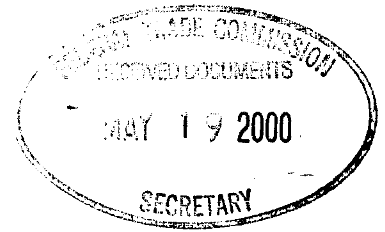



**UNITED STATES OF AMERICA**
**BEFORE THE FEDERAL TRADE COMMISSION**

In the Matter of

**Hoechst Marion Roussel, Inc., et al.,**

**Respondents**

Docket No. 9293

TO: The Honorable D. Michael Chappell
Administrative Law Judge

## OPPOSITION OF AVENTIS PHARMACEUTICALS, INC. TO COMPLAINT COUNSEL'S MOTION TO STRIKE CERTAIN AFFIRMATIVE DEFENSES SET FORTH IN RESPONDENTS' ANSWERS

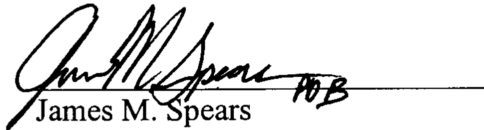
Pursuant to Rule 3.22 of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.22, respondent Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc. ("HMR"), hereby answers and opposes Complaint Counsel's Motion to Strike Affirmative Defense Nos. 2 and 13 asserted in HMR's Answer to the Commission's Complaint.

Respondent HMR further joins in the motions of Co-Respondents Carderm Capital L.P. ("Carderm") and Andrx Corporation ("Andrx") in opposing Complaint Counsel's Motion to Strike affirmative defenses asserted by Carderm, Andrx and HMR.

WHEREFORE, for reasons more fully set forth in the accompanying memorandum in opposition to Complaint Counsel's Motion to Strike, HMR respectfully requests that this Court enter an Order denying Complaint Counsel's motion, and grant such other relief as the Court may deem just and proper.

Dated: May 19, 2000

Respectfully Submitted,

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

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| In the Matter of<br><br>**Hoechst Marion Roussel, Inc., et al.,**<br><br>**Respondents** | Docket No. 9293 |

**AVENTIS PHARMACEUTICALS, INC.'S MEMORANDUM IN OPPOSITION TO COMPLAINT COUNSEL'S MOTION TO STRIKE CERTAIN AFFIRMATIVE DEFENSES SET FORTH IN RESPONDENTS' ANSWERS**

The Complaint in this matter arises from a patent infringement lawsuit that Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc. ("HMR"), filed against Andrx Pharmaceuticals Inc. ("Andrx") in 1996, in which HMR alleged that Andrx's generic formulation of HMR's Cardizem® CD product infringed HMR's U.S. Patent No. 5,470,584.[1] The gravamen of the Commission's Complaint alleges that by agreeing to a stipulated preliminary injunction during the course of that litigation, HMR, Andrx and Carderm Capital L.P. ("Carderm") engaged in allegedly monopolistic practices and allegedly restrained trade such as to constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act (the "FTC Act"), 15 U.S.C. § 45.

In its April 10, 2000 Answer, Respondent HMR asserted 14 affirmative defenses. Among other things, Respondent alleged that the Complaint failed to satisfy the "reason to

1. *See Hoechst Marion Roussel, Inc., et al. v. Andrx Pharmaceuticals, Inc.*, No. 96-06121 (S.D. Fla.).

believe" requirement of Section 5(b) of the FTC Act (HMR's Second Additional Defense)[2] and is in derogation of public policy and the public interest because of its effect in undermining applicable law and policy favoring the prosecution and settlement of patent infringement disputes (HMR's Thirteenth Additional Defense).[3] Complaint Counsel now moves this Court to strike HMR's Second and Thirteenth Additional Defenses, alleging that they are legally insufficient, irrelevant, and prejudicial to Complaint Counsel.

Respondent disagrees. As a threshold matter, Complaint Counsel has utterly failed to make the particularized showings of immateriality and prejudice that are required of any party making a motion to strike, relying instead upon sweeping and conclusory assertions which fail to even recognize, much less address, the specific assertions set forth in HMR's Additional Defenses. Complaint Counsel utterly fails to establish either the immateriality of the issues fairly presented in HMR's defenses or that the maintenance of these defenses would change the scope of discovery to any appreciable degree.

