

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 12-60706-CIV-MIDDLEBROOKS/BRANNON  
(as consolidated with CASE NO. 12-CV-60707-MIDDLEBROOKS/BRANNON)

APOTEX, INC., et al.

Plaintiffs,

vs.

UCB, INC., et al.

Defendants.

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APOTEX, INC., a Canadian corporation and  
APOTEX CORP., a Delaware corporation,

Plaintiffs,

vs.

JURY TRIAL DEMANDED

PADDOCK LABORATORIES, LLC, a  
Delaware corporation, and  
PERRIGO COMPANY, a Delaware  
corporation,

Defendants.

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**SECOND CORRECTED COMPLAINT<sup>1</sup>**

Plaintiffs, Apotex Inc. and Apotex Corp. (collectively “Apotex”), sue Defendants,  
Paddock Laboratories, LLC and Perrigo Company, and state:

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<sup>1</sup> A “Corrected Complaint” was filed (Case No. 12-60707, D.E. 10-1) to correct editing codes that inadvertently appeared in the original filed Complaint (Case No. 12-60707, D.E. 1). This Second Corrected Complaint substitutes Paddock Laboratories, LLC for Paddock Laboratories, Inc. as a party Defendant (pursuant to this Court’s Omnibus Order (D.E. 31)).

### **NATURE OF THE ACTION**

1. This is an action for patent infringement of certain process claims arising under the Patent Laws of the United States, 35 U.S.C. §§ 271 and 281-285. Jurisdiction is based upon 28 U.S.C. §§ 1331 and 1338(a).

### **PARTIES**

2. Plaintiff, Apotex Inc., is a Canadian corporation having its principal place of business in Toronto, Ontario, Canada.

3. Apotex Inc. is a pharmaceutical company that specializes in offering life-saving, generic medications to consumers at a lower cost than branded medications.

4. Plaintiff, Apotex Corp., is a Delaware corporation having its principal place of business in Broward County, Florida.

5. Apotex Corp. is the exclusive licensed distributor of generic moexipril medication in the United States.

6. On information and belief, Paddock Laboratories, LLC (“Paddock LLC”) is a Delaware corporation having its principal place of business in Minneapolis, Minnesota.

7. On information and belief, Perrigo Company (“Perrigo”) is a Delaware corporation having its principal place of business in Allegan, Michigan. Perrigo acquired Paddock LLC on or about July 16, 2011. On information and belief, Paddock LLC products will be converted to the Perrigo brand over the next several months.

8. On information and belief, Defendants develop, manufacture, test, package, market, promote, offer to sell, sell and distribute pharmaceutical products in the United States, including this judicial district.

### JURISDICTION AND VENUE

9. Venue is proper under 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b) and (c) 100 *et seq.* because Defendants committed acts of patent infringement, a substantial part of the events giving rise to this claim occurred, and Defendants are subject to personal jurisdiction, in this judicial district.

10. This Court has personal jurisdiction over Defendants by virtue of Defendants' offers for sale, sales and distribution of products, including the products which are the subject of this Complaint, throughout the State of Florida and in this District. Defendants have also placed, and are continuing to place, products into the stream of commerce in this District, and it is reasonable to expect that such products will continue to enter and be used by consumers in Florida, including in this District.

### GENERAL ALLEGATIONS

11. Apotex Inc. is the lawful owner by assignment of all right, title and interest in United States Patent No. 6,767,556 ("the '556 Patent") entitled "Pharmaceutical Compositions Comprising Moexipril Magnesium," relating to, *inter alia*, processes for making solid pharmaceutical compositions comprising moexipril magnesium made by reacting moexipril or an acid addition salt thereof with an alkaline magnesium compound in the presence of a solvent so as to convert the moexipril or moexipril acid addition salt to moexipril magnesium. Claims 1-15 claim such processes.

12. The '556 Patent was duly and lawfully issued by the U.S. Patent and Trademark Office on July 27, 2004. A true and correct copy is attached hereto as **Exhibit 1**.

13. Apotex Corp. is the exclusive licensee of the '556 Patent.

14. Apotex Inc. manufactures generic moexipril tablets for Apotex Corp. by a process described and claimed in the '556 Patent.

15. Apotex Corp. imports generic moexipril tablets from Apotex, Inc. Such generic moexipril tablets are approved by the U.S. Food and Drug Administration ("FDA") to treat hypertension when administered alone or in combination with thiazide diuretics. Apotex Corp. sells and has sold such FDA-approved moexipril tablets in and throughout the United States.

