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

COMPLAINT COUNSEL'S RESPONSE TO RESPONDENT AVENTIS PHARMACEUTICALS, INC'S FIRST REQUEST FOR ADMISSIONS

Pursuant to Federal Trade Commission ("FTC") Rules of Practice Section 3.32, 16 C.F.R. § 3.32, complaint counsel submit this Response to Respondent Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc., Requests for Admissions to the FTC. Complaint counsel timely submit these Responses within the twenty (20) day time frame set forth in Additional Provision 2 of the Court's Scheduling Order entered on April 26, 2000.

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: Admitted

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: Admitted

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: Admitted

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

Answer: Admitted that Andrx was informed of U.S. Patent No. 5,470,584 on or before December 15, 1995.

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: Admitted that Andrx re-certified to the FDA that its generic product, which was the subject of ANDA 74-752, did not infringe any patents owned or licensed by HMR relating to Cardizem CD, including U.S. Patent No. 5,470,584, but denied that Andrx provided this certification to the FDA on December 30, 1995. To the best of complaint counsel's

knowledge, Andrx's certification to the FDA occurred on January 17, 1996. See Letter from David Gardner to Director, Office of Generic Drugs (68586-87).

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: Admitted

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

Answer: Complaint counsel can neither admit nor deny this Request. To the best of complaint counsel's knowledge, no court has ruled on the validity or enforceability of U.S. Patent No. 5,470,584.

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.*

Answer: Complaint counsel can neither admit nor deny this Request. To the best of complaint counsel's knowledge, no court has held 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.

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.*

Answer: Complaint counsel can neither admit nor deny this Request. To the best of complaint counsel's knowledge, no court has held 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.

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.*

Answer: Complaint counsel can neither admit nor deny this Request. To the best of complaint counsel's knowledge, no court has held 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. Complaint counsel does not contend, however, that HMR's assertion of infringement was objectively baseless.

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: Complaint counsel can neither admit nor deny this Request. To the best of complaint counsel's knowledge, no court has held 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. Complaint counsel does not contend, however, that HMR's assertion of infringement was objectively baseless.

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: Admitted

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: Admitted

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: Admitted that HMR and Andrx entered into the HMR/Andrx Stipulation and Agreement, but denied that the date of this agreement is September 27, 1997. To the best of complaint counsel's knowledge, the HMR/Andrx Stipulation and Agreement was executed on September 24, 1997. See HMR/Andrx Stipulation and Agreement (004291-4300).

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: Admitted that this Request is an accurate recitation of the language in Paragraph 2.A. of the HMR/Andrx Stipulation and Agreement, but it is incomplete. Paragraph 2.A. of the HMR/Andrx Stipulation and Agreement also states that Andrx agreed not to commence the commercial sale of any "other bioequivalent or generic version of Cardizem CD" until the earliest of the three events identified in Request No. 15.

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: Admitted that this Request is an accurate recitation of the language in paragraph 2.A. of the HMR/Andrx Stipulation and Agreement.

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: Admitted to the extent that Paragraph 3 of the HMR/Andrx Stipulation and Agreement states that, in the event Andrx prevailed in the patent infringement litigation, HMR would pay Andrx at a stipulated rate of $100 million per year. Denied to the extent that the stipulated payments of $100 million per year purports to represent the profits Andrx would have otherwise realized had it marketed its generic product following FDA approval but prior to final judgment in the Patent Infringement Litigation.

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.*

Answer: Admitted that this Request is an accurate recitation of the language in Paragraph 3.A. of the HMR/Andrx Stipulation and Agreement, which states that, for the purposes of the HMR/Andrx Stipulation and Agreement, HMR and Andrx stipulated that Lost Profits would amount to $100 million per year.

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

Answer: Admitted that this Request is an accurate recitation of the language in Paragraph 2.B. of the HMR/Andrx Stipulation and Agreement, which states that HMR agreed not to seek further preliminary injunctive relief against Andrx in the Patent Infringement Litigation or otherwise until the entry of Final Judgment, as that term is defined in the HMR/Andrx Stipulation and Agreement.

