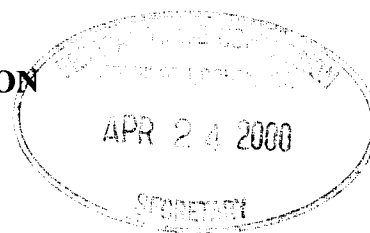


UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION



In the Matter of

HOECHST MARION ROUSSEL, INC.,
a corporation,

CARDERM CAPITAL L.P.,
a limited partnership,

and

ANDRX CORPORATION,
a corporation.

Docket No. 9293

RESPONDENT'S FIRST REQUEST FOR ADMISSIONS

Pursuant to Federal Trade Commission ("FTC") Rules of Practice for Adjudicative Proceedings ("Rule of Practice") § 3.32, Respondent Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc., ("HMR"), by counsel, submits these Requests for Admissions to the FTC. The FTC is requested to respond, in writing, to the following Requests for Admissions within ten (10) days after service hereof.

DEFINITIONS

1. As used herein, "ANDA" means an Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j).

2. As used herein, “ANDA 74-752” means the Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j) by Andrx for a generic bioequivalent version of Cardizem® CD.

3. As used herein, “ANDA 75-984” means the Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j) by Faulding for a generic bioequivalent version of Cardizem® CD.

4. As used herein, “Andrx” means Andrx Pharmaceuticals, Inc., its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

5. As used herein, “Biovail” shall refer to Biovail Corporation, its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

6. As used herein, “Cardizem® CD” means the diltiazem formulation sold under that trademark.

7. As used herein, “District Court” means the U.S. District Court for the Southern District of Florida.

8. As used herein, “Faulding” means Faulding Inc., its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

9. As used herein, "FDA" means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners and laboratories.

10. As used herein, "Hatch-Waxman Amendments" means the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), adding section 505(j) to the Food Drug and Cosmetics Act (21 U.S.C. § 355(j)(5)).

11. As used herein, "HMR" means Hoechst Marion Roussel, Inc., its predecessors, including without limitations Hoechst Inc. and Marion Merrell Dow Inc., and the officers, directors, employees, partners, subsidiaries, corporate parents, affiliates and divisions of each of the foregoing.

12. As used herein, "HMR/Andrx Stipulation and Agreement" means that agreement between Hoechst Marion Roussel, Inc., Carderm Capital, L.P. and Andrx Pharmaceuticals entered into on or about September 26, 1997.

13. As used herein, "patent certification" means the certification provided to the owner of the patent or holder of the application pursuant to 21 U.S.C. § 355(j)(2)(B).

14. As used herein, "Patent Infringement Litigation" means *Hoechst Marion Roussel, Inc. et al. v. Andrx Pharmaceuticals, Inc.*, Case No. 96-06121-Civ-Roettger (S.D. Fla.)

15. As used herein, "'584 Patent" means U.S. Patent No. 5,470,584 issued by the U.S. Patent and Trademark Office on November 28, 1995.

REQUESTS FOR ADMISSIONS

The Patent Infringement Case

Request No. 1: Admit that pursuant to Section 505(j) of the Food, Drug and Cosmetic Act (21 U.S.C. §§ 355(j)), Andrx filed its application for a generic bioequivalent version of Cardizem® CD, ANDA 74-752, on September 22, 1995.

Answer:

Request No. 2: Admit that as part of Andrx's September 22, 1995 filing, Andrx certified that its generic product did not infringe any patents owned or licensed by HMR relating to Cardizem® CD.

Answer:

Request No. 3: Admit that U.S. Patent No. 5,470,584, which pertained to dissolution characteristics of sustained release once-daily diltiazem products, was issued by the United States Patent and Trademark Office on November 28, 1995.

Answer:

Request No. 4: Admit that Andrx became aware of U.S. Patent No. 5,470,584 on December 15, 1995.

Answer:

Request No. 5: Admit that on December 30, 1995, Andrx re-certified to the FDA that its generic product did not infringe any patents owned or licensed by HMR relating to Cardizem® CD, including U.S. Patent No. 5,470,584.

Answer:

Request No. 6: Admit that on December 30, 1995, Andrx provided a copy of its patent certification to HMR which triggered the running of the 45 day period pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

Answer:

Request No. 7: Admit that U.S. Patent No. 5,470,584 is both valid and enforceable.

