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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC.,	:	
Plaintiffs,	:	
v.	:	
ELI LILLY AND COMPANY,	:	Case No. _____
Defendant.	:	

DR. REDDY'S LABORATORIES, LTD.'S AND
DR. REDDY'S LABORATORIES, INC.'S
COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") for their Complaint against Eli Lilly and Company allege as follows:

PARTIES

1. Plaintiff Dr. Reddy's Laboratories, Ltd. is an Indian corporation, with its principal place of business at 7-1-27, Ameerpet, Hyderabad, India.

2. Plaintiff Dr. Reddy's Laboratories, Inc. is a New Jersey corporation, with its principal place of business at 200 Somerset Corporate Boulevard, Bridgewater, New Jersey.

3. Upon information and belief, Defendant Eli Lilly and Company ("Lilly") is a corporation organized under the laws of the State of Indiana having its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture and sale of pharmaceutical products throughout the world.

INTRODUCTION

A. Summary of the Case

4. DRL filed an Abbreviated New Drug Application ("ANDA") to sell a generic version of Lilly's 90 mg fluoxetine delayed release capsules product, marketed by Lilly under the name Prozac® Weekly™. The ANDA number is 78-572.

5. In conjunction with the filing of ANDA No. 78-572, DRL filed "paragraph IV certifications" with respect to each of the patents which were and currently are listed in the "Approved Drug Products With Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book," with respect to Lilly's fluoxetine 90 mg delayed release capsules product. Those patents are U.S. Patent Nos. 5,910,319 ("the '319 patent"), 5,985,322 ("the '322 patent") and RE 39,030 ("the '030 patent").

6. As an ANDA filer, DRL was required to, and did provide Lilly with notice of the filing of its paragraph IV certifications with respect to the '319, '322 and '030 patents, and provided Lilly with a detailed statement of the factual and legal basis of DRL's positions that those patents were invalid, unenforceable, or will not be infringed by DRL's 90 mg fluoxetine delayed release capsules product.

7. DRL has received tentative approval from the U.S. Food and Drug Administration ("FDA") to sell its ANDA product, but cannot obtain final approval to do so until it obtains a court decision that its product does not infringe Lilly's patents or that Lilly's patents are invalid or unenforceable.

8. Specifically, the FDA has informed DRL that its ANDA will not be eligible for final approval until the date that is 180 days after the date the FDA receives notice, with respect to the ANDA which is blocking DRL, of the earlier of 1) the commercial marketing of that ANDA holder's product or 2) a court decision as to the '319, '322 and '030 patents.

9. This situation arises because of a prior settlement of patent litigation between Lilly and Barr Laboratories which has caused a bottleneck in the approval and sale of generic fluoxetine 90 mg delayed release capsules such as DRL's. Because of this roadblock, no generic company can sell a fluoxetine 90 mg product until either it obtains a court decision with respect to the '319, '322 and '030 patents or until after Barr begins selling its product. As a result of its deal with Lilly, Barr is not selling and, accordingly, DRL has no other option but to commence this declaratory judgment action to obtain the required court decision of non-infringement, patent invalidity or patent unenforceability which would then enable it to obtain FDA approval permitting it to sell its fluoxetine 90 mg delayed release product.

10. Even if Barr were to announce that it intended to launch its product prior to the time in which this case could be completed, this action would nonetheless still be required to enable DRL to obtain a decision of non-infringement, patent invalidity or patent unenforceability. Without such a decision, DRL would be at risk of substantial harm from a damages suit by Lilly upon DRL's launch of its fluoxetine 90 mg delayed release product prior to the expiration of the '030 patent. Congress enacted 21 U.S.C. § 355(j)(5)(C), entitled "civil

action to obtain patent certainty," to permit declaratory judgment suits in precisely this circumstance.

B. Background

11. DRL brings, and is entitled by statute to maintain, this action for declaratory judgment of patent non-infringement and invalidity under, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5), which are parts of the Hatch-Waxman Act amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2006 (2003) ("MMA").