16. Defendants, directly or by and/or through their agents, manufacture, import, offer for sale, sell, and/or use tablets made by a process that is covered by claims 1-15 of the '556 Patent.

#### Moexipril Product

17. Paddock Laboratories, Inc. ("Paddock Inc.") received approval from the FDA for Abbreviated New Drug Application No. 077536 to market and sell generic moexipril hydrochloride products ("Paddock's Moexipril Product") in the United States. On information and belief, Paddock LLC products will be converted to the Perrigo brand over the next several months. According to the product label, Paddock LLC's Moexipril Product contains moexipril hydrochloride, magnesium oxide, and magnesium stearate. However, testing of the Paddock LLC's Moexipril Product demonstrates that it contains moexipril magnesium, which is an indication that Paddock LLC's Moexipril Product is made by a process covered by claims 1-15 of the '556 patent. However, Paddock LLC's exact process is not publicly available. After an opportunity for discovery, there is likely to be evidence that the process used to manufacture Paddock LLC's Moexipril Product comprises reacting moexipril or an acid addition salt thereof with an alkaline magnesium compound in the presence of a solvent so as to convert the moexipril

or moexipril acid addition salt to moexipril magnesium, which process is covered by the '556 patent.

Moexipril Combination Product

18. Paddock Inc. also received approval from the FDA for Abbreviated New Drug Application No. 090096 to market and sell generic moexipril hydrochloride and hydrochlorothiazide products ("Paddock's Moexipril Combination Product") in the United States. On information and belief, Paddock LLC products will be converted to the Perrigo brand over the next several months. According to the product label, Paddock LLC's Moexipril Combination Product contains moexipril hydrochloride, magnesium oxide, and magnesium stearate.

19. Apotex is presently not aware of any analytical technique that can be used to *definitively* establish that Paddock LLC's Moexipril Combination Product was made by use of one or more processes claimed in the '556 Patent. However, based on analytical studies available to it, Apotex believes that Defendants are likely practicing processes covered by the claims of the '556 Patent. Apotex resorts to the judicial process and the aid of discovery to determine under appropriate judicial safeguards the exact processes used by Defendants to manufacture Paddock LLC's Moexipril Combination Product and confirm its belief that Defendants infringe one or more claims of the '556 Patent.

**COUNT I**  
**INFRINGEMENT OF THE PROCESS CLAIMS OF U.S. PATENT NO. 6,767,556**  
**(MOEXIPRIL PRODUCT)**

20. The allegations of paragraphs 1-19 are realleged and incorporated herein by reference.

21. Upon information and belief, which is likely to be substantiated through discovery, Defendants have infringed one or more of claims 1-15 of the '556 Patent by using a process covered by those claims to manufacture products, including Paddock LLC's Moexipril Product, and or by importing, selling and/or offering for sale the products of such process into the United States in violation of 35 U.S.C. §271 (a) and/or (g).

**COUNT II**  
**INFRINGEMENT OF THE PROCESS CLAIMS OF U.S. PATENT NO. 6,767,556**  
**(MOEXIPRIL COMBINATION PRODUCT)**

22. The allegations of paragraphs 1-19 are realleged and incorporated herein by reference.

23. Upon information and belief, which is likely to be substantiated through discovery, Defendants have infringed one or more of claims 1-15 of the '556 Patent by using a process covered by those claims to manufacture products, including Paddock LLC's Moexipril Combination Product, and or by importing, selling and/or offering for sale the products of such process into the United States in violation of 35 U.S.C. §271 (a) and/or (g).

**RELIEF REQUESTED**

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against each Defendant and grant the following relief:

- a. A judgment and decree that the '556 Patent is valid and enforceable;
- b. A judgment and decree that each Defendant has infringed the '556 Patent in violation of 35 U.S.C. § 271;
- c. A preliminary and permanent injunction, pursuant to 35 U.S.C. § 283, enjoining each Defendant and their officers, agents, employees and all others in concert or participation with them from acts of infringement of the '556 Patent;

- d. An Order, pursuant to 35 U.S.C. § 284, awarding Plaintiffs damages adequate to compensate for Defendants' infringement of the '556 Patent, in an amount to be determined at trial, but in no event less than a reasonable royalty; and
- e. Such other and further relief that the Court may deem just and proper.

**JURY DEMAND**

Apotex demands a trial by jury.

Dated: July 27, 2012

Respectfully submitted,

/s/ Matthew S. Nelles  
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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 27th day of July 2012, I electronically filed the foregoing Second Corrected Complaint with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record on the service list below via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

/s/ Matthew S. Nelles  
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