Answer:

Request No. 8: Admit that the product that was the subject of Andrx's ANDA 74-752, as filed on September 22, 1995, infringed U.S. Patent No. 5,470,584.

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Request No. 9: Admit that there was a substantial likelihood that the product that was the subject of Andrx's ANDA 74-752, as filed on September 22, 1995, infringed U.S. Patent No. 5,470,584.

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Request No. 10: Admit that HMR was reasonable in asserting that the product that was the subject of Andrx's ANDA 74-752, as filed on September 22, 1995, infringed U.S. Patent No. 5,470,584.

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Request No. 11: Admit that HMR was not unreasonable in asserting that the product that was the subject of Andrx's ANDA 74-752, as filed on September 22, 1995, infringed U.S. Patent No. 5,470,584.

Answer:

Request No. 12: Admit that on January 31, 1996, HMR filed a patent infringement action in the U.S. District Court for the Southern District of Florida against Andrx Pharmaceuticals, alleging that Andrx's generic version of Cardizem® CD infringed its '584 Patent and that the filing of ANDA 74-752 was a statutory act of infringement.

Answer:

Request No. 13: Admit that as a result of HMR filing the patent infringement action on January 31, 1996, the Hatch-Waxman Amendments to the Food Drug and Cosmetics Act (21 U.S.C. § 355(j)(5)(B)(ii)) imposed a statutory stay that prevented the FDA from issuing final approval to Andrx's ANDA 74-752 for a period of thirty months or until a court determined that the patent was invalid or not infringed, whichever occurred earlier.

Answer:

The HMR/Andrx Stipulation and Agreement

Request No. 14: Admit that HMR and Andrx entered into the HMR/Andrx Stipulation and Agreement on September 27, 1997.

Answer:

Request No. 15: Admit that under the HMR/Andrx Stipulation and Agreement, Andrx agreed to maintain the *status quo* by refraining from the commercial sale of its product until the earlier of the date that final judgement was entered in the patent infringement action; the date that Andrx exercised its option under the HMR/Andrx Stipulation and Agreement to obtain a license from HMR to market a generic version of Cardizem® CD; or the date that Andrx received notice under the HMR/Andrx Stipulation and Agreement that HMR had decided to market or license a third party to market a generic version of Cardizem® CD.

Answer:

Request No. 16: Admit that under the HMR/Andrx Stipulation and Agreement, Andrx specifically agreed to diligently prosecute its application for FDA approval of its generic product and not to relinquish or compromise any rights accruing thereunder or pertaining thereto.

Answer:

Request No. 17: Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx prevailed in the patent infringement litigation, HMR agreed to compensate Andrx for those profits that Andrx would have otherwise realized had it marketed its generic product following FDA approval but prior to final judgement in the Patent Infringement Litigation.

Answer:

Request No. 18: Admit that under the HMR/Andrx Stipulation and Agreement, HMR and Andrx stipulated that Lost Profits would amount to \$100 million per year.

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Request No. 19: Admit that under the HMR/Andrx Stipulation and Agreement, HMR agreed to not seek preliminary injunctive relief against Andrx.

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Request No. 20: Admit that under the HMR/Andrx Stipulation and Agreement, HMR agreed to make Interim Payments of \$10 million per quarter to Andrx for each quarter following the FDA's final approval of the Andrx product so long as the HMR/Andrx Stipulation and Agreement remained in effect.

Answer:

Request No. 21: Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx prevailed in the Patent Infringement Litigation, the total amount of any Interim Payments made would be deducted from the stipulated Lost Profits that HMR was otherwise obligated to pay.

Answer:

Request No. 22: Admit that under the HMR/Andrx Stipulation and Agreement, HMR granted Andrx a irrevocable option to acquire a license to all intellectual property owned by HMR that Andrx would need to sell, market and distribute a generic formulation of Cardizem® CD in the United States.

Answer:

Request No. 23: Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx had taken a license from HMR to produce its generic product and was subsequently determined to have infringed the '584 Patent, Andrx would be required to pay an additional \$30 million licensing fee to HMR within 30 days of the Effective Date of Final Judgment and thereafter increase its royalty payments to HMR from 10% of net receipts to 20% of net receipts.