As to its Second Additional Defense, HMR submits that the "reason to believe" standard requires that the Commission have a well-grounded reason to believe that unlawful conduct has occurred. Here, where the putative unlawfulness of the conduct complained of turns

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2. In its Second Additional Defense, HMR alleges:

> The Complaint fails to comply with the requirements of Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b), because the Federal Trade Commission has no reason to believe that [HMR] violated the Federal Trade Commission Act.

3. HMR's Thirteenth Additional Defense alleges as follows:

> The relief sought by the Complaint is contrary to public policy and not in the public interest in that it limits, interferes with and otherwise hampers the orderly maintenance, prosecution and settlement of patent infringement litigation, thereby raising the cost of patent enforcement, reducing the value of patents, and deterring innovation and dynamic efficiencies.

on whether such conduct precipitated a significant anticompetitive effect in the market, the failure of the Complaint to plead any specific anticompetitive effect leaves open the issue of whether the Commission had formed the requisite "reason to believe" as to this critical element of the offense at the time that the Complaint issued.

As to its Thirteenth Additional Defense, HMR respectfully submits that the issue that Complaint Counsel characterizes as "immaterial" – the issue of whether antitrust liability can properly attach to the good-faith efforts of parties to resolve patent infringement litigation – is central to the resolution of this matter. This case presents the question of whether a patent holder who is diligently prosecuting a patent infringement action may properly stipulate to a preliminary injunction pursuant to which he agrees to make good any profits lost by the alleged infringer if the alleged infringer withholds sales of the allegedly infringing product until the infringement case is decided. Complaint Counsel's motion seeks to sidestep the patent issues which lie at heart of this case and would also have this tribunal ignore the defining role that the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act[4] (the "Hatch-Waxman Amendments") play in the process of bringing generic pharmaceutical products to market.

At bottom, Complaint Counsel has employed this motion in an attempt to sweep aside the gaping holes of proof in its own case, to test and probe the Respondents' defenses and to avoid the very significant implications that the Patent Act,[5] the Hatch-Waxman Amendments

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4. These amendments were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

5. 35 U.S.C. § 1 *et seq.*

and the *Noerr-Pennington* doctrine[6] spell for its theory of liability. As such, the motion reflects precisely the sort of dilatory tactics that render motions to strike disfavored under the Federal Rules of Civil Procedure. For the reasons set forth herein, Complaint Counsel's motion should be denied in its entirety.[7]

## ARGUMENT

### 1. Motions to Strike are Disfavored, and Complaint Counsel Has Failed to Satisfy the Stringent Test Governing Motions to Strike.

As a threshold matter, Complaint Counsel's motion fails to acknowledge, much less accept, the substantial showing that a party offering a motion to strike must make in support of its motion. Under the Federal Rules, "because striking a portion of a pleading is a drastic remedy and because it often is sought by the movant simply as a dilatory tactic, motions under Rule 12(f) are viewed with disfavor and are infrequently granted."[8] 5A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1380, at 647-49 (2d ed. 1990) ("*Wright & Miller*"); *see also United States v. Walerko Tool & Eng'g Corp.*, 784 F. Supp. 1385, 1387 (N.D.

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6. *See, e.g., Eastern R.R. Presidents Conference v. Noerr Motor Freight,* 365 U.S. 127 (1961); *United Mine Workers of America v. Pennington,* 381 U.S. 657 (1965); and their progeny.

7. In addition, HMR joins in the motions of Co-Respondents Carderm and Andrx in opposing Complaint Counsel's motion to strike affirmative defenses asserted by Carderm, Andrx and HMR, for the reasons set forth in those motions.

8. In particular, courts have observed that

> Motions to strike are generally disfavored because they are often interposed to create a delay. Indeed, motions to strike can be nothing other than distractions. If a defense is clearly irrelevant, then it will likely never be raised again by the defendant and can be safely ignored. If a defense may be relevant, then there are other contexts in which the sufficiency of the defense can be more thoroughly tested with the benefit of a fuller record – such as on a motion for summary judgment.

