EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
CASE NO. 12-60706-CIV-MIDDLEBROOKS/BRANNON

APOTEX, INC. and APOTEX CORP.,

Plaintiffs,

v.

UCB, INC., SCHWARZ PHARMA, INC., and KREMERS URBAN PHARMACEUTICALS, INC.,

Defendants.

UCB, INC. AND KREMERS URBAN PHARMACEUTICALS, INC.'S MOTION TO DISMISS PLAINTIFFS' COMPLAINT PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6) AND SUPPORTING MEMORANDUM OF LAW

Defendants, UCB, Inc. and Kremers Urban Pharmaceuticals, Inc. (collectively, "UCB"), pursuant to Federal Rule of Civil Procedure 12(b)(6), move to dismiss the Complaint of Plaintiffs, Apotex, Inc. and Apotex Corp. (collectively, "Apotex"). Apotex alleges that UCB's manufacture and sale of Univasc® and Uniretic® hypertension medications infringe U.S. Patent No. 6,767,556 (the "'556 patent"). Apotex's Complaint fails to state a claim on which relief can be granted, and the Court should dismiss it.[1]

I. PRELIMINARY STATEMENT

To obtain the '556 patent, Apotex made a series of statements to the United States Patent and Trademark Office (USPTO) that, as a matter of law, preclude a finding of infringement against UCB. The '556 patent claims a process for making a stable pharmaceutical composition

[1] Schwarz Pharma, Inc. ("Schwarz"), named as a party in the lawsuit, merged into UCB, Inc. on or about December 2010 and is no longer a distinct legal entity. For purposes of this motion, UCB, Inc. shall include Schwarz Pharma, Inc.

containing the ACE-inhibitor moexipril, which has long been known as useful in the treatment of hypertension. Indeed, UCB's Univasc® and Uniretic® hypertension medications, which contain moexipril, had been on the market for years before Apotex filed the application that issued as the '556 patent. In the patent application itself, Apotex stated that its claimed process was significantly different from, and patentable over, the process for making Univasc®, which Apotex identified by name. So sure was Apotex of the difference – in Apotex's process, moexipril is "reacted" with a magnesium stabilizing compound, whereas in the Univasc® process, moexipril is merely "combined" with such a compound – that it repeated its argument throughout prosecution of the patent application, identifying Univasc® by name on each occasion. Without these arguments, the '556 patent would not have issued.

Apotex's public-record statements amount to prosecution disclaimer, a fundamental, logical doctrine under which subject matter that the patentee has distinguished from its claims – in this case the Univasc® process – cannot later be held to infringe those claims. The Univasc® process has not changed since Apotex disclaimed it. Apotex's allegations therefore cannot state a claim for infringement, and, for this reason alone, the Court should dismiss Apotex's Complaint. In addition, if the Univasc® process did somehow infringe any claims of the '556 patent, those claims would be invalid, because the Univasc® process was in the prior art, as Apotex acknowledged in attempting to distinguish it. Apotex would not be entitled to relief in that case, either.

II. STATEMENT OF FACTS

The primary facts come from the Complaint, the '556 patent (attached to the Complaint), and the relevant portions of the prosecution history of the '556 patent, which is an undisputed public record and central to the allegations. The Court may consider this material without converting this motion into a motion for summary judgment. See Horsley v. Feldt, 304 F.3d

1125, 1134 (11th Cir. 2002). If the Court does elect to convert this motion pursuant to Federal Rule of Civil Procedure 12(d), however, UCB submits that summary judgment in its favor is appropriate for the same reasons that support dismissal.

A. UCB's Univasc® and Uniretic® Products, Which Apotex Accuses of Infringement, Have Been on the Market in the United States for Nearly Two Decades

Long before Apotex filed the application that eventually resulted in the '556 patent, Schwarz Pharma, Inc. ("Schwarz") began selling Univasc® tablets in the United States pursuant to New Drug Application (NDA) No. 20-312, which was approved by the United States Food and Drug Administration (FDA) on April 19, 1995. ('556 patent, col. 2, ll. 16-22; Compl. ¶ 18; Declaration of Jeff Siefert ("Siefert Decl."), attached hereto as **Exhibit A**, ¶ 4.) UCB currently owns the NDA and sells Univasc® in the United States, through a recent merger with Schwarz. (Compl. ¶¶ 7-8, 18.)