Answer:

Request No. 24: Admit that under Paragraph 8.B.i of the HMR/Andrx Stipulation and Agreement, the only consequence of Andrx violating any obligation under Paragraph 2 of the HMR/Andrx Stipulation and Agreement would be that the HMR/Andrx Stipulation and Agreement would be terminated and any monies paid to Andrx by HMR under the HMR/Andrx Stipulation and Agreement would be repaid to HMR.

Answer:

Request No. 25: Admit that HMR issued a press release on September 29, 1997, which accurately summarized the essential terms, nature and scope of the HMR/Andrx Stipulation and Agreement.

Answer:

Request No. 26: Admit that HMR provided the Federal Trade Commission with a copy of the HMR/Andrx Stipulation and Agreement on November 21, 1997.

Answer:

Request No. 27: Admit that under the HMR/Andrx Stipulation and Agreement, the Lost Profits Payment and Interim Payment provisions of the HMR/Andrx Stipulation and Agreement would not become effective prior to July 9, 1998, the date upon which FDA final approval would issue.

Answer:

Andrx Supplement

Request No. 28: Admit that on September 11, 1998, Andrx filed a Supplement to ANDA 74-752.

Answer:

Request No. 29: Admit that the September 11, 1998 Supplement to ANDA 74-752 reformulated the product by replacing a small amount of the non-release controlling excipient in the original formulation with a different non-release excipient in the modified formulation.

Answer:

Request No. 30: Admit that the reformulation reflected in the September 11, 1998 Supplement to ANDA 74-752 reduced the probability that the generic product would be found to infringe the '584 Patent.

Answer:

Request No. 31: Admit that on October 7, 1998, Andrx wrote to HMR urging it to reconsider its claims of infringement in light of the revised dissolution profile for the reformulated product.

Answer:

Request No. 32: Admit that on January 22, 1999, Andrx provided HMR with samples of its reformulated product for examination and testing.

Answer:

Request No. 33: Admit that on February 3, 1999, Andrx filed a Supplemental Patent Certification that certified that the reformulated product did not infringe the '584 Patent.

Answer:

Request No. 34: Admit that on March 16, 1999, HMR responded to Andrx's September 11, 1998 Supplement to ANDA 74-752 by stating that it would not assert the '584 Patent claims against Andrx's reformulated product so long as the dissolution values of the SR2

pellets contained in the reformulated product, as manufactured, met or exceeded the values set forth in Andrx's Supplemental Patent Certification.

Answer:

Request No. 35: Admit that the parties entered into a final settlement of the Patent Infringement Litigation on June 8, 1999.

Answer:

Request No. 36: Admit that the HMR/Andrx Stipulation and Agreement terminated on June 8, 1999.

Answer:

Request No. 37: Admit that Andrx received FDA's final approval of its September 11, 1998 Supplement to ANDA 74-752 on June 8, 1999.

Answer:

Request No. 38: Admit that Andrx could not have legally sold the product subject to its September 11, 1998 Supplement to ANDA 74-752 prior to June 8, 1999, the date upon which it received FDA's final approval of its reformulated product.

Answer:

Request No. 39: Admit that as of June 8, 1999, Andrx was no longer permitted to sell or distribute the formulation of its generic product for which it received final FDA approval on July 9, 1998.

Answer:

Faulding

Request No. 40: Admit that Faulding filed its application for a generic bioequivalent version of Cardizem® CD, ANDA 75-984, on September 11, 1996.

Answer:

Request No. 41: Admit that as part of Faulding's September 11, 1996 filing, that Faulding certified that its generic product did not infringe any patents owned or licensed by HMR relating to Cardizem® CD.

Answer:

Request No. 42: Admit that U.S. Patent No. 5,439,689 is valid and enforceable.

Answer:

Request No. 43: Admit that the product that was the subject of Faulding's ANDA 74-984 infringed U.S. Patent No. 5,439,689.

Answer:

Request No. 44: Admit that there was a substantial likelihood that the product that was the subject of Faulding's ANDA 74-984 infringed U.S. Patent No. 5,439,689.

Answer:

Request No. 45: Admit that HMR was reasonable in asserting that the product that was the subject of Faulding's ANDA 74-984 infringed U.S. Patent No. 5,439,689.