*RTC v. Gregor,* No. 94 CV 2578, 1995 WL 931093, at *1 (E.D.N.Y. Sept. 29, 1995) (quoting *Van Schouwen v. Connaught Corp.,* 782 F. Supp. 1240, 1245 (N.D. Ill. 1991)).

Ind. 1992) (denying government's motion to strike equitable defenses of estoppel, release and/or waiver, and laches); *Dura Lube Corp.,* 2000 FTC Lexis 1, at *31 (Jan. 14, 2000) ("motions to strike are generally disfavored"); *Home Shopping Network, Inc.,* 1995 FTC Lexis 259, at *4 (July 24, 1995) ("It is axiomatic that motions to strike are not favored and are, therefore, infrequently granted."). "[I]n order to succeed on a motion to strike surplus matter from an answer, it must be shown that the allegations being challenged are so unrelated to plaintiff's claims as to be unworthy of any consideration as a defense and that their presence in the pleading throughout the proceeding will be prejudicial to the moving party." 5A *Wright & Miller* § 1380, at 649-50. Like any other motion, a motion to strike must state with particularity the grounds upon which the motion is based. 5A *Wright & Miller* § 1380, at 655. Such motions may not be used by Complaint Counsel simply to test the sufficiency of Respondents' defenses. *Home Shopping Network, Inc.,* 1995 FTC Lexis 259, at *4.

Because, as Complaint Counsel acknowledges, the Commission has no specific Rule of Practice governing a motion to strike, these same standards guide this tribunal in consideration of Complaint Counsel's motion. *See Dura Lube Corp.,* 2000 FTC Lexis 1, at *31; U.S. Federal Trade Comm'n, *Operating Manual* ch. 10.7 (1991); *see also* Pl.'s Br. at 2. As summarized in a comparable proceeding, "a motion to strike defenses or portions of an answer will be granted when the answer or defense (1) is unmistakably unrelated or so immaterial as to have no bearing on the issues and (2) prejudices Complaint Counsel by threatening an undue broadening of the issues or by imposing a burden on Complaint Counsel." *Dura Lube Corp.,* 2000 FTC Lexis 1, at *34; *see also Home Shopping Network, Inc.,* 1995 FTC Lexis 259, at *4; *Synchronal Corp.,* 1992 FTC Lexis 61, at *1 (Mar. 5, 1992).

As set forth in greater detail below, Complaint Counsel has utterly failed to make these requisite threshold showings of immateriality and prejudice, particularly as to those portions of the motion which relate to Respondent HMR's Additional Defenses. Here, in a case arising from a patent infringement suit and a complex drug regulatory scheme administered by the Food and Drug Administration ("FDA"), Complaint Counsel argues that the Patent Act and the Hatch-Waxman Amendments are "immaterial" to the resolution of this case. (Pl.'s Br. at 7-9.) Here, in a case which is subject to analysis under the Rule of Reason but where the Complaint is absolutely silent on the critical element of anticompetitive effect, Complaint Counsel argues that Respondents may not challenge whether the Commission possessed the requisite "reason to believe" that a law violation had occurred at the time that the Complaint issued. (Pl.'s Br. at 3.)

At bottom, Complaint Counsel has employed this motion to strike, not to secure the elimination of issues immaterial and unrelated to this case, but instead in an attempt to score a preemptive strike on issues which are properly in dispute and which lie at the heart of this case. In a case where Respondents and this tribunal are forced by the Commission's rules to adhere to an exceedingly stringent schedule, these sorts of dilatory pleadings should not be countenanced.

**2. Respondents May Properly Challenge Whether the Complaint is Supported by the Requisite "Reason to Believe" as to Elements of the Offense Which are Not Pled Specifically in the Complaint.**