The active ingredient in Univasc® is moexipril hydrochloride, which is among a class of compounds known as "ACE inhibitors" that are useful as antihypertensives. (See Product label for Univasc® ("Product Label")[2] attached hereto as **Exhibit B**; '556 patent, col. 1, ll. 12-16.) The current manufacturing process for Univasc® is the same as when it was approved by the FDA. (Siefert Decl. ¶ 4.) The process has not changed during that time, except to accommodate for differences in scale. (Id.)

UCB also sells Uniretic® tablets in the United States, pursuant to NDA No. 20-729. (Compl. ¶ 23.) Uniretic®, like Univasc®, contains moexipril hydrochloride as an active ingredient. (Id.) Although Uniretic® includes an additional ingredient, hydrochlorothiazide, the

[2] In its Complaint, Apotex refers to the publicly available Product Label and relies on information contained therein. (Compl. ¶ 18.) The Product Label is thus central to Apotex's allegations and is incorporated by reference into the Complaint. See Horsley, 304 F.3d at 1134.

manufacturing process for Uniretic® is the same as that for Univasc® with respect to the moexipril active ingredient, and it has not changed over time except to accommodate for difference in scale. (Siefert Decl. ¶ 5.)

Kremers Urban Pharmaceuticals, Inc. ("Kremers") manufactures all Univasc® and Uniretic® products sold in the United States pursuant to their respective NDAs. (Siefert Decl. ¶ 6.) Kremers also manufactures and sells a generic version of Univasc®. (Compl. ¶ 20.) There are other generic versions of Univasc® on the market, as well. For example, in a related Complaint filed in this District, Apotex has sued Paddock Laboratories, Inc. and Perrigo Company (collectively, "Paddock") for infringement of the '556 patent based on Paddock's generic version of Univasc®. (Apotex, Inc., et al. v. Paddock Laboratories, Inc., et al., Case No. 12-60707-CIV-MOORE (S.D. Fla. Apr. 20, 2012)). Indeed, Apotex itself sells a generic version of Univasc®. (Compl. ¶ 16.)

B. The '556 Patent Issued Nearly 10 and 7 Years, Respectively, After Univasc® and Uniretic® Entered the Market

In 2001, long after Univasc® and Uniretic® had entered the market, Apotex filed a patent application in which it claimed an allegedly novel process for making a more stable pharmaceutical formulation of moexipril. The application was granted in July 2004 and issued as the '556 patent. Claim 1 of the '556 patent is the only independent claim:

> "A process of making a solid pharmaceutical composition comprising moexipril magnesium, said process comprising the step of reacting moexipril or an acid addition salt thereof with an alkaline magnesium compound in a controlled manner in the presence of a sufficient amount of solvent for a predetermined amount of time so as to convert greater than 80% of the moexipril or moexipril acid addition salt to moexipril magnesium."

('556 patent, col. 6, ll. 24-31.)

C. Apotex Disclaims the Univasc® Process From the Scope of Its Claimed Invention on the First Page of the '556 Patent

The object of the '556 patent is to "enable a stable composition comprising a moexipril salt." ('556 patent col. 2, l. 41.) In the patent, Apotex states that some ACE inhibitors, including moexipril, are "susceptible to degradation by cyclization, hydrolysis or oxidation" ('556 patent, col. 1, ll. 12-15), and "various methods of improving the stability of these compounds are disclosed in the prior art." ('556 patent, col. 1, ll. 21-22.) The specification describes those prior art methods, including the manufacturing process for Univasc®, which Apotex identifies by name:

> "Tablets containing moexipril hydrochloride are sold in the United States and elsewhere under the tradename Univasc® by Schwarz Pharma. The labeling of these tablets indicates that the tablets contain moexipril hydrochloride and magnesium oxide. This indicates that these tablets are compositions in accordance with the teaching of U.S. Pat. No. 4,743,450."

('556 patent, col. 2, ll. 16-22.) In the '556 patent, Apotex admits that U.S. Patent No. 4,743,450 (the "'450 patent") is prior art with respect to the claimed invention. ('556 patent, col. 1, ll. 24-27, 48-56.) The '450 patent, which issued in 1988, discloses stabilized compositions of ACE inhibitors, including quinapril hydrochloride. ('556 patent, col. 1, ll. 48-55.) Schwarz listed the '450 patent in an FDA publication known as Approved Drug Products with Therapeutic Equivalents Evaluations ("Orange Book") for Univasc®. By listing the '450 patent in the Orange Book, Schwarz indicated to the public that the '450 patent claims Univasc® and/or a method of using Univasc®. See 21 U.S.C. § 355(b).

