Analysis to Aid Public Comment

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with Hoechst Marion Roussel, Inc. ("HMR"), Carderm Capital, L.P. ("Carderm"), and Andrx Corporation ("Andrx") to resolve the matters alleged in an administrative complaint issued by the Commission on March 16, 2000. The proposed consent order has been placed on the public record for 30 days to receive comments from interested members of the public. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by HMR, Carderm, or Andrx (collectively "the Respondents") that they violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true. Respondents deny all other allegations of the complaint.

The Complaint

The complaint alleges that the Respondents entered into an agreement that had the tendency or capacity to restrain competition unreasonably by discouraging generic competition to Cardizem CD. Cardizem CD is a prescription drug manufactured and sold by HMR and is used to treat two chronic conditions that affect millions of Americans: hypertension (high blood pressure) and angina pectoris (chest pain). Andrx is a generic drug manufacturer that developed a generic version of Cardizem CD.

Generic drugs typically are sold at substantial discounts from the price of branded drugs. Generic drugs can have a swift marketplace impact, the complaint states, because pharmacists generally are permitted, and in some instances are required, to substitute lower-priced generic drugs for their branded counterparts, unless the prescribing physician directs otherwise. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, state Medicaid programs and many private health plans) encourage or insist on the use of generic drugs wherever possible.

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as "the Hatch-Waxman Act," to facilitate the entry of lower priced generic drugs while maintaining incentives to invest in new drug development. A company seeking approval from the Food and Drug Administration ("FDA") to market a new drug must file a New Drug Application ("NDA") demonstrating the safety and efficacy of its product. In order to receive FDA approval to market a generic version of a brand name drug a company must file an Abbreviated New Drug Application ("ANDA") demonstrating that its product is bioequivalent to its brand-name counterpart.

The Hatch-Waxman Act establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic drug prior to the expiration of a patent or patents relating to the brand name drug upon which the generic is based. In such cases, the applicant must: (1) certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a "paragraph IV certification"); and (2) notify the patent holder of the filing of the certification. If the holder of the patent rights files a patent infringement suit within 45 days, FDA approval to market the generic drug is automatically stayed for 30 months,

under certain circumstances, unless before that time the patent expires or the patent is judicially determined to be invalid or not infringed. This automatic 30-month stay allows the patent holder time to seek judicial protection of its patent rights before a generic competitor is permitted to market its product.

In addition, the Hatch-Waxman Act provides an incentive for generic drug companies to bear the cost of patent litigation that may arise when they challenge invalid patents or design around valid ones. Under current FDA regulations, the Act grants the first company to file an ANDA with a paragraph IV certification a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. No other generic manufacturer may obtain FDA approval to market its product until the first filer's 180-day exclusivity period has expired. At the time the Respondents entered into the challenged agreement in 1997, the governing FDA regulations required that an ANDA applicant successfully defend the patent holder's patent suit in order to be entitled to this exclusivity.

Andrx was the first company to file an ANDA for a generic version of Cardizem CD. It filed a paragraph IV certification with the FDA stating its belief that the product did not infringe any valid patent covering Cardizem CD. In January 1996, HMR sued Andrx for patent infringement. The lawsuit triggered a 30-month stay of final FDA approval of Andrx's generic product, until July 1998.

According to the complaint, HMR and Andrx entered into an agreement in September 1997, in the midst of this patent lawsuit. At the time of the agreement, approximately nine months before the 30-month stay of FDA approval of Andrx's application would expire, the patent lawsuit had already been pending for twenty-one months and both sides had filed numerous dispositive motions with the trial court that had not been acted on. Also by that time, two other companies, Purepac Pharmaceutical Co. and Biovail Corporation International, had filed for FDA approval of a generic Cardizem CD product, neither of which had yet obtained tentative approval from the FDA.

HMR's forecasts, the complaint states, projected that a generic once-a-day diltiazem product would capture roughly 40 percent of Cardizem CD sales within the first year following its launch. Cardizem CD was HMR's largest selling product at the time. Accordingly, the complaint charges, HMR sought to delay Andrx – and all other potential generic competition to Cardizem CD – from entering the market because of the threat they represented to the high profits it was making from Cardizem CD.

The complaint alleges that on September 24, 1997, HMR, Carderm, and Andrx entered into a "Stipulation and Agreement." The Stipulation and Agreement did not settle the lawsuit. Instead, under this agreement, the complaint alleges that Andrx agreed not to enter the market with its generic Cardizem CD product until the earliest of: (1) final resolution of the patent infringement litigation; (2) Andrx's exercise of an option to obtain a license from HMR in the future; or (3) notice by HMR that it would allow entry of another generic Cardizem CD product

or market its own generic version of Cardizem CD. According to the complaint, Andrx also agreed to refrain from selling during the patent infringement suit any other bioequivalent or generic version of Cardizem CD. In addition, the complaint alleges that Andrx agreed not to withdraw its pending ANDA or to relinquish or otherwise compromise any right accruing under its ANDA, including its 180-day exclusivity right. In return, the complaint alleges, HMR agreed to pay Andrx $10 million per quarter during the litigation beginning when Andrx received final FDA approval of its ANDA, unless the litigation was resolved prior to that time. Under the agreement, if HMR lost the patent infringement suit it would pay Andrx an additional $60 million per year for that same time period. On September 25, 1997, the parties made public disclosures of the existence of the agreement. The Commission's complaint alleges that this agreement, at the time it was entered into, had the potential to affect Andrx's incentive to compete once it received final FDA approval.