12. Upon information and belief, Lilly is the holder of approved New Drug Application ("NDA") No. 21-235, and markets Prozac® Weekly™, known generically as fluoxetine hydrochloride 90 mg delayed release capsules, throughout the United States pursuant to NDA No. 21-235.

13. Upon information and belief, Lilly owns U.S. Patent Nos. 5,910,319 ("the '319 patent"), 5,985,322 ("the '322 patent") and RE 39,030 ("the '030 patent"). By virtue of patent information that Lilly submitted to the FDA in connection with NDA No. 21-235, the '319, '322 and '030 patents are listed in FDA's compilation of approved drugs and their respective patents entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book."

14. As a consequence of such Orange Book listing, Lilly has maintained and affirmatively represented to the world that the '319, '322 and '030 patents claim the approved drug Prozac® Weekly™, or a method of using that drug, and that a claim for patent infringement could reasonably be asserted against any generic ANDA applicant, including DRL, that attempts

to market a generic version of Prozac® Weekly™ before expiration of the '319, '322 and '030 patents.

15. The '030 patent is a re-issue of the '319 patent and therefore the '319 patent has been surrendered. Also, on January 25, 2002, Lilly seems to have disclaimed all claims of the '322 patent. Nevertheless, the '319 and '322 patents continue to be listed in the Orange Book for Prozac® Weekly™.

16. As evidence of Lilly's desire to enforce its patents, Lilly previously filed a lawsuit in the U.S. District Court for the Southern District of Indiana entitled *Eli Lilly & Company v. Barr Laboratories, Inc.*, Case No. 1:06-cv-0741-LJM-JMS ("the *Lilly-Barr* litigation") against one such generic ANDA applicant.

17. In the *Lilly-Barr* litigation, Lilly alleged that there existed "a real, substantial and justiciable controversy between Lilly and Barr" and sought, *inter alia*, a declaratory judgment that the '030 patent was valid, enforceable and infringed by Barr's ANDA product. (*See* Docket # 1, ¶ 29, Relief Requested (A), (B).)

18. DRL seeks to market a generic version of Prozac® Weekly™ before expiration of the '319, '322 and '030 patents. Therefore, as required by the FFDCA, DRL has submitted an ANDA and certified to the FDA that its ANDA product will not infringe any claim of the '319, '322 or '030 patents and/or that those patents are invalid or unenforceable, and has further notified Lilly of the legal and factual basis for that certification. DRL's submission of the so-called "paragraph IV certifications" to the '319, '322 and '030 patents constitutes an artificial act of patent infringement putting DRL at considerable risk of being sued by Lilly both before and after DRL's market entry.

19. DRL has satisfied all substantive requirements for approval of its ANDA and is prepared to begin commercial marketing of its competing generic fluoxetine delayed release product promptly and well prior to the expiration of the '319, '322 and '030 patents. However, DRL is being excluded from selling its generic 90 mg fluoxetine delayed release capsules, notwithstanding that its product does not infringe any valid or enforceable claim of the '319, '322 or '030 patents, because Lilly has entered into a settlement agreement with Barr which has delayed and will further delay FDA approval of DRL's ANDA.

20. Upon information and belief, Barr is eligible for a blocking period of 180-day marketing exclusivity beginning either from the date it begins commercial marketing of its generic drug product, or from the date of a court decision finding the Orange Book-listed patent invalid, unenforceable or not infringed, whichever date is first.

21. By virtue of Lilly's choice to sue Barr only on the '030 patent and the settlement agreement between Lilly and Barr, no court decision has ever been or will be reached as to any of the '319, '322 and '030 patents. DRL is thus blocked from the market.

22. A declaratory judgment from this Court as to the validity, enforceability and/or non-infringement of the '319, '322 and '030 patents will alleviate DRL's harm by allowing DRL to obtain final approval of its ANDA product and compete in the market for fluoxetine 90 mg delayed release capsules.