Apotex thus specifically identifies Univasc® as an example of a product made by a process disclosed in the prior art; that is, by a process that is necessarily different from the one Apotex claims in the '556 patent. ('556 patent, col. 2, ll. 16-22.) Apotex then describes "certain problems inherent" in the prior art '450 patent ('556 patent, col. 2, l. 23), and concludes that its

own invention, that of the '556 patent, "overcomes these limitations of the prior art." ('556 patent, col. 2, l. 42.) Specifically, Apotex solved the alleged prior art stability problem by "reacting the moexipril or acid addition salt with an alkaline magnesium compound, so as to convert most or all (i.e. more than half) of the moexipril or acid addition salt to moexipril magnesium." ('556 patent, col. 2, ll. 53-56.) In the prior art processes, including the one used to make Univasc®, Apotex explains that moexipril is stabilized by the mere presence of the alkaline compound in the final composition, but that no reaction of the two occurs. ('556 patent, col. 2, ll. 12-15.)

D. Apotex Repeatedly Disclaimed the Univasc® Process From the Scope of Its Claimed Invention During Prosecution of the Application that Led to the '556 Patent

To obtain its patent, Apotex distinguished its claimed process from the prior art on several occasions, in response to rejections by the USPTO. As in the patent specification, Apotex's primary argument during prosecution was that in its process, moexipril was "reacted" with an alkaline magnesium compound (a stabilizer), in the presence of a solvent, causing conversion of moexipril into moexipril magnesium, whereas in prior art processes moexipril was merely "combined" or "contacted" with an alkaline magnesium compound, without a reaction and conversion. (See, e.g., Amendment & Remarks dated February 11, 2004 ("Feb. 2004 Amendment"), attached hereto as **Exhibit C**, at 9.) Also as in the patent specification, one of the prior art processes from which Apotex distinguished its claimed invention was the process for making Univasc®. Id. at 16-17.

In an office action dated March 21, 2002, the Examiner rejected the claims in Apotex's application as obvious in view of the '450 patent. (Office Action dated March 21, 2002, attached hereto as **Exhibit D**, at 3.) In response, Apotex argued that Univasc® tablets – as an embodiment of the prior art '450 patent – merely "include magnesium oxide, unreacted but

combined and functioning as a stabilizer." (Amendments & Remarks dated September 18, 2002 ("Sept. 2002 Amendment"), attached hereto as **Exhibit E**, at 11.) In the same response, Apotex again identified Univasc® as an example of a product made by a prior art process, referring to "the product monograph of the moexipril hydrochloride tablets manufactured by Schwarz Pharma [Univasc®]," and explained that the claimed process "is not 'combining' but is 'reacting' the active and the agents to result in the moexipril magnesium." (Id. at 12-13.) Twice in the same response, therefore, Apotex identified the Univasc® process by name, argued that it exemplified a prior art process that differed from its claimed invention, and identified the critical difference: reaction rather than combination of moexipril with a magnesium compound. Id.

Apotex reinforced this difference in subsequent arguments in favor of patentability. In a response to the Examiner's rejection of the claims over the '450 patent in combination with another prior art reference, Apotex again referred to the Product Monograph for Univasc®, "wherein the tablets marketed by Schwarz Pharma…include magnesium oxide, **unreacted but combined** and functioning as a stabilizer (see first page)." (Amendments & Remarks dated June 11, 2003, attached hereto as **Exhibit F**, at 7 (emphasis in original).)

In its next response, following a rejection over the same prior art, Apotex similarly argued that:

> Even if one skilled in the art were to combine Gu et al with Harris [the '450 patent] they would arrive at moexipril hydrochloride which is stabilized by an alkaline agent and preferably magnesium oxide as per the product monograph of the moexipril hydrochloride tablets manufactured by Schwarz Pharma attached in the prior Information Disclosure Statement provided. Applicant is not 'combining' but is 'reacting' the active and the agents to result in the moexipril magnesium.