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: Admitted that this Request accurately paraphrases the language in Paragraph 4 of the HMR/Andrx Stipulation and Agreement.

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: Admitted that this Request accurately paraphrases the language in Paragraph 3.B. of the HMR/Andrx Stipulation and Agreement, which states that, in the event that Andrx prevailed in the patent infringement litigation, the total amount of Interim Payments would be deducted from the stipulated Lost Profits that HMR was otherwise obligated to pay.

Request No. 22: *Admit that under the HMR/Andrx Stipulation and Agreement, HMR granted Andrx an 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: Admitted that this Request accurately paraphrases the language in Paragraph 5 of the HMR/Andrx Stipulation and Agreement, which states that HMR grants to Andrx an option to acquire a license to all intellectual property owned or controlled by HMR that Andrx would need to sell, market and distribute the Andrx Product, as that term is defined in the HMR/Andrx Stipulation and Agreement. Paragraph 6 of the HMR/Stipulation and Agreement identifies three opportunities for exercise of this option: (1) within 30 days of final resolution of the patent infringement suit; (2) January, 2000 – a date 18 months following FDA approval; or (3) in the event HMR notifies Andrx of its intent to license said intellectual property to any other party for the purposes of selling a bioequivalent or generic version of Cardizem CD or of its intent to use said intellectual property for the purposes of selling its own bioequivalent or generic version of Cardizem CD.

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: Admitted that this Request accurately paraphrases the language in Paragraph 7.B.ii of the HMR/Andrx Stipulation Agreement, which states that, in the event that Andrx had chosen to exercise its option to acquire a license to HMR's intellectual property prior to the Effective Date of Final Judgment in the Patent Infringement Litigation and was subsequently determined to have infringed the '584 Patent, Andrx would be required to pay an additional license fee of $30 million within 30 days of the Effective Date of Final Judgment and thereafter pay HMR a royalty of 20% of net receipts.

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: Admitted in part and denied in part. Admitted that under Paragraph 8.B.i of the HMR/Andrx Stipulation and Agreement, a 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. Denied to the extent that the Request refers to this as the only consequence. An additional consequence of Andrx violating any obligation under Paragraph 2 of the HMR/Andrx Stipulation and Agreement is that

Andrx forfeits any future right to the $10 million a quarter non-refundable interim payments pursuant to Paragraph 4 of the HMR/Andrx Stipulation and Agreement, as well as any right to recover additional payments of up to $60 million a year in the event Andrx prevails in the patent infringement litigation.

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: Denied. HMR issued a press release on September 25, 1997, which does not accurately summarize the essential terms, nature and scope of the HMR/Andrx Stipulation and Agreement and which contains, among others, the following inaccurate or incomplete statements:

- *Andrx's product "infringes [HMR's] patent for that product."*

  This statement is inaccurate because no court has ever made such a finding.

- *Under the HMR/Andrx Stipulation and Agreement, Andrx agrees to defer marketing of its product until final resolution of the litigation.*

  This statement is incomplete because under the HMR/Andrx Stipulation and Agreement, Andrx also agreed to defer marketing of any "bioequivalent or generic versions of Cardizem CD," including versions which did not infringe any patent controlled by HMR.

- *Under the HMR/Andrx Stipulation and Agreement, HMR would compensate Andrx for any lost profits in the event that Andrx ultimately prevailed in the litigation.*

  This statement is both inaccurate and incomplete. It is inaccurate because, under the HMR/Andrx Stipulation and Agreement, no actual determination of lost profits would occur. In the event Andrx ultimately prevailed in the litigation, Andrx would be paid at the stipulated amount of $100 million per year, regardless

of whether this amount exceeded Andrx's actual lost profits. This statement is incomplete because, under the HMR/Andrx Stipulation and Agreement, HMR also compensates Andrx $10 million a quarter even if Andrx loses the litigation.