Answer:

Request No. 46: Admit that HMR was not unreasonable in asserting that the product that was the subject of Faulding's ANDA 74-984 infringed U.S. Patent No. 5,439,689.

Answer:

Request No. 47: Admit that on December 23, 1996, Faulding provided a copy of its patent certification relating to ANDA 75-984 to HMR.

Answer:

Request No. 48: Admit that on January 31, 1997, HMR filed the patent infringement action in the District of New Jersey, alleging that Faulding's generic product

infringed U.S. Patent No. 5,439,689 and that the filing of Faudling's ANDA constituted a statutory act of infringement.

Answer:

Request No. 49: Admit that HMR/Faulding patent infringement litigation was filed within the time frame contemplated by 21 U.S.C. § 355(j)(5)(B)(iii) and that pursuant to thirty-month statutory stay imposed by 21 U.S.C. § 355(j)(5)(B)(ii), FDA could not have granted final approval for Faulding's generic product any earlier than on or about June 1, 1999.

Answer:

Request No. 50: Admit that Faulding did not receive the FDA's tentative approval of its generic product until October 26, 1998, over two years after it filed its original ANDA.

Answer:

Request No. 51: Admit that HMR and Faulding settled the HMR/Faulding patent infringement litigation on May 3, 1999 under a settlement agreement in which Faulding obtained

a license to HMR's technology in exchange for a licensing fee and a royalty rate applicable to the sales of Faulding's product.

Answer:

Request No. 52: Admit that as a part of that settlement, Faulding admitted that U.S. Patent No. 5,439,689 was both valid and enforceable and that the Faulding generic formulation that was encompassed by ANDA 75-984 and was the subject of the HMR/Faulding patent infringement litigation infringed U.S. Patent No. 5,439,689.

Answer:

Request No. 53: Admit that sales of Faulding's generic Cardizem® CD product commenced on December 21, 1999.

Answer:

Biovail

Request No. 54: Admit that Biovail filed its application for a generic bioequivalent version of Cardizem® CD, ANDA 75-1169, on June 19, 1997.

Answer:

Request No. 55: Admit that as part of Biovail's June 19, 1997 filing, that Biovail certified that its generic product did not infringe any patents owned or licensed by HMR relating to Cardizem® CD.

Answer:

Request No. 56: Admit that on June 18, 1997, Biovail provided a copy of its patent certification to HMR which triggered the commencement of the 45 day period pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

Answer:

Request No. 57: Admit that in response to HMR's efforts to obtain information relating to Biovail's generic product, Biovail took the position that HMR was legally precluded from initiating any patent infringement action based upon earlier agreements.

Answer:

Request No. 58: Admit that the 45 day period provided by 21 U.S.C. § 355(j)(5)(B)(iii) expired without HMR having filed a patent infringement action against Biovail.

Answer:

Request No. 59: Admit that Biovail did not receive the FDA's tentative approval of its generic product until late- October 1999, almost two and one-half years after it filed its ANDA 75-1169.

Answer:

Request No. 60: Admit that apart from Andrx, Biovail and Faulding, no other generic companies have filed applications with the FDA to manufacture and sell generic versions of Cardizem® CD.

Answer:

Request No. 61: Admit that following the introduction of Cartia XT, Andrx's reformulated generic version of Cardizem® CD, Andrx enjoyed gross sales of over \$175 million and net sales of over \$125 million during the seven month period running from June 23, 1999, the date that Cartia XT first shipped and January 31, 2000.

Answer:

Request No. 62: Admit that had Andrx been able to launch a non-infringing generic version of Cardizem® CD in July 1998, it would have enjoyed gross and net sales comparable to that which it enjoyed following the introduction of its non-infringing product in late-June 1999.

Answer:

**UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION**

In the Matter of

HOECHST MARION ROUSSEL, INC.,
a corporation,

CARDERM CAPITAL L.P.,
a limited partnership,

and

ANDRX CORPORATION,
a corporation.

Docket No. 9293

RESPONDENT'S FIRST REQUEST FOR ADMISSIONS

Pursuant to Federal Trade Commission ("FTC") Rules of Practice for Adjudicative Proceedings ("Rule of Practice") § 3.32, Respondent Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc., ("HMR"), by counsel, submits these Requests for Admissions to the FTC. The FTC is requested to respond, in writing, to the following Requests for Admissions within ten (10) days after service hereof.