23. Moreover, unless DRL obtains a court order finding the '030 patent invalid, unenforceable and/or not infringed, DRL will be unable to market its generic product prior to patent expiration without fear of suit. Only a declaratory judgment from this Court can alleviate this harm and allow DRL to obtain approval of its ANDA product and compete in the market for fluoxetine 90 mg delayed release capsules free from such potential liability.

24. Were it not for the bottleneck which prevents DRL from obtaining final approval, Lilly would likely have sought to assert its patent rights against DRL. In fact, there is a substantial threat of future litigation at least with respect to the '030 patent which Lilly has previously asserted in prior litigation. DRL should be able to avoid any potential liability for infringement by obtaining a declaratory judgment of non-infringement or invalidity and thus reach the market free from such potential liability.

25. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between DRL and Lilly regarding the validity, enforceability and infringement of the '030 patent over which this Court can and should exercise jurisdiction and declare the rights of the parties.

26. DRL is entitled by law to bring and maintain this action for declaratory judgment of patent non-infringement, unenforceability and/or invalidity under the Declaratory Judgment Act and the MMA where, as here, Lilly did not sue DRL within 45 days of receipt of DRL's notice of paragraph IV certification as to the '319, '322 and '030 patents, and DRL provided Lilly an Offer of Confidential Access to DRL's ANDA for its generic fluoxetine 90 mg delayed release capsule product.

27. DRL is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of DRL's proposed generic fluoxetine 90 mg delayed release capsule product does not and will not infringe any valid or enforceable claim of the '319, '322 and '030 patents.

28. Absent the exercise of jurisdiction by this Court and such declaratory relief, DRL and the American public will be irreparably harmed by the substantial delay in the market entry and availability of lower-priced generic Prozac® Weekly™.

JURISDICTION AND VENUE

29. DRL realleges and incorporates by reference each of the allegations of paragraphs 1-28.

30. A substantial, present, genuine and justiciable controversy exists between DRL and Lilly with respect to each of the '319, '322 and '030 patents.

31. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the MMA, 28 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5).

32. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because this action involves substantial claims arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.*; under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because it is an actual controversy concerning the '319, '322 and '030 patents; and under the MMA, 28 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5), because Congress has directed that district courts maintain and exercise jurisdiction in such cases.

33. This Court can and should declare the rights and legal relations of the parties regarding the '319, '322 and '030 patents pursuant to, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the MMA, 28 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5).

34. This Court has personal jurisdiction over Lilly, *inter alia*, because of Lilly's continuous and systematic contacts with the State of New Jersey, including its conducting of substantial and regular business therein through the marketing and sales of its pharmaceutical products in New Jersey, and because Lilly has availed itself of the jurisdiction of this Court by initiating litigation in this District. *See, e.g., Eli Lilly and Company v. Actavis Elizabeth LLC*,

No. 3:08-cv-06136-FLW-JJH, filed December 12, 2008; *Eli Lilly and Company v. Lupin Pharmaceuticals, Inc. et al.*, No. 03:08-cv-06139-FLW-JJH, filed December 22, 2008.

35. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) and/or 1400(b).

THE THREE PATENTS-IN-SUIT

36. The '319 patent, entitled "Fluoxetine Enteric Pellets and Methods For Their Preparation and Use" – a copy of which is attached as Exhibit A – issued on June 8, 1999, and is assigned on its face to Lilly. Upon information and belief, Lilly is the owner of the '319 patent. The '319 patent is currently listed in the Orange Book for Prozac® Weekly™.

37. The '322 patent, entitled "Fluoxetine Enteric Pelllets and Methods For Their Preparation" – a copy of which is attached as Exhibit B – issued on November 16, 1999, and is assigned on its face to Lilly. Upon information and belief, Lilly is the owner of the '322 patent. The '322 patent is currently listed in the Orange Book for Prozac® Weekly™.