(Feb. 2004 Amendment at 16-17 (emphasis added).) To support its arguments, Apotex submitted the declaration of Dr. Michael Mantle Lipp, a Chemical Engineering Ph.D, to the

USPTO and quoted extensively from the declaration throughout its response. For example, Apotex quoted Dr. Lipp's conclusion:

> "[N]either of the references, Gu et al. [or] Harris [the '450 patent] et al., make obvious the inventions of the '173 patent application. As I described above, neither of these references teaches or makes obvious a process for the conversion of moexipril hydrochloride to moexipril magnesium via a reaction with an alkaline magnesium compound for the purpose of increased stability."

(Id. at 18.)

Following these remarks, the Examiner allowed the claims. (See Notice of Allowability dated April 7, 2004, attached hereto as **Exhibit G**, at 3.) In short, Apotex was able to secure its patent only by repeatedly emphasizing a fundamental difference between its claimed invention and the Univasc® process.

III. ARGUMENT

The Court should dismiss Apotex's Complaint for failure to state a claim, because, given Apotex's repeated, explicit disclaimers of subject matter, UCB's manufacture and sale of Univasc® and Uniretic® cannot infringe the '556 patent as a matter of law. A complaint shall be dismissed where it "fail[s] to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Dismissal is warranted when, after accepting the nonmovant's allegations as true and viewing the facts in the light most favorable to the nonmoving party, the nonmovant has failed to state a claim that is "plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). In making this determination, the Court should not consider allegations that are merely legal conclusions. Ashcroft v. Iqbal, 556 U.S. 662, 678-79 (2009). Courts, including this one, will dismiss a complaint under Rule 12(b)(6) if the patentee cannot state a claim for infringement as a matter of law. Desenberg v. Google, Inc., 392 F. App'x 868, 871 (Fed. Cir. 2010) (affirming dismissal of complaint where defendant did not itself perform all steps of patented method and thus could not infringe as a matter of law); Corebrace LLC v. Star Seismic LLC, 566

F.3d 1069, 1075 (Fed. Cir. 2009) (valid license precluded infringement claim); Moody v. Morris, 608 F. Supp. 2d 575, 579 (S.D.N.Y. 2009) (dismissing complaint where a "fundamental difference" between accused product and claimed invention meant no infringement was possible); Global Patent Holdings, LLC v. Panthers BRHC LLC, 586 F. Supp. 2d 1331, 1335-36 (S.D. Fla. 2008) (divided infringement theory precluded relief against accused infringer and required dismissal as matter of law).

In the specification of the '556 patent, and during prosecution of the application leading to it, Apotex unequivocally disclaimed the manufacturing process for Univasc® from the scope of the claimed invention, making it repeatedly clear that Apotex understood from the start that its invention could not cover the Univasc® process. As a result of this disclaimer, the Univasc® process cannot infringe the '556 patent as a matter of law. If the Univasc® process did infringe the claims of the '556 patent, moreover, the claims would be invalid because, as Apotex conceded in the '556 patent itself and throughout prosecution, the Univasc® process was in the prior art. Accordingly, Apotex cannot state a claim on which relief can be granted, and the Court should dismiss its Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

A. UCB's Manufacture and Sale of Univasc® and Uniretic® Cannot Infringe the '556 Patent, Because Apotex Disclaimed Their Manufacturing Process from the Scope of the '556 Claims

In the '556 patent itself, as well as during prosecution, Apotex consistently disclaimed the Univasc® process from the scope of the '556 patent.

1. Statements in the '556 patent constitute disclaimer of the Univasc® process

Where the specification of a patent contains "an intentional disclaimer, or disavowal, of claim scope by the inventor," the inventor's statement is dispositive and the patent cannot be construed to cover the disclaimed subject matter. Phillips v. AWH Corp. 415 F.3d 1303, 1316 (Fed. Cir. 2005). For example, "[w]here the specification makes clear that the invention does not

include a particular feature, that feature is deemed to be outside the reach of the claims of the patent…." SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed. Cir. 2001). If the patent specification discusses disadvantages associated with the prior art and distinguishes the claimed invention on that basis, the court must find that the claimed invention does not encompass the distinguished prior art. Id. at 1342-43; Tronzo v. Biomet, Inc., 156 F.3d 1154, 1159 (Fed. Cir. 1998). In SciMed, the specification of the patent at issue stated that prior art catheters with shortened guide wires suffered from several disadvantages due to a "dual lumen configuration." Id. at 1342. After describing these disadvantages in detail, the specification pointed out the advantages of "coaxial lumens" used in the catheters of the claimed invention. Id. at 1343. Based on these statements, the Federal Circuit held that the patentee disclaimed the dual lumen configuration and that "the claims should not be read so broadly as to encompass the distinguished prior art structure." Id. at 1340, 1343.

