New Product itself contains mometasone furoate monohydrate and therefore infringes at least claim 1 of the ’353 patent.

45. Merck did not receive any warning or notification before the FDA approved Defendants’ New Product.

46. Defendants’ infringing New Product competes and will compete directly with Merck’s Nasonex® nasal spray.

47. Upon offering to sell and selling Defendants’ New Product in the United States, Defendants’ infringing acts as described herein began to cause Merck to suffer monetary damages and to immediately and irreparably harm Merck, and that harm continues.

COUNT I (DIRECT INFRINGEMENT)

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

49. Defendants’ manufacture, use, sale, offer for sale, and or importation of its New Product directly infringes at least claim 1 of the ’353 patent.

50. Defendants have been on notice of the ’353 patent since at least as early as their filing of ANDA 91-161 and have been or should have been aware of the presence of the infringing mometasone furoate monohydrate in their New Product at least as early as

Defendants' awareness of the publication of the Müller Study or Defendants' decision to change their product from the sample provided to Merck for testing in the Previous Litigation (HW9234) to the New Product that Defendants are now manufacturing, using, selling, offering for sale, and/or importing in the United States. As a result, Defendants' infringement has been willful at least as early as Defendants' launch of the New Product in the United States, but in no event later than Defendants' receipt of a copy of Merck's proposed Second Amended Complaint, a copy of which was filed with the Court as ECF No. 50-1.

51. Merck has suffered and will continue to suffer financial harm as a result of Defendants' infringing activities.

52. Merck is being and will continue to be substantially and irreparably harmed if Defendants are not enjoined from infringing the '353 patent.

53. Merck is entitled to monetary damages but has no complete, adequate remedy at law and, therefore, is entitled to injunctive relief. Because Defendants' infringement of the '353 patent has been willful, wanton and deliberate, this action is an exceptional case, and the damages to be paid by Defendants should be trebled.

COUNT II (INDUCED INFRINGEMENT)

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

55. Defendants have induced and continue to induce the infringement of the '353 patent under 35 U.S.C. § 271(b) by actively inducing others, including wholesalers, pharmacies, and patients, to infringe at least claim 1 of the '353 patent by their use, sale, offer for sale, and/or importation of mometasone furoate nasal spray (Defendants' New Product) in the United States that directly infringes at least claim 1 of the '353 patent. Defendants have had actual knowledge of the '353 patent since at least as early as their filing of ANDA 91-161. Defendants have had actual knowledge of the specific manner of infringement by their

New Product, since at least as early as Defendants' awareness of the publication of the Müller Study or Defendants' decision to change their product from the sample provided to Merck for testing in the Previous Litigation (HW9234) to the New Product that Defendants are now manufacturing, using, selling, offering for sale, and/or importing in the United States, but in no event later than Defendants' receipt of a copy of Merck's proposed Second Amended Complaint, a copy of which was filed with the Court as ECF No. 50-1. As a result, Defendants have engaged in the foregoing actions with either the specific intent to cause infringement or with willful blindness to the infringement that Defendants' actions are causing. For example, Apotex actively induces wholesalers and pharmacies to directly infringe the '353 patent by selling or offering the New Product for sale in the United States, which infringes at least claim 1 of the '353 patent. On information and belief, at least one pharmacy has sold and/or offered for sale the New Product and directly infringed at least claim 1 of the '353 patent as a result of Defendants' inducement. As another example, Apotex actively induces patients to directly infringe at least claim 1 of the '353 patent by their use of the New Product. On information and belief, at least one patient has used the New Product in the United States and has directly infringed at least claim 1 of the '353 patent as a result of Defendants' inducement.

56. Merck has suffered and will continue to suffer financial harm as a result of Defendants' infringing activities.

57. Merck is being and will continue to be substantially and irreparably harmed if Defendants are not enjoined from infringing the '353 patent.

58. Merck is entitled to monetary damages but has no complete, adequate remedy at law and, therefore, is entitled to injunctive relief. Because Defendants' inducement of

infringement of the ’353 patent has been willful, wanton and deliberate, this action is an exceptional case, and the damages to be paid by Defendants should be trebled.

COUNT III (DECLARATORY JUDGMENT)

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

60. On information and belief, Apotex filed ANDA No. 91-161 to obtain approval under the FFDCA to market a drug product which is claimed in the ’353 patent, before the expiration of the ’353 patent. On information and belief, by filing the ANDA, Defendants sought to make, use, offer to sell, sell and/or import their New Product in the United States. On information and belief, Defendants have committed an act of infringement under 35 U.S.C. § 271(a) or (e)(2)(A), and Defendants further infringe at least one claim of the ’353 patent by making, using, offering to sell, and selling their New Product in the United States and/or importing such copies into the United States.