38. The '030 patent, entitled "Fluoxetine Enteric Pellets and Methods For Their Preparation and Use," – a copy of which is attached as Exhibit C – issued on March 21, 2006 and is assigned on its face to Lilly. Upon information and belief, Lilly is the owner of the '030 patent. The '030 is currently listed in the Orange Book for Prozac® Weekly™.

39. Each of the three patents-in-suit is listed in the Orange Book as expiring on May 29, 2017.

THE CONTROVERSY BETWEEN DRL AND LILLY

The Hatch-Waxman Regulatory Framework

A. FDA Approval of New Drug Applications (NDAs).

40. Under the Hatch-Waxman Act, an applicant seeking to market a new brand-name drug must prepare an NDA for consideration by FDA. *See* 21 U.S.C. § 355.

41. An NDA must include, *inter alia*, the number of any patent that claims the "drug" or "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against a person not licensed by the owner of the drug who engaged in the manufacture, use or sale of that drug product. *See* 21 U.S.C. § 355(b)(1); *see also* 21 U.S.C. § 355(c)(2); 21 C.F.R. §§ 314.53(b), 314.53(c)(2).

42. Upon approval of the NDA, FDA publishes patent information for the approved drug in the Orange Book. *See* 21 U.S.C. § 355(j)(7)(A)(iii).

43. By filing an NDA and submitting a patent for listing in the Orange Book, the NDA-holder/patent owner, by law, necessarily maintains that the listed patent claims the approved drug, or a method of using that drug, and that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, use or sale of the drug, and, in particular, against any company seeking to make a generic bioequivalent of the NDA drug before patent expiration.

44. Thus, the NDA-holder/patent owner necessarily puts all prospective generic ANDA applicants on notice that a suit for infringement can and will be asserted against any ANDA applicant that attempts to seek approval for and market a generic bioequivalent of the NDA drug before patent expiration.

45. Such conduct by the NDA-holder/patent owner gives rise to a real and concrete belief on the part of the generic applicant that it will face an infringement suit if it markets a generic version of the NDA drug before patent expiration.

B. Generic Competition – Abbreviated New Drug Applications (ANDAs).

46. Generic drugs are versions of brand-name drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients, as the brand-name original.

47. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 217(e)). Among the purposes for which Congress passed the Hatch-Waxman Act were to expedite the approval of generic drugs and to decrease the cost of pharmaceuticals for the American public through increased competition.

48. To receive approval of its ANDA, an applicant must show, *inter alia*, that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

49. An ANDA must also contain a "certification" to each patent that the NDA holder has submitted to FDA for listing in the Orange Book in connection with the listed reference drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

50. A so-called "paragraph IV" certification asserts that the listed patent is invalid, unenforceable and/or will not be infringed and, on that basis, seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

51. The submission of a paragraph IV certification has two important consequences.

52. First, a generic applicant that is first to submit a substantially complete ANDA containing a paragraph IV certification to a listed patent ("the first ANDA filer" or "first-filer")

is entitled to 180 days of generic marketing exclusivity during which no other competing generic drug products may be marketed. 21 U.S.C. § 355(j)(5)(B)(iv). This statutory benefit to the first ANDA filer is commonly known as "180-day exclusivity."

53. In particular, the statutory provision of the FFDCA applicable here provides that "[i]f the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this section [containing] such a certification, the application shall be made effective not earlier than one hundred and eighty days after" the earlier of: (a) the first commercial marketing of that ANDA applicant's proposed drug; or (b) a court decision – whether it involves the first applicant or not – that the particular patent that is the subject of the paragraph IV certification is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv). Thus, unless a subsequent generic applicant can obtain a decision of non-infringement and/or invalidity as Congress intended, the approval of its ANDA can be delayed indefinitely by the purported exclusivity of the first-filer.