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: Admitted that HMR initially delivered a copy of the HMR/Andrx Stipulation and Agreement to the Federal Trade Commission on or around November 21, 1997, as part of a submission of approximately 4400 pages in the context of a separate investigation – the Commission's review of the proposed acquisition of the Rugby Group, Inc. a subsidiary of HMR, by Watson Pharmaceuticals, Inc. In the context of the investigation which gave rise to this complaint (FTC File No. 981-0368), HMR first delivered the HMR/Andrx Stipulation and Agreement to the Commission on or around November 25, 1998.

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: Denied to the extent that this request calls for a legal conclusion. Admitted to the extent that payments under the Lost Profit Payments and Interim Payment provisions of the HMR/Andrx Stipulation and Agreement were not made until July 9, 1998.

ANDRX SUPPLEMENT

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

Answer: Admitted

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: Admitted

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: Complaint counsel can neither admit nor deny this Request. To the best of complaint counsel's knowledge, no court has determined whether 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. In addition, Complaint counsel is not privy to any opinions of patent counsel received by either HMR or Andrx on the likelihood that the reformulation reflected in the September 11, 1998 Supplement to ANDA 74-752 infringed the '584 Patent.

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: Admitted

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

Answer: Admitted

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: Admitted

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: Admitted in part and denied in part. Admitted that, in a March 16, 1999 letter, HMR stated 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 certain values. Denied to the extent that HMR's letter purports to refer to the values set forth in Andrx's Supplemental Patent Certification, rather than the attached data sheets. See Letter from Ed Stratemeier to Scott Lodin (01680-84).

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

Answer: Admitted

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

Answer: Admitted that, pursuant to Paragraph 13 of the Stipulation and Order entered on June 8, 1999, the HMR/Andrx Stipulation and Agreement terminated on the date that

the U.S. Food & Drug Administration approved Andrx's September 11, 1998 Supplement to ANDA 74-752. Such approval occurred on June 8, 1999.

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: Admitted

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: Admitted to the extent that the Request is limited to Andrx's ability to legally sell in the United States the product subject to its September 11, 1998 Supplement to ANDA 74-752.

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: Admitted that this Request accurately recites complaint counsel's best understanding of applicable FDA regulations.

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: Admitted that Faulding filed its application for a generic bioequivalent version of Cardizem CD, ANDA 75-984, but denied that such application was filed on September 11, 1996. To the best of complaint counsel's knowledge, Faulding's application was submitted to the FDA on October 11, 1996. See Faulding's Abbreviated New Drug Application for Diltiazem Hydrochloride Extended-Release Capsules (F10 00015-36).

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: Admitted, except to the extent that the Request refers incorrectly to the date on which Faulding submitted its application to the FDA. See Response to Request for Admission No. 40.

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

Answer: Complaint counsel can neither admit nor deny this Request. To the best of complaint counsel's knowledge, no court has ruled on the validity or enforceability of U.S. Patent No. 5,439,689.

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: Complaint counsel can neither admit nor deny this Request. To the best of complaint counsel's knowledge, no court has held that the product that was the subject of Faulding's ANDA 74-984 infringed U.S. Patent No. 5,439,689.

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: Complaint counsel can neither admit nor deny this Request. To the best of complaint counsel's knowledge, no court has held 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.

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: Complaint counsel can neither admit nor deny this Request. To the best of complaint counsel's knowledge, no court has held 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. Complaint counsel does not contend, however, that HMR's assertion of infringement was objectively baseless.

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: Complaint counsel can neither admit nor deny this Request. To the best of complaint counsel's knowledge, no court has held 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. Complaint counsel does not contend, however, that HMR's assertion of infringement was objectively baseless.

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: Denied. To the best of complaint counsel's knowledge, Faulding provided HMR with notice of its patent certification relating to ANDA 74-984 on December 17, 1996. See Letter from Andrew Berdon to J. Michael Dixon (HMRI S12 001542-58).