As Complaint Counsel correctly notes, Section 5 of the FTC Act mandates that the Commission find, as a necessary predicate to the issuance of a complaint, that the Commission has "reason to believe" a law violation has occurred and that action by the Commission would be in the public interest. (*See* Pl.'s Br. at 3.) Complaint Counsel is clearly

incorrect, however, in suggesting that the Commission's issuance of a complaint irrevocably forecloses any inquiry into whether the Commission properly discharged its statutory responsibilities. To the contrary, noting that the Commission's authority under Section 5 "is strictly limited" by these statutory factors, the Supreme Court long ago found that the Commission's predicate determinations to the issuance of a complaint are reviewable, and that defects in these findings may render the complaint subject to challenge and dismissal. *See FTC v. Klesner,* 280 U.S. 19, 27, 30 (1929) ("the Commission's action in authorizing the filing of a complaint, like its action in making an order thereon, is subject to judicial review," and "[i]f it appears at any time during the course of the proceeding before it [that the proceeding so authorized is not in the public interest], the Commission should dismiss the complaint"); *see also John Bene & Sons, Inc. v. FTC,* 299 F. 468, (2d Cir. 1924) (on review of Commission cease and desist order under Section 5, court "hold[s] that, there being no proof of a public interest herein, or of its being to the interest of the public that this proceeding should have been begun, or the order complained of made, said order must be reversed"); *Home Shopping Network, Inc.,* 1995 FTC Lexis 259, at *1 (denying Complaint Counsel's motion to strike affirmative defense that generally denied proceedings were in public interest or that there was reason to believe FTC Act violation occurred; "By this conclusory defense respondents merely put complaint counsel to their proof, and it is legally sufficient."); *Outdoor World Corp.,* 1989 FTC Lexis 140, at *1 (Oct. 2, 1989) (denying motion to strike affirmative defense challenging putative "reason to believe" determination); *Texas Dental Ass'n,* 1981 FTC Lexis 120, at *2 (May 19, 1981) (denying motion to strike affirmative defense alleging that proceeding is contrary to public interest and complaint is insufficient as a matter of law, and noting that respondent may "state a theoretical defense to this complaint as a matter of law"); *Driver Training Inst.,* 1976 FTC Lexis 114, at *1 (Oct. 18,

1976) (noting prior order denying complaint counsel's motion to strike public interest challenge and permitting respondents "to plead and prove that this proceeding is not in the public interest"); *cf. Ford Motor Co.*, 1976 FTC Lexis 38, at *1 (Dec. 3, 1976) (granting respondent's motion to amend and denying complaint counsel's cross-motion to strike affirmative defenses, court notes that "[g]enerally purely legal issues are always viable irrespective of respondent's chances of prevailing thereon in view of past Commission decisions.").[9]

In asserting its Second Additional Defense, HMR submits that the "reason to believe" standard requires the Commission to have a well-grounded reason to believe that each of the elements defining the alleged offense exist. Because this matter proceeds under the Rule of Reason standard, a necessary and indispensable element of the alleged offense is a showing that the conduct that is the subject of the Complaint had a substantial anticompetitive effect in the marketplace. *See California Dental Ass'n v. FTC,* 526 U.S. 756, 759, 769-81 (1999) ("where, as here, any anticompetitive effects of given restraints are far from intuitively obvious, the rule of reason demands a more thorough enquiry into the consequences of those restraints"); *Fortner Enters., Inc. v. United States Steel Corp.*, 394 U.S. 495, 500 (1969) (Rule of Reason analysis entails "a more thorough examination of the purposes and effects of the practices involved"). Indeed, Complaint Counsel will be required to make this showing before the case

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9. More recently, when confronted with the sweeping language of the Commission's *Exxon* decision and arguments indistinguishable from those presented by Complaint Counsel here (*see* Pl.'s Br. at 3-4), the Supreme Court explicitly refused to accept the invitation to rule, as Complaint Counsel urges here, that the Commission's predicate "reason to believe" determination is unreviewable, holding instead that the Commission's determination constitutes "agency action" under the Administrative Procedure Act and leaving for another day the question of whether such matters are committed to agency discretion. *FTC v. Standard Oil Co. of Calif.,* 449 U.S. 232, 235 n.5, 238 (1980). Significantly, the Court stressed the importance of the Commission's "conscientious compliance with the 'reason to believe' obligation," noting that "[w]ithout a well-grounded reason to believe that unlawful conduct has occurred, the Commission does not serve the public interest by subjecting business enterprises to" the substantial burdens of defending themselves in Commission adjudicatory proceedings. *Id.* at 246 n.14.

can proceed, and absent a threshold showing of substantial anticompetitive effect, it is unnecessary for this tribunal to analyze the motives of the parties or to require Respondents to develop and consider the procompetitive benefits of the allegedly anticompetitive behavior. *K.M.B. Warehouse Distribs., Inc. v. Walker Mfg. Co.,* 61 F.3d 123, 127-28 (2d Cir. 1995); *U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 596 (1st Cir. 1993).

