

Anne M. Patterson (AP-3305)
apatterson@riker.com
RIKER, DANZIG, SCHERER, HYLAND & PERRETTI LLP
Headquarters Plaza
One Speedwell Avenue
Morristown, NJ 07962-1981
(T): 973.538.0800
(F): 973.538.1984

Attorneys for Plaintiff Abbott Laboratories

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ABBOTT LABORATORIES, an Illinois Corporation,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No.
)	
DR. REDDY’S LABORATORIES, INC., a New Jersey corporation, and DR. REDDY’S LABORATORIES, LTD., an Indian corporation,)	COMPLAINT
)	
Defendants.)	
)	

Plaintiff Abbott Laboratories (“Abbott”), for its complaint against Defendants Dr. Reddy’s Laboratories, Inc. (“DRL USA”) and Dr. Reddy’s Laboratories, Ltd. (“DRL India”), alleges as follows:

THE PARTIES

1. Abbott is a corporation organized under the laws of the State of Illinois, having its headquarters and principal place of business at Abbott Park, Illinois 60064.
2. DRL India is a corporation organized under the laws of India, having its headquarters at 7-1-27 Ameerpet, Hyderabad, Andhra Pradesh 500 016, India.

3. DRL USA is a corporation organized under the laws of the State of New Jersey, having its headquarters at 200 Somerset Corporate Boulevard, Building 2, 7th Floor, Bridgewater, New Jersey, 08807. DRL USA is a wholly-owned subsidiary of DRL India, and operates as the authorized U.S. agent of DRL India with regard to the product described in Abbreviated New Drug Application No. 90-161 (“the ANDA”).

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this suit pursuant to 28 U.S.C. § 1331 and § 1338(a), as it arises under an Act of Congress relating to patents, Title 35, United States Code, §§ 1, *et seq.*

5. This Court has personal jurisdiction over DRL USA, by virtue of, among other things, its systematic and continuous contacts with this judicial district.

6. This Court has personal jurisdiction over DRL India because it maintains a presence in this jurisdiction through its wholly-owned subsidiary, DRL USA. Additionally, DRL India is the named applicant for the ANDA, which it submitted to FDA by and through its U.S. agent, DRL USA. DRL India is, therefore, subject to personal jurisdiction in this judicial district for purposes of this action, which arises directly from the filing of the ANDA.

7. Venue properly exists in this judicial district pursuant to 28 U.S.C. § 1391 and § 1400(b).

FACTUAL BACKGROUND

A. The Abbott Patents

8. Abbott sells a prescription drug product under the trademark Depakote[®], which product is indicated for the treatment of epileptic seizures or convulsions, bipolar disease, and migraine headaches. The active ingredient in Depakote[®] is divalproex sodium.

9. On August 4, 2000, the United States Food and Drug Administration (“FDA”) approved Abbott’s New Drug Application No. 21-168 to market Depakote[®] ER (extended-release) tablets in a 500 mg dosage strength. Depakote[®] ER was subsequently approved in a 250 mg dosage strength on May 31, 2002. As a result, Depakote[®] ER is included in FDA’s list of “Approved Drug Products With Therapeutic Equivalence Evaluations,” also known as the “Orange Book.” Approved drugs listed in the Orange Book may be used as the basis of a later applicant’s Abbreviated New Drug Application to obtain approval of the applicant’s generic drug product under the provisions of 21 U.S.C. § 355(j).

10. Abbott is the owner of and has the right to enforce United States Patent No. 6,511,678 (the “‘678 patent”), entitled Controlled Release Formulation of Divalproex Sodium. (A copy of the ‘678 patent is attached as Exhibit A, and is incorporated by reference.) The ‘678 patent issued on January 28, 2003, and expires December 18, 2018.

11. Abbott is the owner of and has the right to enforce United States Patent No. 6,528,090 (the “‘090 patent”), entitled Controlled Release Formulation of Divalproex Sodium. (A copy of the ‘090 patent is attached as Exhibit B, and is incorporated by reference.) The ‘090 patent issued on March 4, 2003, and expires December 18, 2018.