In July 1998, upon expiration of the 30-month stay under Hatch-Waxman, Andrx received final FDA approval to market its original formulation of generic Cardizem CD that was subject to the still on-going lawsuit with HMR. Pursuant to the terms of the Stipulation and Agreement, HMR began making quarterly payments of $10 million to Andrx.

Andrx filed a supplement to its ANDA reflecting a reformulation of its generic Cardizem CD product in September 1998. This reformulation altered the dissolution profile of the Andrx product, which was the basis of the patent dispute between Andrx and HMR. The FDA required Andrx to file a new certification and give notice to HMR of the reformulated product under the Hatch-Waxman procedures described above. Following its analysis of the reformulated product, HMR agreed that it would not assert a patent claim against the reformulated product. By June 1999, Andrx had solved the difficulties it had encountered since the summer of 1997 in consistently manufacturing commercial scale quantities of its formulations of its product in conformity with FDA regulations. Andrx received FDA approval in June 1999 to market its reformulated version of Cardizem CD. On or about the day Andrx received FDA approval of its reformulated product, the Respondents entered into a stipulation dismissing the litigation, with an agreement by Andrx not to sell its original formulation and an agreement by HMR not to sue Andrx for patent infringement on Andrx's reformulated product. The challenged agreement terminated.

On or about June 23, 1999, the federal district court dismissed the patent suit, and Andrx commenced marketing its reformulated generic Cardizem CD product, triggering its 180-day exclusivity period. At that time, Biovail Corporation International had not received tentative FDA approval for its product, and Purepac Pharmaceutical Co. had entered into a licensing arrangement with HMR for manufacture of generic Cardizem CD. Andrx's 180-day exclusivity period expired on December 19, 1999. Purepac launched its generic Cardizem CD product the next day pursuant to a license from HMR. Biovail obtained final FDA approval on December 23, 1999, and launched its product shortly thereafter.

Based on the FTC's investigation, it does not appear that there was any delay in the entry into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD. The agreement terminated in June 1999. It was at that time that Andrx received FDA approval to market, and commenced marketing, a reformulated generic version of Cardizem CD that HMR stipulated did not infringe any HMR patent.

The complaint alleges that the challenged agreement was not justified by countervailing efficiencies. In its complaint, the Commission alleged that the presence in the agreement of a licensing provision (permitting Andrx to obtain a license from HMR to market generic Cardizem CD in January 2000, in the event Andrx lost the patent litigation, or if another generic company obtained final FDA approval) did not justify the agreement. The complaint alleges that entry by Andrx under a license, had it occurred, likely would have been later than entry by Andrx or another generic manufacturer absent the agreement.

Finally, the complaint charges that HMR had a monopoly in the market for once-a-day diltiazem, and, that by entering into the agreement with Andrx, HMR sought to preserve its dominance by delaying the entry of Andrx and other generic companies into the market. At the time of the challenged agreement, HMR accounted for 70% of the sales of once-a-day diltiazem in the United States. Other drugs, the complaint alleges, are not effective substitutes for once-a-day diltiazem because they are different in efficacy and side effects, and because of risks associated with switching patients from one treatment to another. In addition, the complaint alleges that HMR and Andrx conspired to monopolize the market for once-a-day diltiazem products. The complaint alleges that HMR and Andrx acted with specific intent that HMR monopolize the market for once-a-day diltiazem, and entered into a conspiracy to achieve that goal. Finally, the complaint charges that the Respondents' agreement otherwise amounts to an unfair method of competition in violation of Section 5 of the FTC Act.

The Proposed Order

In a statement issued at the time of the filing of the complaint in this matter, the members of the Commission stated that cases like this one "must be examined with respect to [their] particular facts," and that the "development of a full factual record in the administrative proceeding . . . will help to shape further the appropriate parameters of permissible conduct in this area, and guide other companies and their legal advisors."[1] Although the particular agreement challenged in the complaint has been terminated, the Commission believes prospective relief is necessary to prevent a recurrence of the types of agreements covered by the proposed order. Private agreements in which the brand name drug company (the "NDA Holder") pays the first

[1] Statement of Chairman Pitofsky, Commissioner Anthony, Commissioner Thompson, Commissioner Swindle, and Commissioner Leary concerning Abbott Laboratories and Geneva Pharmaceuticals, Inc., File No. 981-0395 (March 16, 2000).

generic to seek FDA approval (the "ANDA First Filer"), and the ANDA First Filer agrees not to enter the market, have the potential to delay generic competition and raise serious antitrust issues. Moreover, the FDA has observed that the incentives for companies to enter into such arrangements are becoming greater, as the returns to a brand name company from extending its monopoly increasingly exceed the potential economic gains to the generic applicant from its 180 days of market exclusivity.[2]

The proposed order strikes an appropriate balance, on a prospective basis, between the legitimate interests of the Respondents and the Commission's concerns with the possible competitive effects of agreements between NDA Holders and ANDA First Filers. By not imposing any broad prohibitions on the Respondents' ability to compete, the order maintains HMR's incentive to develop and sell new drug products and Andrx's incentive to develop and sell generic products that do not infringe valid intellectual property rights held by others. In addition, the order preserves Andrx's ability to decide for itself whether to market a product in the face of a claim of patent infringement, so long as such decision is otherwise lawful.