As described in detail above (Section II.C), in the specification of the '556 patent, Apotex distinguishes the manufacturing process for Univasc® from the claimed invention, and also touts the advantages of its own invention in comparison. Having identified Univasc® tablets, by name, as an example of products made in accordance with the teachings of the prior art, including the '450 patent ('556 patent, col. 2, ll. 16-22), Apotex then describes certain problems with the prior art processes ('556 patent, col. 2, ll. 23-39), and claims that its invention "overcomes these limitations" by "reacting" moexipril hydrochloride so as to "convert" it to moexipril magnesium. ('556 patent, col. 2, ll. 40-56.) These steps, Apotex explains, do not take place in the Univasc® process. ('556 patent, col. 2, ll. 16-22, 47-56.) Accordingly, Apotex disclaimed the Univasc® process from the scope of the '556 patent claims. See SciMed, 242 F.3d at 1342-43.

The manufacturing process for Univasc® has not changed since it was approved in 1995. (Siefert Decl. ¶ 4.) Therefore, Apotex's disclaimer regarding the prior art Univasc® process applies to all Univasc® products sold in the United States since it was approved. With respect to moexipril, the manufacturing process for Uniretic® is the same as that for Univasc®, and this process has not changed since Uniretic® was approved. (Siefert Decl. ¶ 5.) On the basis of specification-based disclaimer alone, the Court should dismiss Apotex's Complaint for failure to state a claim on which relief can be granted. See Desenberg, 392 F. App'x at 871-72 (affirming dismissal of complaint where patentee could not state a claim for infringement against defendant).

2. The prosecution history of the '556 patent reaffirms that Apotex disclaimed the Univasc® and Uniretic® processes

The well-established doctrine of prosecution disclaimer "preclud[es] patentees from capturing through claim interpretation specific meanings disclaimed during prosecution." Omega Engineering, Inc. v. Raytec Corp., 334 F.3d 1314, 1323 (Fed. Cir. 2003), citing Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211 (1940). In particular, "where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." Omega Engineering, Inc., 334 F.3d at 1324; see also Mintz v. Dietz & Watson, Inc., 679 F.3d 1372, 1382 (Fed. Cir. 2012); Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1379 (Fed. Cir. 2008) ("[patentee] cannot recapture claim scope disavowed during prosecution to prove infringement"). Courts should consider "the entire prosecution history, which includes amendments to claims and all arguments to overcome and distinguish references." Seachange Int'l, Inc. v. C-COR Inc., 413 F.3d 1361, 1372 (Fed. Cir. 2005).

In Computer Docking Station, the Court held that by repeatedly distinguishing prior art laptop computers from the claimed "portable computer," patentee had disclaimed such laptops and, as a result, defendant's accused laptops could not infringe. Computer Docking Station, 519 F.3d at 1379. In Omega, patentee "repeatedly insisted [during prosecution] that its invention differed from the prior art," arguing, for example, that "the clear advantage offered by [the claimed invention] is that it only directs energy at the edge of the energy zone to be measured to outline same and, as such, has virtually no effect on the temperature measurement to be taken. Such a concept is neither taught nor suggested in [the prior art]." Omega, 334 F.3d at 1327. By making such arguments, the Federal Circuit held that patentee "stated in a public record what his invention could not be," id. at 1326 (emphasis added), and, as a result, made a "deliberate surrender of claim scope." Id. at 1327.

