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HONORABLE BARBARA JONES

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CAESAR, RIVISE, L.L.C. v. STELLER
COHEN & POKOTILOV LTD

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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In re CEFRAZOLE PATENT LITIGATION : M-21-81 (BSJ)
: MDL Docket No. 1291
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ASTRAZENECA AB, et al., :
: Plaintiffs, : 00 Civ. 6749 (BSJ)
:

v. :

MYLAN LABORATORIES INC., et al., :
: Defendants. :
:

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ASTRAZENECA AB, et al., :
: Plaintiffs, : 03 Civ. 6057 (BSJ)
:

v. :

LABORATORIOS DR. ESTEVE, S.A., :
et al., :
: Defendants. :
:

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ASTRAZENECA AB, et al., :
: Plaintiffs, : 00 Civ. 4541 (BSJ)
: 03 Civ. 8719 (BSJ)
:

v. :

LEH PHARMACEUTICAL AND CHEMICAL :
CO., D., et al., :
: Defendants. :
:

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ASTRAZENECA AB, et al., :
: Plaintiffs, : 01 Civ. 9351 (BSJ)
:

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003/007

v. :

APOTEX CORP., et al., :

Defendants. :

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ASTRAZENECA AB, et al., :

Plaintiffs, :

v. :

IMPAX LABORATORIES, INC., :

Defendant. :

-----x :

00 Civ. 7597 (BSJ)
01 Civ. 2998 (BSJ)

Judgment



BARBARA S. JONES
UNITED STATES DISTRICT JUDGE

This matter having come to trial on the merits before the undersigned Honorable Barbara S. Jones (without a jury), and the Court having duly rendered its Opinion and Order dated May 31, 2007, it is hereby

ORDERED, ADJUDGED and DECREED as follows:

APOTEX

1. Defendants Apotex Corp., Apotex Inc., and TorPharm, Inc. (collectively "Apotex") have failed to meet their burden of proving that the asserted claims (claim 1, 5, 6, and 10) of U.S. Patent No. 4,786,505 ("the '505 Patent") and asserted claims (claims 1, 6, 7, and 13) of U.S. Patent No. 4,853,230 ("the '230 Patent" are invalid.

2. Apotex infringed claims 1, 5, 6, and 10 of the '505 Patent, and claims 1, 6, 7, and 13 of the '230 Patent by filing

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Abbreviated New Drug Application ("ANDA") No. 76-048 with the Food and Drug Administration ("FDA") including a certification under 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Apotex's omega-3 formulations sold, offered for sale, used and imported into the United States, described in ANDA No. 76-048, and which were the subject of the Court's May 31, 2007 Opinion and Order, literally infringe '505 Patent claims 1, 5, 6, and 10, and '230 Patent claims 1, 6, 7, and 13.

3. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of approval for the aforementioned products and related ANDAs shall be not earlier than October 20, 2007, the date on which the six-month period of pediatric exclusivity under 21 U.S.C. § 355a(b)(2)(B) expires.

IMPAX

4. Defendant Impax Laboratories, Inc. ("Impax") has failed to meet its burden of proving that the asserted claims (1, 5, 8, and 10) of U.S. Patent No. 4,786,505 ("the '505 Patent" and the asserted claims (1, 6, 7, 10, and 13) of U.S. Patent No. 4,853,230 ("the '230 Patent") are invalid.

5. Impax infringed claims 1, 5, 6, 8, and 10 of the '505 Patent, and claims 1, 6, 7, 10, and 13 of the '230 Patent by filing an Abbreviated New Drug Application ("ANDA") No. 75-785 with the Food and Drug Administration ("FDA") including a

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certification under 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Impak's omeprazole formulations sold, offered for sale, used and imported into the United States, described in ANDA No. 75-785, and which were the subject of the Court's May 31, 2007 Opinion and Order, literally infringe '505 Patent claims 1, 5, 6, 8, and 10, and '230 Patent claims 1, 6, 7, 10, and 13.

6. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of approval for the aforementioned products and related ANDAs shall be not earlier than October 20, 2007, the date on which the six-month period of pediatric exclusivity under 21 U.S.C. § 355a(b)(2)(B) expires.

MYLAND AND ESTEVE

7. Defendants Mylan Laboratories Inc., and Mylan Pharmaceuticals Inc. (collectively "Mylan"), and Esteve Quimica, S.A. and Laboratorios Dr. Esteve, S.A. (collectively "Esteve") have failed to meet their burden of proving that the asserted claims (1, 3, 4, 5, 6, 7, 10, 11, and 14) of U.S. Patent No. 4,785,515 ("the '505 Patent") and the asserted claims (1, 6, 7, 8, 9, 11, 13 and 15) of U.S. Patent No. 4,853,230 ("the '230 Patent") are invalid.

8. The omeprazole formulation described in ANDA No. 75-876 of defendants Mylan and Esteve, which was the subject of the Court's May 31, 2007 Opinion and Order, does not infringe the

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asserted claims (1, 3, 4, 5, 6, 7, 10, 11, and 14) of the '505 Patent and the asserted claims (1, 6, 7, 8, 9, 12, 13, and 15) of the '230 Patent, either literally or under the doctrine of equivalents.

9. Plaintiffs' allegations that Defendants Mylan and Esteve have willfully infringed the '505 and '230 Patents are dismissed as moot.

LEK

10 The omeprazole formulations described in ANDA Nos. 75-757 and 76-515 of Defendants Lek Pharmaceuticals d.d. and Lek Service, Inc. (collectively "Lek"), which were the subject of the Court's May 31, 2007 Opinion and Order do not infringe the asserted claims (1, 5, 7, 8, 9, and 10) of the '505 Patent and the asserted claims (1, 6, 8, 10, 11, and 13) of the '230 Patent, either literally or under the doctrine of equivalents.

ALL PARTIES

11 The Parties reserve the right to assert remaining claims not the subject of the Court's previous orders and opinion, and to seek or oppose damages, enhanced damages, attorneys' fees and further relief.


12 There being no just reason for delay, pursuant to Federal Rule of Civil Procedure 54(b), the Clerk of Court shall enter final judgment for Astrazeneca, pursuant to paragraphs 1 through 11.

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SC ORDERED:


Barbara S. Jones
UNITED STATES DISTRICT JUDGE

Dated: New York, New York
June 14, 2007