DEFINITIONS

1. As used herein, "ANDA" means an Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j).

2. As used herein, “ANDA 74-752” means the Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j) by Andrx for a generic bioequivalent version of Cardizem® CD.

3. As used herein, “ANDA 75-984” means the Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j) by Faulding for a generic bioequivalent version of Cardizem® CD.

4. As used herein, “Andrx” means Andrx Pharmaceuticals, Inc., its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

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6. As used herein, “Cardizem® CD” means the diltiazem formulation sold under that trademark.

7. As used herein, “District Court” means the U.S. District Court for the Southern District of Florida.

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10. As used herein, "Hatch-Waxman Amendments" means the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), adding section 505(j) to the Food Drug and Cosmetics Act (21 U.S.C. § 355(j)(5)).

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15. As used herein, "584 Patent" means U.S. Patent No. 5,470,584 issued by the U.S. Patent and Trademark Office on November 28, 1995.

REQUESTS FOR ADMISSIONS

The Patent Infringement Case

Request No. 1: Admit that pursuant to Section 505(j) of the Food, Drug and Cosmetic Act (21 U.S.C. §§ 355(j)), Andrx filed its application for a generic bioequivalent version of Cardizem® CD, ANDA 74-752, on September 22, 1995.

Answer:

Request No. 2: Admit that as part of Andrx's September 22, 1995 filing, Andrx certified that its generic product did not infringe any patents owned or licensed by HMR relating to Cardizem® CD.

Answer:

Request No. 3: Admit that U.S. Patent No. 5,470,584, which pertained to dissolution characteristics of sustained release once-daily diltiazem products, was issued by the United States Patent and Trademark Office on November 28, 1995.

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Request No. 7: Admit that U.S. Patent No. 5,470,584 is both valid and enforceable.

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Request No. 8: Admit that the product that was the subject of Andrx's ANDA 74-752, as filed on September 22, 1995, infringed U.S. Patent No. 5,470,584.

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Answer:

Request No. 34: Admit that on March 16, 1999, HMR responded to Andrx's September 11, 1998 Supplement to ANDA 74-752 by stating that it would not assert the '584 Patent claims against Andrx's reformulated product so long as the dissolution values of the SR2

pellets contained in the reformulated product, as manufactured, met or exceeded the values set forth in Andrx's Supplemental Patent Certification.

Answer:

Request No. 35: Admit that the parties entered into a final settlement of the Patent Infringement Litigation on June 8, 1999.

Answer:

Request No. 36: Admit that the HMR/Andrx Stipulation and Agreement terminated on June 8, 1999.

Answer:

Request No. 37: Admit that Andrx received FDA's final approval of its September 11, 1998 Supplement to ANDA 74-752 on June 8, 1999.

Answer:

Request No. 38: Admit that Andrx could not have legally sold the product subject to its September 11, 1998 Supplement to ANDA 74-752 prior to June 8, 1999, the date upon which it received FDA's final approval of its reformulated product.

Answer:

Request No. 39: Admit that as of June 8, 1999, Andrx was no longer permitted to sell or distribute the formulation of its generic product for which it received final FDA approval on July 9, 1998.

Answer:

Faulding

Request No. 40: Admit that Faulding filed its application for a generic bioequivalent version of Cardizem® CD, ANDA 75-984, on September 11, 1996.

Answer:

Request No. 41: Admit that as part of Faulding's September 11, 1996 filing, that Faulding certified that its generic product did not infringe any patents owned or licensed by HMR relating to Cardizem® CD.

Answer:

Request No. 42: Admit that U.S. Patent No. 5,439,689 is valid and enforceable.

Answer:

Request No. 43: Admit that the product that was the subject of Faulding's ANDA 74-984 infringed U.S. Patent No. 5,439,689.

Answer:

Request No. 44: Admit that there was a substantial likelihood that the product that was the subject of Faulding's ANDA 74-984 infringed U.S. Patent No. 5,439,689.

Answer:

Request No. 45: Admit that HMR was reasonable in asserting that the product that was the subject of Faulding's ANDA 74-984 infringed U.S. Patent No. 5,439,689.