12. Abbott is the owner of and has the right to enforce United States Patent No. 6,713,086 (the “‘086 patent”), entitled Controlled Release Formulation of Divalproex Sodium. (A copy of the ‘086 patent is attached as Exhibit C, and is incorporated by reference.) The ‘086 patent issued on March 30, 2004, and expires December 18, 2018.

13. Abbott is the owner of and has the right to enforce United States Patent No. 6,720,004 (the “‘004 patent”), entitled Controlled Release Formulation of Divalproex Sodium.

(A copy of the '004 patent is attached as Exhibit D, and is incorporated by reference.) The '004 patent issued on April 13, 2004, and expires December 18, 2018.

14. The '678 patent, the '090 patent, the '086 patent, the '004 patent, and other patents, are listed in FDA's Orange Book in association with the 250 mg strength of Depakote[®] ER.

B. DRL Notifies Abbott Regarding the Filing of the ANDA.

15. Abbott received a letter from both DRL USA and DRL India (collectively, "DRL") dated April 7, 2008, which stated, *inter alia*, that (i) DRL had submitted ANDA No. 90-161 to FDA, requesting approval to market a generic version of Depakote[®] ER in a 250 mg dosage strength; (ii) the ANDA included a Paragraph IV Certification (pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)) directed to the '678, '090, '086, and '004 patents; and (iii) DRL seeks FDA approval to market the proposed generic product before these patents expire.

16. DRL attached to its letter a memorandum that purportedly provided the "Detailed Factual and Legal Basis for Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Assertion of Non-Infringement, Invalidity or Unenforceability of U.S. Patent Nos. 6,419,953, 6,511,678, 6,528,090, 6,528,091, 6,713,086, and 6,720,004 in Connection with Paragraph IV Certifications Re: Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Proposed Divalproex Sodium Extended-Release Tablet Product." *See* 21 U.S.C. § 355(j)(2)(B)(iv); *see also* 21 C.F.R. § 314.95(c)(6)(i) - (ii). In that memorandum, DRL stated its position regarding whether its proposed product would infringe the '678, '090, '086, and '004 patents, but did not argue that any of these patents are invalid or unenforceable.

17. The applicant for the ANDA is DRL, with DRL USA acting as the authorized U.S. agent for all matters relating to the ANDA, including submitting the ANDA to FDA, coordinating communications with FDA relating to the ANDA, and other responsibilities.

18. A representative of DRL USA signed the official application form submitted to FDA, certifying under penalty of perjury that all information in the ANDA is true and accurate and that all applicable laws and regulations governing approved applications – including regulations governing drug manufacture, labeling, and marketing – would be followed.

19. On information and belief, if the ANDA is approved by FDA, the proposed generic product will be manufactured by DRL and marketed, distributed, and/or sold in the United States by DRL USA. In addition, if the ANDA is approved by FDA, DRL USA will continue to have responsibility for communicating with FDA post-approval regarding the generic drug product, including the submission of periodic reports relating to adverse events, distribution information, and other relevant matters.

20. The active ingredient in DRL's proposed generic drug product is divalproex sodium, and the ANDA purports to describe a formulation for achieving a controlled release of divalproex sodium in patients.

COUNT I: INFRINGEMENT OF THE '678 PATENT

21. Abbott repeats and incorporates by reference each and every allegation of paragraphs 1-20 as if fully set forth herein.

22. Under 35 U.S.C. § 271(e)(2), the submission of an ANDA under 21 U.S.C. § 355(j) for a drug product or formulation claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent. DRL's submission of The ANDA for approval to sell Divalproex Sodium ER Tablets in a 250 mg dosage strength before the expiration of the '678 patent constitutes an act of infringement of that patent pursuant to 35 U.S.C. § 271(e)(2).