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 Faulding's ANDA constituted a statutory act of infringement.*

Answer: Admitted

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: Admitted

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: Denied. To the best of complaint counsel's knowledge, Faulding received FDA tentative approval of its generic product on October 23, 1998. See Letter from Douglas Sporn, Director of Office of Generic Drugs, to Purepac Pharmaceuticals (HMRI S18 001514).

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: Admitted

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: Admitted to the extent that, as a condition to the execution of the settlement and the grant of the license, Faulding acknowledged that the generic formulation of Cardizem CD that was the subject of the HMR/Faulding patent infringement litigation infringed U.S. Patent NO. 5,439,689 and that U.S. Patent No. 5,439,689 was valid and enforceable.

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

Answer: Admitted

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: Denied. To the best of complaint counsel's knowledge, Biovail submitted to the FDA its application for a generic bioequivalent version of Cardizem CD, ANDA 75-1169, on April 21, 1997. See Biovail's Abbreviated New Drug Application for Diltiazem Hydrochloride Extended-Release Capsules (BVL0005990-6059).

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: Admitted, except to the extent that the Request refers incorrectly to the date on which Biovail submitted its application to the FDA. See Response to Request for Admission No. 53.

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: Admitted that Biovail provided a copy of its patent certification to HMR on or around June 18, 1997.

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: Admitted that Biovail took the position that HMR was legally precluded from initiating any patent infringement action based upon earlier agreements, including the Settlement Agreement and Release entered into on April 28, 1995. See Settlement Agreement and Release (BVL0006368-406). Complaint counsel can neither admit nor deny whether Biovail took this position in response to HMR's efforts to obtain information relating to Biovail's generic product.

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: Admitted

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: Admitted

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: Admitted that apart from Andrx, Biovail and Faulding, no other generic companies have filed applications to manufacture and sell generic version of Cardizem CD, as of May 15 , 2000.

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.*

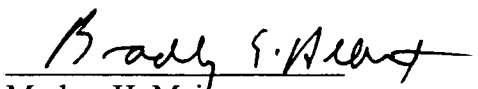
Answer: Complaint counsel has insufficient knowledge to either admit or deny this Request. Complaint counsel notes that, in correspondence with FTC staff dated February 11, 2000, Andrx reported $162,265,956 in gross sales and $115,568,020 in net sales for Cartia XT for the period from June through December 1999. For the month of January 2000, Andrx reported preliminary figures of $15,124,898 in gross sales and $12,060,913 in net sales. Since complaint counsel has not yet had the opportunity to review the data supporting these totals, we can neither admit nor deny the accuracy of these figures at this time.

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: Complaint counsel can neither admit nor deny this Request. Andrx's sales of generic Cardizem CD are dependant on various factors, including, but not limited to: Andrx's pricing strategy, marketing and contracting efforts, manufacturing capacity and availability of raw materials, as well as HMR's pricing and marketing strategy in response to Andrx's entry. At

this time, complaint counsel has no basis to evaluate how each of these factors would have affected Andrx's sales of generic Cardizem CD had Andrx launched its product in July 1998, rather than in June 1999.

Respectfully Submitted,



Markus H. Meier
Bradley S. Albert

Counsel Supporting the Complaint

Bureau of Competition
Federal Trade Commission
Washington, D.C. 20580

Dated: May 15, 2000

CERTIFICATE OF SERVICE

I, Bradley S. Albert, hereby certify that on May 15, 2000, I caused a copy of the following documents to be served upon the following persons via hand delivery, or facsimile and overnight delivery: (1) Complaint Counsel's Response to Aventis Pharmaceuticals, Inc.'s First Request for Admissions; (2) Complaint Counsel's Responses and Objections to Aventis Pharmaceuticals, Inc.'s First Request for Production of Documents; and (3) Complaint Counsel's Responses and Objections to Andrx Corporation's First Set of Interrogatories.

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