The Complaint, in its current form, fails to allege any specific anticompetitive effect stemming from the allegedly anticompetitive conduct. Instead, it contains only the most generalized and conclusory assertions of harm[10] which, under any standard, are inadequate. Whether a claim arises under Section 1 or Section 2 of the Sherman Act, the law is clear that the proponent of the complaint must properly allege and support the anticompetitive impact of the putative antitrust violations attributed to a respondent. *See, e.g., United States Football League v. National Football League,* 842 F.2d 1335, 1358-60 (2d Cir. 1988); *see also Texaco Puerto Rico, Inc. v. Medina,* 834 F.2d 242, 247 (1st Cir. 1987) (counterclaim allegations "that Texaco, as a monopoly, instituted a pricing system that manipulated the market and controlled distributors, resulting in an anticompetitive effect," were conculsory, insufficient to defeat

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10. The Complaint in this case alleges that the Respondents, in negotiating and entering into a stipulated preliminary injunction in connection with their ongoing patent case, engaged in unlawful restraints of trade and a conspiracy to monopolize a putative United States market for once-a-day diltiazem, and that HMR unlawfully attempted to monopolize the same putative market. (*See* Compl. ¶¶ 12-13, 36-38.) In asserting these violations, the Complaint repeatedly alleges that Respondents' actions had "the tendency or capacity" to restrain competition and injure consumers or otherwise demonstrated an anticompetitive "nature and tendency" (*see, e.g.*, Compl. ¶¶ 29, 39), and that the Respondents' stipulated preliminary injunction had "the purpose and intended effect" of deterring competitive entry (*see, e.g.*, Compl. ¶¶ 31-33). Yet nowhere does the Complaint identify the product which could have reached the market earlier "but for" the putatively illegal conduct of Respondents. Nowhere does the Complaint allege that the Respondents' actions delayed the introduction of a non-infringing FDA-approved generic product by even a single day.

motion for summary judgment, and "what modicum of factual elements could be extracted form the conclusory pleadings did not support an antitrust cause of action").[11]

The inadequacy of the Commission's Complaint is particularly troubling in light of the staff's intention, expressed in the Commission's press release announcing this action, to use these proceedings "to further consider the issues as it examines the arrangement in that case in light of a record developed during an administrative hearing." FTC Press Release, *FTC Charges Drug Manufacturers With Stifling Competition in Two Prescription Drug Markets* 2 (Mar. 16, 2000). Respondents respectfully suggest that administrative proceedings are intended to serve as vehicles for the adjudication of disputes rather than simply extending the investigative process.[12] That Respondents now face a Commission-imposed expedited hearing schedule which threatens to terminate Respondents' discovery rights prior to their being provided with a clear, unambiguous and complete articulation of the charges against them is more than just a failure of pleading -- instead, it presents the very real prospect of a denial of fundamental due process.

Respondent HMR has made clear its view that the current Complaint fails to make the requisite allegations of anticompetitive effect with the required degree of specificity and has served discovery on Complaint Counsel in an effort to ascertain the anticompetitive effect which serves as the basis for Complaint Counsel's case. In the event that this critical omission in the

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11. No different standard should apply simply because the Commission has chosen to bring this action under the FTC Act rather than the Sherman Act. *See, e.g., General Foods Corp.*, 103 F.T.C. 204, 366 (1984) (the Commission "do[es] not believe th[e] standard" for attempted monopolization under Sherman Act Section 2 "should be changed when a case is brought under Section 5"; "[i]f the conduct at issue here cannot reach the early threshold of doubt under the Sherman Act, we will not condemn it under the Federal Trade Commission Act").

12. As previously noted, it is well established that "[w]ithout a well-grounded reason to believe that unlawful conduct has occurred, the Commission does not serve the public interest by subjecting business enterprises to these burdens." *Standard Oil Co. of California,* 449 U.S. at 496 n.14.