Answer:

Request No. 46: Admit that HMR was not unreasonable in asserting that the product that was the subject of Faulding's ANDA 74-984 infringed U.S. Patent No. 5,439,689.

Answer:

Request No. 47: Admit that on December 23, 1996, Faulding provided a copy of its patent certification relating to ANDA 75-984 to HMR.

Answer:

Request No. 48: Admit that on January 31, 1997, HMR filed the patent infringement action in the District of New Jersey, alleging that Faulding's generic product

infringed U.S. Patent No. 5,439,689 and that the filing of Faudling's ANDA constituted a statutory act of infringement.

Answer:

Request No. 49: Admit that HMR/Faulding patent infringement litigation was filed within the time frame contemplated by 21 U.S.C. § 355(j)(5)(B)(iii) and that pursuant to thirty-month statutory stay imposed by 21 U.S.C. § 355(j)(5)(B)(ii), FDA could not have granted final approval for Faulding's generic product any earlier than on or about June 1, 1999.

Answer:

Request No. 50: Admit that Faulding did not receive the FDA's tentative approval of its generic product until October 26, 1998, over two years after it filed its original ANDA.

Answer:

Request No. 51: Admit that HMR and Faulding settled the HMR/Faulding patent infringement litigation on May 3, 1999 under a settlement agreement in which Faulding obtained

a license to HMR's technology in exchange for a licensing fee and a royalty rate applicable to the sales of Faulding's product.

Answer:

Request No. 52: Admit that as a part of that settlement, Faulding admitted that U.S. Patent No. 5,439,689 was both valid and enforceable and that the Faulding generic formulation that was encompassed by ANDA 75-984 and was the subject of the HMR/Faulding patent infringement litigation infringed U.S. Patent No. 5,439,689.

Answer:

Request No. 53: Admit that sales of Faulding's generic Cardizem® CD product commenced on December 21, 1999.

Answer:

Biovail

Request No. 54: Admit that Biovail filed its application for a generic bioequivalent version of Cardizem® CD, ANDA 75-1169, on June 19, 1997.

Answer:

Request No. 55: Admit that as part of Biovail's June 19, 1997 filing, that Biovail certified that its generic product did not infringe any patents owned or licensed by HMR relating to Cardizem® CD.

Answer:

Request No. 56: Admit that on June 18, 1997, Biovail provided a copy of its patent certification to HMR which triggered the commencement of the 45 day period pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

Answer:

Request No. 57: Admit that in response to HMR's efforts to obtain information relating to Biovail's generic product, Biovail took the position that HMR was legally precluded from initiating any patent infringement action based upon earlier agreements.

Answer:

Request No. 58: Admit that the 45 day period provided by 21 U.S.C. § 355(j)(5)(B)(iii) expired without HMR having filed a patent infringement action against Biovail.

Answer:

Request No. 59: Admit that Biovail did not receive the FDA's tentative approval of its generic product until late- October 1999, almost two and one-half years after it filed its ANDA 75-1169.

Answer:

Request No. 60: Admit that apart from Andrx, Biovail and Faulding, no other generic companies have filed applications with the FDA to manufacture and sell generic versions of Cardizem® CD.

Answer:

Request No. 61: Admit that following the introduction of Cartia XT, Andrx's reformulated generic version of Cardizem® CD, Andrx enjoyed gross sales of over \$175 million and net sales of over \$125 million during the seven month period running from June 23, 1999, the date that Cartia XT first shipped and January 31, 2000.

Answer:

Request No. 62: Admit that had Andrx been able to launch a non-infringing generic version of Cardizem® CD in July 1998, it would have enjoyed gross and net sales comparable to that which it enjoyed following the introduction of its non-infringing product in late-June 1999.

Answer:

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of

Hoechst Marion Roussel, Inc., et al.,

Respondents

Docket No. 9293

CERTIFICATE OF SERVICE

I, Peter D. Bernstein, hereby certify that on April 24, 2000, a copy of the First Request for Admissions of Respondent Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc., was served upon the following persons by hand delivery and/or Federal Express as follows:

Donald S. Clark, Secretary
Federal Trade Commission
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Markus Meier
Federal Trade Commission
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Peter D. Bernstein