61. On information and belief, when Apotex filed ANDA No. 91-161 seeking approval to market generic mometasone furoate nasal spray before the expiration of the ’353 patent, Defendants were aware of the existence of the ’353 patent and that the filing of ANDA No. 91-161 constituted an act of infringement of that patent. Defendants also knew that the bottle that contains their mometasone furoate nasal spray is an inseparable and integral part of their ANDA product and that the bottle can affect infringement. Defendants also have known since before the filing of this Second Amended Complaint that the New Product would include a bottle different from the one that Defendants provided in the Previous Litigation and similar or identical to the one in which Apotex sold its mometasone furoate nasal spray in Canada.

62. On information and belief, Defendants acted without a reasonable basis for a good faith belief that Defendants would not be liable for infringing the ’353 patent when

Defendants changed their product from the sample provided to Merck for testing in the Previous Litigation (HW9234) to the New Product that Defendants are now manufacturing, using, selling, offering for sale, and/or importing in the United States. As a result, Defendants have willfully infringed and continue to willfully infringe the ’353 patent.

63. Defendants have been on notice of the ’353 patent since at least as early as their filing of ANDA 91-161 and have been or should have been aware of the presence of the infringing mometasone furoate monohydrate in their New Product at least as early as Defendants’ awareness of the publication of the Müller Study or Defendants’ decision to change their product from the sample provided to Merck for testing in the Previous Litigation (HW9234) to the New Product that Defendants are now manufacturing, using, selling, offering for sale, and/or importing in the United States. As a result, Defendants’ infringement has been willful at least as early as Defendants’ launch of the New Product in the United States, but in no event later than Defendants’ receipt of a copy of Merck’s proposed Second Amended Complaint, a copy of which was filed with the Court as ECF No. 50-1.

64. On information and belief, if Defendants’ 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 both monetary damages and substantial and irreparable harm for which there is no remedy at law.

COUNT IV (TORTIOUS INTERFERENCE UNDER NEW JERSEY COMMON LAW)

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

66. Defendants’ conduct constitutes tortious interference under the common law of the State of New Jersey.

67. On information and belief, despite Defendants’ representations to the Court in the Previous Litigation, Defendants planned to conform (and now have since conformed) their

U.S. mometasone furoate nasal spray product to Apotex's Canadian mometasone furoate nasal spray product, in an effort to leverage lower production costs and maintain profits while offering their product at a substantially reduced price.

68. Defendants represented to the Court in the Previous Litigation that batch HW9234 was the "exhibit batch" and that any other batches "would be irrelevant to the question of infringement because the [other] batches are not the exhibit batch and would not have received FDA approval nor been placed on the market!" *Schering v. Apotex*, 3:09-cv-06373, D.I. 467-1 (April 2, 2012 Letter from A. Calmann to Hon. T.J. Bongiovanni, U.S.M.J.) at 15 (exclamation point in original) (attached as Exhibit 3). Defendants' FDA approved product is the New Product—not HW9234—and thus the only batch that was provided to Merck in the Previous Litigation was not relevant to the question of infringement.

69. On information and belief, Defendants had a legal obligation to disclose in the Previous Litigation their plans to change the product for which Defendants were seeking FDA approval from the HW9234 sample to the New Product that Defendants are now manufacturing, using, selling, offering for sale, and/or importing in the United States. On information and belief, though Defendants planned to change its product to be different from the one at issue in the Previous Litigation, Defendants failed to inform the Court or Merck of its plans thereby preventing Merck from seeking relief from the Court, such as an extension of the thirty-month stay of FDA approval available pursuant to the FFDCA. In failing to do so, Defendants interfered with Merck's a protectable right in the prospective economic or contractual relationships flowing from its marketing and selling of Merck's Nasonex® nasal spray, and a reasonable expectation of economic advantage related thereto.

70. Merck has invested time, money, and other resources in the development of Merck's Nasonex® nasal spray and in the submission and approval of New Drug Application No. 20762, including, but not limited to, the submission and acceptance of pediatric studies.

71. By virtue of Merck's patent rights and the exclusivity right afforded to Merck under the FFDCA, Merck has a protectable right in the prospective economic or contractual relationships flowing from its marketing and selling of Merck's Nasonex® nasal spray, and a reasonable expectation of economic advantage related thereto.

72. Defendants intentionally and maliciously interfered with Merck's protectable rights in the prospective economic or contractual relationship and/or reasonable expectation of economic advantage derived from Merck's patent rights covering Merck's Nasonex® nasal spray and the exclusivity right afforded to Merck under the FFDCA. Defendants intentionally and maliciously entered Merck's exclusive market guaranteed by the '353 patent and its related pediatric exclusivity, thereby depriving Merck of the value of its rights and the economic advantages they protect.

73. Defendants knowingly entered Merck's exclusive markets intentionally and without justification or excuse by introducing its New Product that infringes at least claim 1 of the '353 patent. By its actions, Defendants sought to harm and harmed Merck and its business interests and prospective economic advantages.

74. Defendants' wrongful and unlawful conduct was the reasonable, foreseeable, and the proximate cause of Merck's loss of the prospective economic gain promised by the prospect of Merck's continued exclusive markets guaranteed by its rights, including its pediatric exclusivity right. Defendants' interference caused and is causing Merck's loss of prospective gain.