Complaint is not cured, Respondents would be well within their rights to file a dispositive motion which, in part, would argue that the Commission failed to form the requisite "reason to believe" as to this critical element of the offense at the time that the Complaint issued.[13]

Accordingly, in offering its Second Additional Defense, Respondent HMR has responded to this glaring omission in the Complaint by properly reserving argument on the question of whether the Commission possessed the requisite reason to believe as to that element of the alleged offense at the time that the Complaint was authorized. Given that the Supreme Court's holdings in *Klesner* and *Standard Oil* hold out the prospect that the basis upon which the Commission brings an action can be challenged in an appropriate proceeding, and in light of Complaint Counsel's utter failure to assert a necessary element of its cause of action, Complaint Counsel's argument as to the immateriality of this defense in this case cannot be sustained. Accordingly, Complaint Counsel's motion to strike HMR's Second Additional Defense should be denied for Counsel's failure to establish immateriality.[14]

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13. The Respondents submit that the Complaint's failure to set forth any clear allegations of anticompetitive effect is not the product of oversight but, instead, is reflective of the fact that the Complaint cannot be sustained under any recognized theory of antitrust liability. The purpose and effect of the Stipulation and Agreement was to insure that Andrx was made whole in the event that it elected to refrain from marketing its allegedly infringing good during the pendency of the patent infringement litigation. According to a leading treatise, the question of whether the settlement of a patent case presents antitrust concerns turns on whether the parties had a bona fide dispute and whether the settlement was reasonable and not more anticompetitive than the likely outcome of the litigation. XII Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 2046, at 266 (1999). Yet now, even after two and one-half years of investigation, Complaint Counsel indicates that it has formed no opinion on either the legitimacy of the underlying action or the likelihood of Andrx's infringement. *See* Complaint Counsel's Response to Respondent Aventis Pharmaceuticals, Inc.'s First Request for Admissions Nos. 8, 9, 10, 11 (May 15, 2000). As a result, both Respondents and this tribunal are being compelled to expend considerable effort, energy and resources responding to a case in which the central elements do not exist.

14. Respondent HMR would also note that Complaint Counsel has utterly failed to establish that the maintenance of Respondent HMR's Second Additional Defense would have any discernable impact on the scope of discovery in this case. Moreover, it is difficult to understand just how Complaint Counsel could be prejudiced by being required to articulate its views of anticompetitive effect at the outset of this proceeding, particularly when it will be required to articulate and prove such effect in order to advance its case at trial.

### 3. Respondents May Properly Challenge Whether the Remedy Sought by the Complaint is in the Public Interest Because it Interferes With or Unduly Hampers the Orderly Maintenance, Prosecution and Settlement of Patent Infringement Litigation.

The argument offered by Complaint Counsel in support of its efforts to strike HMR's Thirteenth Additional Defense – as well as Andrx's Second, Fourteenth and Fifteenth Affirmative Defenses – illustrates the degree to which Complaint Counsel has improperly used this motion to strike to urge its substantive position on matters which lie at the heart of this case. It also underscores the degree to which Complaint Counsel's case is legally and factually undermined by the Patent Act, the Hatch-Waxman Amendments and the *Noerr-Pennington* doctrine.

In asserting its Thirteenth Additional Defense, HMR has asserted nothing more than reserving its right to argue that it has a right under the Patent Act to enforce its patents against a would-be infringer, that the enforcement of such rights is in the public interest, and that the legitimate assertion of such rights cannot be reduced, eliminated or interfered with by the application of federal antitrust law.[15] In this regard, the views asserted by Respondent HMR in its Thirteenth Additional Defense are indistinguishable from those recently voiced by the United States Court of Appeals for the Federal Circuit. While intellectual property rights do not confer a privilege to violate the antitrust laws, the court noted that "it is also correct that the antitrust laws do not negate the patentee's right to exclude others from patent property." *Intergraph Corp. v.*

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15. *See, e.g., Augat, Inc. v. John Mezzalingua Assocs., Inc.*, 642 F. Supp. 506, 509 (N.D.N.Y. 1986) (on motion for preliminary injunction, court notes that "[t]he public interest in a patent case is strongly weighted toward protecting the rights of patent holders. Defendant argues that the public interest is in favoring free and full competition. Generally, this is so in our free market system, but patents are a clear exception to this rule: patent law protects inventors in assuring that inventors and patent holders will enjoy financial protection in marketing their invention." (citations omitted).)

*Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999). "The commercial advantage gained by new technology and its statutory protection by patent do not convert the possessor thereof into a prohibited monopolist." *Abbott Labs. v. Brennan*, 952 F.2d 1346, 1354 (Fed. Cir. 1991), *cert. denied*, 505 U.S. 1205 (1992).

Contrary to the strawman presented in Complaint Counsel's motion, Respondent HMR has not argued that any agreement arising in the context of patent litigation is "immune from the application of the antitrust laws." (Pl.'s Br. at 8.) Rather, Respondent HMR believes, like the Federal Circuit, that "[i]n the absence of any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws." *In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1327 (Fed. Cir. 2000).

Respondent HMR submits that, as an initial matter, this tribunal will be called upon to decide whether, by entering into the Stipulation and Agreement, HMR and Andrx were engaged in conduct incidental to the prosecution and defense of a legitimate patent infringement suit. *See Columbia Pictures Indus., Inc. v. Professional Real Estate Investors, Inc.*, 944 F.2d 1525, 1528 (9th Cir. 1991), *aff'd*, 508 U.S. 49 (1993).[16] Beyond that, this tribunal may be called upon to determine whether the manufacturer of an infringing good can properly be deemed a potential competitor under the FTC Act or whether a cognizable anticompetitive effect is produced when the manufacturer of an allegedly infringing good elects not to sell that good

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16. Complaint Counsel attempts to preempt this tribunal's orderly consideration of the *Noerr-Pennington* doctrine by offering its own hasty and incomplete assessment of the issue in its motion to strike. Pl.'s Br. at 8. Clearly, this tribunal should reserve judgment on the *Noerr-Pennington* issues until such facts as may be reasonably relevant to a proper *Noerr* analysis have been developed and placed in the record.

during the pendency of the patent infringement suit.[17] Ultimately, this tribunal may be called upon to decide whether a patent holder who is engaged in a reasonable and good-faith effort to protect his patent rights can be properly charged with engaging in monopolistic behavior that violates the strictures of Section 5.

Given that the courts have been clear and consistent for the proposition that the antitrust laws cannot be invoked in a manner which interferes with the ability of a patent holder to protect its rights, it is difficult to see how Complaint Counsel could argue in good faith that Respondent HMR's rights under the patent laws are "'so immaterial as to have no bearing on the issue' to be decided by this Court." (Pl.'s Br. at 8.) Moreover, it is difficult to see how a finding of liability could be premised on anything other than a careful examination of the facts relating to the initiation, prosecution and ultimate resolution of the HMR/Andrx patent infringement suit.

Complaint Counsel's suggestion that this matter can be resolved without reference to the Hatch-Waxman Amendments and the regulations promulgated by the FDA is equally flawed. (*See* Pl.'s Br. at 9.) Indeed, in Paragraph 11 of the Complaint, Complaint Counsel describes how the Hatch-Waxman Amendments guarantee 180 days of market exclusivity to the first party to file a generic application for a particular product. (*See also* Compl. ¶ 17.) In Paragraphs 33 and 36, the Complaint charges HMR and Andrx with an unreasonable restraint of trade, based upon a provision in the Stipulation and Agreement that relieves HMR of its obligation to make good Andrx's lost profits in the event that Andrx were to relinquish that right to some other party. So, while Complaint Counsel relies on the Hatch-Waxman Amendments to

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17. In that regard, unless Complaint Counsel is prepared to stipulate as to the substantial likelihood that Andrx's initial formulation infringed HMR's patents, evidence will have to be presented to this tribunal which will demonstrate the strength and substance of HMR's claim.

make out their affirmative case, they simultaneously argue that Respondents' defenses to these allegations would "embroil[] the parties, and this Court, in the fruitless exercise of discovering and interpreting the meaning and intent of the Hatch-Waxman Act and FDA regulations." (Pl.'s Br. at 9.) This is not a serious argument.