As described more fully below, the proposed order:

- bars (except in certain licensing arrangements) two particular types of agreements between brand name drug companies and potential generic competitors – restrictions on giving up Hatch-Waxman 180-day exclusivity rights and on entering the market with a non-infringing product;

- requires that interim settlements of patent litigation involving payments to the generic company in which the generic company temporarily refrains from bringing its generic product to market, be approved by the court, with notice to the Commission to allow it time to present its views to the court; and

- requires the Respondents to give the Commission written notice 30 days before entering into such agreements in other contexts.

Paragraph II prohibits two kinds of agreements between an NDA Holder and the ANDA First Filer (that is, the party possessing an unexpired right to Hatch-Waxman 180-day exclusivity). Paragraph II.A. bars agreements in which the first company to file an ANDA agrees with the NDA Holder not to relinquish its right to the 180-day exclusivity period (as interpreted by the courts at the time of the agreement). Paragraph II.B. prohibits the ANDA First Filer from agreeing not to develop or market a generic drug product that is not the subject of a claim of patent infringement. The order recognizes, however, that even these types of agreements, in the context of certain licensing arrangements, might not raise competitive concerns. Accordingly, conduct otherwise falling within the conduct described in Paragraph II would not be prohibited where the ANDA First Filer agrees to license and introduce a competitive product to the market, its 180-day exclusivity right is not extended, and the Commission is provided notice.

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[2] FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42882-83 (August 6, 1999).

Paragraph II's focus on agreements between an NDA Holder and the ANDA First Filer does not mean that the Commission believes that there is no risk of competitive harm in other types of agreements. In particular substantial competitive concerns could arise from an agreement in which a generic company (other than the ANDA First Filer) agrees with the NDA Holder to refrain from marketing a non-infringing product. Given the variety of circumstances in which the restraints may arise, however, and the possibility that some legitimate justifications might exist for such arrangements, the Commission believes that it is appropriate at this time to limit the bans in Paragraph II to the described agreements between NDA Holders and ANDA First Filers.

Paragraph III covers certain private agreements involving payments from the NDA Holder to the ANDA First Filer during patent infringement litigation. Generally, the Respondents can enter into such arrangements only if (a) the agreement is presented to the court and embodied in a court-ordered preliminary injunction, and (b) the following other conditions are met: (i) along with any stipulation for preliminary injunction, Respondents provide the court with a copy of the Commission's complaint, order, and the Analysis to Aid Public Comment in this matter, as well as the proposed agreement; (ii) at least 30 days before submitting the stipulation to the court, they provide written notice (as set forth in Paragraph V of the order) to the Commission; and (iii) they do not oppose Commission participation in the court's consideration of the request for preliminary relief.

This part of the proposed order is designed to enhance the court's ability to assess the competitive implications of such agreements. This remedy, in addition to facilitating the court's access to information about the Commission's views, may also make the process more public and thereby may prompt other generic drug manufacturers (or other interested parties) to participate.

Paragraph IV addresses private agreements in which an ANDA First Filer agrees with the NDA Holder not to enter the market. Such situations would include agreements that are part of a final settlement of the litigation, and situations in which no litigation has been brought. In these circumstances, there may be no judicial role in ordering relief agreed to by the Respondents. Thus, the order requires that the Respondents notify the Commission at least 30 days before entering into such agreements. Such notice will assist the Commission because of the potential for competitive harm that these agreements may create. Absent the order, there may be no effective mechanism for the Commission to find out about such agreements.

The form of notice that the Respondents must provide to the Commission under Paragraphs II, III and IV of the order is set forth in Paragraph V. In addition to supplying a copy of the proposed agreement, the Respondents are required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the order requires the Respondents to identify, among other things, all others who have filed an ANDA for a product containing the same chemical entities as the product at issue, and the court that is hearing any relevant legal proceedings involving either party. In addition, the

Respondents must provide the Commission with all documents that evaluate the proposed agreement.

The proposed order also contains certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The order will expire in 10 years.

Opportunity for Public Comment

The proposed order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed order and the comments received and will decide whether it should withdraw from the proposed order or make the proposed order final.

By accepting the proposed order subject to final approval, the Commission anticipates that the competitive issues alleged in the complaint will be addressed. The purpose of this analysis is to facilitate public comment on the agreement. It is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.