75. In the absence of Defendants' entry into Merck's exclusive markets protected by its patent rights covering Merck's Nasonex® nasal spray and the exclusivity right afforded to Merck under the FFDCA, there is at least a reasonable probability that Merck would have received the anticipated economic advantages and benefits flowing therefrom, which advantages and benefits have been and are being captured by Defendants.

76. Defendants' unlawful entry into the exclusive markets protected by Merck's patent rights covering Merck's Nasonex® nasal spray and the exclusivity right afforded to Merck under the FFDCA undermined and is undermining Merck's position in the markets and has caused and is causing Merck to suffer significant, irreparable economic and reputational harms as a result. Merck suffered and will continue to suffer both monetary damages and other damages in the form of lost sales, lost market share, lost business opportunities, lost prospective economic advantage, and lost goodwill, all contributing to irreparable harm for which Merck has no adequate remedy at law. Merck is entitled to recover its damages, and further to recover punitive or exemplary damages based on Defendants' actual malice in an amount appropriate to punish and to make an example of Defendant to the community.

COUNT V (UNJUST ENRICHMENT UNDER NEW JERSEY COMMON LAW)

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

78. Defendants' foregoing acts conferred a benefit upon Defendants in that Defendants obtained FDA approval to market their New Product prior to the end of the pediatric exclusivity period for the '353 patent and have marketed and sold its New Product prior to the end of the pediatric exclusivity period for the '353 patent. Defendants received those benefits, and it would be inequitable for Defendants to retain those benefits without payment of their value to Merck.

79. Defendants' making, using, offering for sale, selling, and/or importing of its New Product prior to the end of the pediatric exclusivity period for the '353 patent has caused Defendants to be unjustly enriched to the detriment of Merck.

80. Accordingly, Merck is entitled to monetary damages in the amount of Defendants' unjust enrichment.

JURY DEMAND

Plaintiff Merck hereby demands a trial by jury on all issues so triable.

REQUESTED RELIEF

WHEREFORE, Plaintiff Merck respectfully seeks the following relief:

a) That judgment be entered that Defendants Apotex and Apotex USA have directly infringed the '353 patent by submitting ANDA No. 91-161;

b) That judgment be entered directing the FDA to rescind the final approval of ANDA No. 91-161 and that the effective date of any approval of ANDA No. 91-161 be a date that is not earlier than the date of the expiration of the '353 patent, including any period of pediatric exclusivity;

c) That both a preliminary injunction and a permanent injunction be issued under 35 U.S.C. § 271(e) restraining or enjoining Defendants Apotex and Apotex USA, 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;

d) That judgment be entered that Defendants Apotex and Apotex USA have infringed or will directly infringe the '353 patent by manufacturing, using, offering to sell,

selling, or importing generic mometasone furoate nasal spray within the United States, or importing the same into the United States;

e) That judgment be entered that Defendants Apotex and Apotex USA have induced infringement of the ’353 patent by encouraging others to use, sell, offer for sale, and/or import generic mometasone furoate nasal spray within the United States;

f) That judgment be entered that Defendants Apotex and Apotex USA have committed both direct and induced willful infringement of the ’353 patent;

g) That judgment be entered awarding Merck the amount of Defendants Apotex and Apotex USA’s unjust enrichment;

h) That judgment be entered that Defendants Apotex and Apotex USA have committed tortious interference under New Jersey common law and awarding Merck monetary relief for Defendants Apotex and Apotex USA’s tortious interference;

i) To the extent that Defendants Apotex and Apotex USA have or will commercially manufacture, use, offer to sell, or sell generic mometasone furoate nasal spray within the United States, or import the same into the United States, before the expiration of the ’353 patent, including the applicable pediatric exclusivity, a judgment awarding Merck a preliminary injunction and any applicable monetary relief together with interest, such monetary relief to be determined by a jury, and if necessary to adequately compensate Merck for the infringement, such monetary relief to be trebled and awarded with pre-judgment and post-judgment interest;

j) 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

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

DATED: December 20, 2016

Respectfully submitted,

By: s/ David E. De Lorenzi

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 3:15 cv-2384-PGS-TJB
	)	
APOTEX INC. and APOTEX CORP.,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

CERTIFICATE OF SERVICE

I, David E. De Lorenzi, an attorney duly admitted to practice before the Bar of this Court, hereby declare as follows:

1. I am an attorney at law of the State of New Jersey and am a Director of the law firm of Gibbons P.C., attorney for the Plaintiff, Merck Sharp & Dohme Corp. ("Plaintiff") in the above-captioned matter.

2. On December 20, 2016, the following document was electronically filed with the Clerk of Court:

- Second Amended Complaint for Patent Infringement and Declaratory Judgment of Patent Infringement.

and was served upon all counsel in accordance with the Federal Rules of Civil Procedure and the District of New Jersey's Local Civil Rules on Electronic Service.

I certify under penalty of perjury that the foregoing is true and correct.

DATED: December 20, 2016

Respectfully submitted,

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