Likewise, in Seachange, the Federal Circuit reversed a district court's finding of infringement after concluding that the patentee made a "deliberate surrender of claim scope" during prosecution. Seachange, 413 F.3d at 1375. In that case, the patentee had argued that the prior art did not suggest certain elements of the claimed invention ("point-to-point two-way channel interconnections") and, therefore, did not render the claimed invention obvious. Id. at 1370-71. The Court concluded that patentee's arguments narrowed the claimed invention and precluded the patentee from construing the claims inconsistent with the disavowal. Id. at 1374. As a result, the Court held that the accused products did not infringe the patent, because they lacked the key element relied upon by patentee to distinguish the claimed invention from the prior art. Id. at 1378. In Mintz, patentee had added a limitation to the claims in order to distinguish its invention from certain prior art structures. Patentee simultaneously argued that the prior art lacked the newly introduced "intersecting in locking engagement" claim limitation

and so did not render the claimed invention obvious. Id. at 1377. The Court concluded that the accused products did not infringe because, like the prior art structures, they lacked the added claim limitation. Id. at 1381-82.

Apotex's infringement allegations are similarly barred by the doctrine of prosecution disclaimer. In fact, Apotex was clearer in its disclaimers than patentees were in Omega, Seachange, and Mintz, because Apotex distinguished its claimed invention not only from prior art concepts, but from the specific, identified Univasc® process. As detailed above, on three different occasions Apotex argued that its claimed process was non-obvious over prior art processes, identifying Univasc® by name as an example of a product made by such processes on each occasion. (See Section II.D above.) Apotex also submitted and directed the Examiner's attention to the Product Monograph for Univasc®, in support of its argument that the prior art processes resulted in products in which moexipril and a stabilizing magnesium compound were merely combined, rather than "reacted" and converted into moexipril magnesium, as in Apotex's claimed invention. Id. Apotex repeated this specific argument later as well, supporting it with the declaration of a chemical engineer that detailed the technical differences between the prior art Univasc® process and the claimed process. Id.

By repeatedly emphasizing the fundamental difference between the claimed invention and the Univasc® process – "reacting" moexipril hydrochloride with an alkaline magnesium compound so as to "convert" it to moexipril magnesium – Apotex relinquished any right to assert the '556 patent against that same Univasc® process. Omega, 334 F.3d at 1326-27. Apotex's arguments to the Examiner during prosecution represent an unambiguous general disclaimer of any process that lacks "reacting" moexipril hydrochloride in a "controlled" manner, and a specific disclaimer of the Univasc® process. See Mintz, 679 F.3d at 1381-82.

The Court should dismiss Apotex's Complaint for failure to state a claim because the doctrine of prosecution disclaimer precludes a finding that the Univasc® and Uniretic® processes infringe the claims of the '556 patent.

B. Even If The Univasc® and Uniretic® Processes Did Infringe the '556 Patent, The Court Should Dismiss the Complaint for Failure To State a Claim Because the '556 Patent Would Then Be Invalid

If the Univasc® process does fall within the scope of the '556 patent, then the patent is invalid, because, as Apotex conceded in the patent and its prosecution history, the Univasc® process was prior art to Apotex's invention. A person is entitled to a patent unless "before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g). Therefore, if a product or process accused of infringing a patent is found in the prior art, the patent is invalid. Upsher-Smith Labs., Inc. v. Pamlab, LLC, 412 F.3d 1319, 1322 (Fed. Cir. 2005) ("[that] which would literally infringe if later in time anticipates if earlier").

This is a principle with which Apotex should be especially familiar. In Apotex USA, Inc. v. Merck & Co., 254 F.3d 1031 (Fed. Cir. 2001), a case with remarkably similar facts, Apotex claimed to have invented a process for manufacturing stable enalapril sodium tablets, a product that Merck had been selling since long before Apotex had filed its patent application, and sued Merck for infringement. Id. at 1033-34. Because Merck's process was prior art to Apotex's claimed invention, Apotex could not establish that it both infringed the patent and that the patent was valid, and the Federal Court ultimately held that the patent was invalid. Id. at 1039-40. Apotex is in an identical position here: if the Univasc® process infringes the '556 patent, the patent is invalid, as in Merck.

Either the Univasc® and Uniretic® processes do not infringe the '556 patent, in light of Apotex's disclaimer, or they do infringe and the '556 patent is invalid. Because Apotex cannot obtain relief in either case, the Court should dismiss its Complaint.

IV. CONCLUSION

For the foregoing reasons, UCB respectfully requests that the Court dismiss Apotex's Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

Dated: June 29, 2012

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 29th day of June, 2012, I electronically filed the foregoing document 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 or pro se parties on the attached Service List 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 Notices of Electronic Filing.

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