54. Second, the submission of a paragraph IV certification for an Orange Book-listed patent constitutes an artificial act of infringement that creates the necessary case or controversy and subject matter jurisdiction to enable the early resolution of an action for patent infringement – before the generic drug is actually made, used, or sold – to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

55. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and the NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

56. If the NDA holder/patent owner files an infringement suit within 45 days of receiving notice of the paragraph IV certification, the FDA is not permitted to issue final

approval of the generic applicant's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii); *see also* 35 U.S.C. § 271(c)(2)(A).

C. The ANDA-Filer May Bring a Declaratory Judgment Action.

57. The submission of a paragraph IV certification likewise creates the necessary case or controversy and subject matter jurisdiction for an ANDA applicant to file a declaratory judgment action against the NDA-holder/patent owner if the ANDA applicant is not sued on the listed patent within the applicable 45-day period.

58. Under the MMA, which was signed into law on December 8, 2003, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to institute and maintain a declaratory judgment action against an NDA-holder/patent owner if: (1) the 45-day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the NDA-holder brought an action for infringement of the patent within the 45-day period; and (3) the notice of paragraph IV certification contains an Offer of Confidential Access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)((I)(aa)-(cc).

59. Once these three conditions are met, the MMA explicitly provides that an ANDA applicant "may, in accordance with section 2201 of Title 28 [of the U.S. Code] bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II).

60. The new declaratory judgment provision contained in Section 1101 of the MMA, 117 Stat. 2066, 2454-56, applies to all ANDAs pending on or after December 8, 2003, which includes DRL's fluoxetine hydrochloride 90 mg ANDA.

61. Congress enacted this declaratory judgment provision to allow ANDA applicants to obtain court decisions that would expedite the introduction of generic drugs by allowing an ANDA applicant to obtain approval of its ANDA and to clear up any bottleneck in the market created by another applicant's 180-day exclusivity.

62. The Hatch-Waxman Act provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of marketing exclusivity beginning either from the date it begins commercial marketing of its generic drug product, or from the date of a court decision finding the listed patent invalid, unenforceable or not infringed, whichever date is first.

63. These two events – first commercial marketing and a court decision – are often called "triggering events" because they trigger the beginning of the 180-day exclusivity.

64. The 180-day exclusivity period begins to run when any ANDA applicant obtains a court decision of invalidity, unenforceability or non-infringement, even if the first-filer has not yet received approval for its ANDA, or before the first-filer has begun commercial marketing of its ANDA product. In that circumstance, some or all of the 180-day exclusivity period could expire without the first ANDA filer marketing its generic drug.

65. Conversely, if there is no court decision on an Orange Book-listed patent and the first-filer does not begin commercial marketing of the generic drug, there may be prolonged or indefinite delays in the beginning of the first applicant's 180-day exclusivity period.

66. Until an eligible first ANDA filer's 180-day exclusivity period has been triggered and expired, FDA cannot statutorily approve any subsequently-submitted ANDAs for the same drug, even if the subsequent ANDAs are otherwise ready for approval, a subsequent applicant is willing to begin marketing its generic drug product immediately and the generic drug product

does not infringe any Orange Book-listed patent for the brand-name drug product, and/or those Orange Book-listed patents are invalid or unenforceable.

67. Thus, the date on which the 180-day exclusivity period is triggered is critical both to NDA holders and to subsequent ANDA paragraph IV filers. Subsequent ANDA-filers have a strong economic incentive to generate a triggering event allowing the FDA to approve their ANDAs immediately following the expiration of the first-filer's exclusivity. In contrast, NDA holders have a strong economic incentive to prevent a triggering event, because no subsequent paragraph IV filer's ANDA can be approved until the first-filer's exclusivity has expired.