23. DRL USA has actively, knowingly, intentionally, and deliberately induced, aided, and abetted DRL to infringe the '678 patent through the submission of the ANDA, and will

continue to aid and abet DRL's infringing activities post-approval by directly or indirectly conducting, commissioning, directing, and/or supporting the manufacture, use, importation, testing, packaging, marketing, and/or sale of the infringing product described in the ANDA, as well as any ongoing matters of regulatory compliance with FDA.

24. DRL's proposed generic version of Depakote[®] ER, as described in the ANDA, utilizes a controlled-release formulation that infringes the '678 patent.

25. DRL is liable for infringement of the '678 patent.

26. Abbott has no adequate remedy at law to redress DRL's infringement.

COUNT II: INFRINGEMENT OF THE '090 PATENT

27. Abbott repeats and incorporates by reference each and every allegation of paragraphs 1-20 as if fully set forth herein.

28. Under 35 U.S.C. § 271(e)(2), the submission of an ANDA under 21 U.S.C. § 355(j) for a drug product or formulation claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent. DRL's submission of The ANDA for approval to sell Divalproex Sodium ER Tablets in a 250 mg dosage strength before the expiration of the '090 patent constitutes an act of infringement of that patent pursuant to 35 U.S.C. § 271(e)(2).

29. DRL USA has actively, knowingly, intentionally, and deliberately induced, aided, and abetted DRL to infringe the '090 patent through the submission of the ANDA, and will continue to aid and abet DRL's infringing activities post-approval by directly or indirectly conducting, commissioning, directing, and/or supporting the manufacture, use, importation, testing, packaging, marketing, and/or sale of the infringing product described in the ANDA, as well as any ongoing matters of regulatory compliance with FDA.

30. DRL's proposed generic version of Depakote[®] ER, as described in the ANDA, utilizes a controlled-release formulation that infringes the '090 patent.

31. DRL is liable for infringement of the '090 patent.

32. Abbott has no adequate remedy at law to redress DRL's infringement.

COUNT III: INFRINGEMENT OF THE '086 PATENT

33. Abbott repeats and incorporates by reference each and every allegation of paragraphs 1-20 as if fully set forth herein.

34. Under 35 U.S.C. § 271(e)(2), the submission of an ANDA under 21 U.S.C. § 355(j) for a drug product or formulation claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent. DRL's submission of The ANDA for approval to sell Divalproex Sodium ER Tablets in a 250 mg dosage strength before the expiration of the '086 patent constitutes an act of infringement of that patent pursuant to 35 U.S.C. § 271(e)(2).

35. DRL USA has actively, knowingly, intentionally, and deliberately induced, aided, and abetted DRL to infringe the '086 patent through the submission of the ANDA, and will continue to aid and abet DRL's infringing activities post-approval by directly or indirectly conducting, commissioning, directing, and/or supporting the manufacture, use, importation, testing, packaging, marketing, and/or sale of the infringing product described in the ANDA, as well as any ongoing matters of regulatory compliance with FDA.

36. DRL's proposed generic version of Depakote[®] ER, as described in the ANDA, utilizes a controlled-release formulation that infringes the '086 patent.

37. DRL is liable for infringement of the '086 patent.

38. Abbott has no adequate remedy at law to redress DRL's infringement.

COUNT IV: INFRINGEMENT OF THE '004 PATENT

39. Abbott repeats and incorporates by reference each and every allegation of paragraphs 1-20 as if fully set forth herein.

40. Under 35 U.S.C. § 271(e)(2), the submission of an ANDA under 21 U.S.C. § 355(j) for a drug product or formulation claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent. DRL's submission of The ANDA for approval to sell Divalproex Sodium ER Tablets in a 250 mg dosage strength before the expiration of the '004 patent constitutes an act of infringement of that patent pursuant to 35 U.S.C. § 271(e)(2).