68. By specifically allowing declaratory judgment actions under these circumstances, Congress intended that full generic competition would not be delayed indefinitely, or blocked, by the first ANDA filer's 180-day exclusivity. A declaratory judgment action by a subsequent ANDA applicant can result in a court decision that would trigger the first-filer's 180-day exclusivity, thereby clearing the way for approval of the subsequent-filers' ANDAs.

69. Second, Congress intended to allow generic applicants to obtain patent certainty before marketing their generic products in order to avoid potentially catastrophic infringement damages. Accordingly, Congress mandated that an ANDA-filer is entitled to maintain a declaratory judgment action when it is not sued by the NDA holder/patent owner. 21 U.S.C. § 355(j)(5)(C).

DRL's ANDA NO. 78-572

A. DRL Has the Right to Bring a Declaratory Judgment Action on the '319, '322 and '030 patents.

70. DRL realleges and incorporates by reference each of the allegations of paragraphs 1-69.

71. DRL has filed an ANDA (No. 78-572) with FDA seeking approval for DRL's proposed 90 mg fluoxetine delayed release capsules ("DRL's ANDA product").

72. Lilly listed the '319, '322 and '030 patents in the Orange Book in connection with NDA 21-235 and the brand-name drug Prozac® Weekly™. Lilly's listing of the '319, '322 and '030 patents in the Orange Book alone objectively creates the necessary case or controversy and subject matter jurisdiction for an ANDA filer, such as DRL, that makes a paragraph IV certification as to the '319, '322 and '030 patents.

73. On January 16, 2008, DRL sent to Lilly a statutorily-required notice letter of its paragraph IV certification with respect to the '319, '322 and '030 patents together with a memorandum setting forth DRL's detailed factual and legal basis supporting its paragraph IV certification as to why the '319, '322 and '030 patents are invalid, unenforceable and/or not infringed by DRL's ANDA products.

74. In connection with the filing of its paragraph IV certification, DRL extended to Lilly an Offer of Confidential Access to certain information in DRL's ANDA in accordance with 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(cc) and (III).

75. Upon information and belief, Lilly received DRL's notice letter and detailed factual and legal basis supporting DRL's paragraph IV certification on or about January 25, 2008.

76. The 45-day period following Lilly's receipt of DRL's notice of Paragraph IV certification has expired.

77. Lilly has not sued DRL with respect to the '319, '322 or '030 patents.

78. By providing the Offer of Confidential Access and because Lilly did not sue DRL on the '319, '322 and '030 patents within 45 days of receipt of DRL's notice of paragraph IV

certification, DRL is statutorily entitled to file and maintain a declaratory judgment action against Lilly under 28 U.S.C. §§ 2201 and 2202 pursuant to 21 U.S.C. § 355(j)(5)(C).

B. The Harm to DRL Can Be Redressed by a Court Decision With Respect To the Patents-in-Suit.

1. The *Lilly-Barr* Litigation

79. DRL realleges and incorporates by reference each of the allegations of paragraphs 1-78.

80. DRL is not only entitled to bring and maintain this lawsuit, but requires a Court decision to avoid a lengthy delay in the approval of its ANDA No. 78-572 notwithstanding that its ANDA product does not infringe any valid or enforceable claim of any of the patents-in-suit.

81. Upon information and belief, DRL is not the first ANDA paragraph IV filer with respect to the '319, '322 or '030 patents.

82. Upon information and belief, Barr Laboratories, Inc. ("Barr") is the first ANDA paragraph IV filer with respect to each of the '319, '322 and '030 patents, and thus, arguably is entitled to a 180-day period of marketing exclusivity with respect to each of those patents.

83. Upon information and belief, Barr first notified Lilly of its paragraph IV certification with respect to the '319 patent on or about December 11, 2001.

84. Upon information and belief, on or about March 21, 2006, Barr filed a paragraph IV certification to the '030 patent as an amendment to its ANDA.

85. On May 10, 2006, Lilly filed a complaint against Barr in the Southern District of Indiana alleging, *inter alia*, that Barr's ANDA product for a fluoxetine delayed release capsules infringed the '030 patent, and that there existed "a real, substantial and justiciable controversy between Lilly and Barr." (*See* S.D. Ind. Case No. 1:06-cv-0741-LJM-JMS, Docket # 1.)

86. In its complaint, Lilly also alleged that Barr's actions had "created in Lilly's mind a reasonable apprehension of irreparable harm and loss resulting from Barr's threatened imminent actions," (*id.*, ¶ 29), and requested, *inter alia*, that Barr be enjoined from marketing its ANDA product in the U.S. prior to the expiration of the '030 patent, i.e., May 29, 2017. (*Id.*, Relief Requested (E).)

87. In its Reply to Barr's Counterclaims seeking declarations of invalidity and non-infringement of the '030 patent filed on June 15, 2006, Lilly admitted that subject matter jurisdiction over Barr's counterclaims was proper under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. (Docket # 23, ¶ 19; *see* Docket # 15, ¶ 19.)

88. On April 12, 2007, Barr moved to compel Lilly to respond to discovery after what Barr said was a five-month effort to resolve the parties' discovery disputes. (Docket # 62,) Barr asserted, *inter alia*, that Lilly refused to produce information related to the circumstances surrounding its decision to seek reissue of the '319 patent, which was relevant to Lilly's claims of infringement and Barr's defenses as to the invalidity of the '030 reissue patent. (Docket # 63, at 1-2, 5.)

89. Barr also argued that Lilly improperly sought to recapture subject matter – subject matter that it gave up to get the '319 patent issued in the first place – during the reissue. (Docket # 63, at 13; *see also id.* at 15.)

90. Lilly opposed Barr's motion to compel, and moved for a protective order on April 30, 2007. (*See* Docket ## 65, 68.)

91. In its concurrent reply brief in support of its motion to compel and opposition to Lilly's motion for a protective order filed on May 14, 2007, Barr contended that it had gathered evidence suggesting that Lilly had engaged in inequitable conduct in its prosecution of the '030

patent and that it intended to challenge the patent on that basis, too. (*See* Docket # 79 at 2, 11 n.9, 13-14.) In particular, Barr argued, "Lilly filed its reissue application for the '319 patent after receiving Barr's December 11, 2001 Notice Letter, which identified the reasons why Barr's product did not infringe the claims of the '319 patent. Given the timing and other evidence disclosed during discovery, Barr believes that Lilly's reissue application was false and submitted to prevent entry of Barr's ANDA product in the marketplace." (*Id.* at 13-14.)

92. On May 29, 2007, Lilly filed a reply brief in support for its motion for a protective order. (Docket # 80.)

93. Two days later, on May 31, 2007, the parties participated in a telephonic conference with Magistrate Judge Magnus-Stinson regarding their discovery dispute, and were ordered to submit any legal authority they wished the Court to consider by noon on June 1, 2007. (Docket # 84.)

94. Instead, on June 1, 2007, Lilly reached an agreement with Barr and filed a Joint Stipulation of Dismissal With Prejudice whereby all claims asserted by Lilly against Barr were dismissed with prejudice. (Docket # 85.)

2. Lilly's Termination of Its Litigation With Barr Effectively Prevents FDA Approval of DRL's ANDA Absent a Judgment Declaring That the Patents-in-Suit Are Not Infringed, Are Invalid and/or Are Unenforceable.

95. As a consequence of Lilly's agreement with Barr and the dismissal of the *Lilly-Barr* litigation, DRL's sale of Prozac® Weekly™ will be delayed until 180 days after Barr begins the commercial marketing of its generic fluoxetine 90 mg delayed release capsule product.

96. Barr has not begun the commercial marketing of its generic fluoxetine 90 mg delayed release product, and upon information and belief, reached an agreement with Lilly to delay such marketing despite its claim that the relevant patent was invalid and unenforceable.