41. DRL USA has actively, knowingly, intentionally, and deliberately induced, aided, and abetted DRL to infringe the '004 patent through the submission of the ANDA, and will continue to aid and abet DRL's infringing activities post-approval by directly or indirectly conducting, commissioning, directing, and/or supporting the manufacture, use, importation, testing, packaging, marketing, and/or sale of the infringing product described in the ANDA, as well as any ongoing matters of regulatory compliance with FDA.

42. DRL's proposed generic version of Depakote[®] ER, as described in the ANDA, utilizes a controlled-release formulation that infringes the '004 patent.

43. DRL is liable for infringement of the '004 patent.

44. Abbott has no adequate remedy at law to redress DRL's infringement.

PRAYER FOR RELIEF

WHEREFORE, Abbott prays for the following relief:

(a) a judgment that the '678 patent remains valid and enforceable and is infringed under 35 U.S.C. § 271(e)(2) by the filing of the ANDA;

(b) an order declaring that the ANDA cannot be approved earlier than the expiration

date of Abbott's '678 patent;

(c) an injunction prohibiting DRL, any of its affiliates, or those working in concert with it, from commercially manufacturing, selling, offering to sell, importing, or using a formulation covered by the '678 patent, or otherwise infringing one or more claims of the '678 patent during the life of the patent;

(d) a judgment that the '090 patent remains valid and enforceable and is infringed under 35 U.S.C. § 271(e)(2) by the filing of the ANDA;

(e) an order declaring that the ANDA cannot be approved earlier than the expiration date of Abbott's '090 patent;

(f) an injunction prohibiting DRL, any of its affiliates, or those working in concert with it, from commercially manufacturing, selling, offering to sell, importing, or using a formulation covered by the '090 patent, or otherwise infringing one or more claims of the '090 patent during the life of the patent;

(g) a judgment that the '086 patent remains valid and enforceable and is infringed under 35 U.S.C. § 271(e)(2) by the filing of the ANDA;

(h) an order declaring that the ANDA cannot be approved earlier than the expiration date of Abbott's '086 patent;

(i) an injunction prohibiting DRL, any of its affiliates, or those working in concert with it, from commercially manufacturing, selling, offering to sell, importing, or using a formulation covered by the '086 patent, or otherwise infringing one or more claims of the '086 patent during the life of the patent;

(j) a judgment that the '004 patent remains valid and enforceable and is infringed under 35 U.S.C. § 271(e)(2) by the filing of the ANDA;

(k) an order declaring that the ANDA cannot be approved earlier than the expiration date of Abbott's '004 patent;

(l) an injunction prohibiting DRL, any of its affiliates, or those working in concert with it, from commercially manufacturing, selling, offering to sell, importing, or using a formulation covered by the '004 patent, or otherwise infringing one or more claims of the '004 patent during the life of the patent;

(m) an award of Abbott's costs and attorneys' fees pursuant to 35 U.S.C. § 271(e)(4) and § 285; and

(n) such other and further relief as this Court may deem just and proper.

Dated: May 21, 2008

Respectfully submitted,

RIKER, DANZIG, SCHERER, HYLAND &
PERRETTI LLP

By: s/ Anne M. Patterson
Anne M. Patterson (AP-3305)
apatterson@riker.com
Headquarters Plaza
One Speedwell Avenue
Morristown, NJ 07962-1981
(T): 973.538.0800
(F): 973.538.1984

Attorneys for Abbott Laboratories

Of Counsel
Daniel E. Reidy; Bar No. 2306948
E-mail: dereidy@jonesday.com
James R. Daly; Bar No. 6181714
Email: jrdaly@jonesday.com
Jason G. Winchester; Bar No. 6238377
Email: jgwinchester@jonesday.com
Melissa B. Hirst; Bar No. 6282498
Email: mbhirst@jonesday.com
JONES DAY
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601-1692
(T): 312.782.3939
(F): 312.782.8585

Perry C. Siatis
ABBOTT LABORATORIES
100 Abbott Park Road
Abbott Park, Illinois 60064-6034