97. Lilly's agreement with Barr and its refusal to litigate the validity, enforceability and/or non-infringement of the '319, '322 and '030 patents with DRL is preventing a court decision of invalidity, unenforceability and/or non-infringement of those three patents, a decision which would trigger Barr's 180-day exclusivity for the patents-in-suit and permit DRL to sell its product.

98. As such, Lilly and DRL have adverse legal interests in the subject matter of this dispute.

99. Moreover, unless and until DRL obtains a court decision of invalidity, unenforceability and/or non-infringement of the patents-in-suit, particularly with respect to the '030 patent, which Lilly has shown a propensity to litigate, it faces potentially enormous infringement liability if it commences commercial marketing before the '030 patent-expires.

COUNT I
DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND UNENFORCEABILITY OF THE '319 PATENT

100. DRL realleges and incorporates by reference each of the allegations of paragraphs 1-99.

101. The '319 patent was reissued on March 21, 2006 as U.S. Patent No. RE 39,030.

102. Accordingly, the '319 patent has been surrendered and, as a matter of law, cannot be infringed by or enforced against DRL in DRL's commercial manufacture, use, offer for sale, sale or importation of the products covered by ANDA No. 78-572.

COUNT II
DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND UNENFORCEABILITY OF THE '322 PATENT

103. DRL realleges and incorporates by reference each of the allegations of paragraphs 1-102.

104. On January 22, 2002, Lilly filed a disclaimer under 37 C.F.R. § 1.321 to disclaim all the claims of the '322 patent.

105. Accordingly, the claims of the '322 patent have been surrendered and, as a matter of law, cannot be infringed by or enforced against DRL in DRL's commercial manufacture, use, offer for sale, sale or importation of the products covered by ANDA No. 78-572.

COUNT III
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '030 PATENT

106. DRL realleges and incorporates by reference each of the allegations of paragraphs 1-105.

107. DRL's commercial manufacture, use, offer for sale, sale or importation of the products covered by ANDA No. 78-572 will not infringe any of the claims of the '030 patent.

COUNT IV
DECLARATORY JUDGMENT OF INVALIDITY OF THE '030 PATENT

108. DRL realleges and incorporates by reference each of the allegations of paragraphs 1-107.

109. Claims of the '030 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112 and/or 251, and/or under the recapture rule.

PRAYER FOR RELIEF

WHEREFORE, DRL respectfully requests the Court enter judgment and Order in its favor and against Lilly to include:

A. A declaration that DRL's manufacture, use, offer for sale, sale or importation of the products covered by ANDA No. 78-572 will not infringe the claims of U.S. Patent No. 5,910,319 and that U.S. Patent No. 5,910,319 cannot be enforced against the products covered by ANDA No. 78-572;

B. A declaration that DRL's manufacture, use, offer for sale, sale or importation of the products covered by ANDA No. 78-572 will not infringe the claims of U.S. Patent No. 5,985,322 and that U.S. Patent No. 5,985,322 cannot be enforced against the products covered by ANDA No. 78-572;

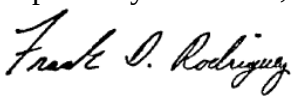
C. A declaration that DRL's manufacture, use, offer for sale, sale or importation of the products covered by ANDA No. 78-572 will not infringe the claims of U.S. Patent No. RE 39,030;

D. A declaration that all of the claims of U.S. Patent No. RE 39,030 are invalid;

E. An award of attorneys' fees, costs, expenses and such other and further relief as the Court may deem just and proper.

Dated: January 8, 2009

Respectfully submitted,



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LOCAL CIVIL RULE 11.2 CERTIFICATION

Plaintiffs, by its attorneys, hereby certify that, to the best of their knowledge, the specific matters in controversy herein are not the subject of any action pending in any court, or of any pending arbitration or administrative proceeding.

I hereby certify that the following statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: January 8, 2009

Frank D. Rodriguez

Frank D. Rodriguez