At bottom, Respondents believe that Complaint Counsel's theory of liability fails in this case because it presumes that patent infringers constitute legitimate competition under the antitrust laws and attempts to make private parties responsible for limitations on competition that Congress imposed as part of a comprehensive drug regulatory regime. Complaint Counsel seeks to sidestep the unavoidable complexities of this case by arguing that this tribunal can properly ignore other federal law and regulations in passing upon "the legality of respondents' conduct under Section 5 of the FTC Act." (Pl.'s Br. at 9.) Such argument is manifestly incorrect in that there is nothing about Section 5 of the Federal Trade Commission Act that permits either the Commission or this tribunal to apply Section 5 in a manner that ignores the application of other federal statutes.[18]

For the purposes of the present motion, however, it seems obvious that the underlying patent dispute, the Patent Act, the Hatch-Waxman Amendments, as well as the substance and status of the various applications relating to generic versions of Cardizem® CD,

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18. For example, under the standards asserted by Complaint Counsel in its motion, the Commission would have the authority under Section 5 to maintain an action against a patent holder who had successfully asserted a patent claim against an infringer. Clearly this result would not be countenanced because no court would construe the Federal Trade Commission Act as presumptively preempting or displacing other federal statutes such as the Patent Act. *See In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d at 1325. *New England Motor Rate Bureau, Inc.* does not hold to the contrary and, in fact, presumed that *state law* could displace Section 5 where the requirements of the state action doctrine were satisfied. *See* 112 F.T.C. 200 (1989). Similarly, while *Metagenics, Inc.* properly rejected the respondent's argument that compliance with a federal regulatory scheme conferred federal antitrust immunity, nothing in that case can properly suggest, as Complaint Counsel argues here, that the application and operation of other federal statutes and regulations are irrelevant and immaterial to any potential application of Section 5. *See Metagenics, Inc.*, 1995 FTC Lexis 2, at *4-5 (Jan. 5, 1995).

are not "unrelated" to Complaint Counsel's claims. Accordingly, Complaint Counsel's motion to strike HMR's Thirteenth Additional Defense should be denied.

#### 4. **The Balance of Complaint Counsel's Motion to Strike is Without Merit and Should be Denied.**

The balance of Complaint Counsel's motion to strike relates to the Affirmative Defenses raised by Andrx in its answer. While Respondent HMR takes no position as to the merits of Andrx's remaining affirmative defenses, it does not appear that such defenses would unduly broaden the scope of the evidence which will have to be examined in the conduct of this litigation. Conversely, in asserting its objections to these defenses, Complaint Counsel has demonstrated its intention to use this motion to strike as a *de facto* motion *in limine* to curtail legitimate discovery. (*See* Pl.'s Br. at 4-5.) Respondent HMR strenuously objects to Complaint Counsel's efforts improperly to transform its motion to strike into a *de facto* motion *in limine*, by which Complaint Counsel may in the future attempt to circumscribe or preclude the legitimate and proper development of evidence in this case. Accordingly, both because Complaint Counsel cannot establish prejudice as to these affirmative defenses and because Complaint Counsel's misuse of this motion would unduly prejudice Respondent, the motion to strike should be denied in its entirety.

For example, while Complaint Counsel complains about being forced to produce records of communications between the FTC and any reporter regarding this case or the investigation that preceded it (Pl.'s Br. at 4), it is obvious in this Rule of Reason case that Respondents are entitled to demand the production of any non-privileged communications that the FTC staff may have had with any third party regarding the substance of this matter or the reasonableness or unreasonableness of the Respondents' conduct. In this respect, it would not be

unreasonable to request the production of records which reflect such communications. Similarly, while Complaint Counsel might not wish to produce the rules and regulations governing the handling of confidential materials in a non-public investigation (Pl.'s Br. at 5), it can hardly be argued that the production of this limited collection of Commission rules and regulations works a hardship on Complaint Counsel by substantially expanding the scope of production. And while Complaint Counsel appears ready to object to the production of material that the Commission may have collected regarding the efforts of other pharmaceutical companies to protect their patent rights in comparable situations (Pl.'s Br. at 6), it is clear that in a case governed by the Rule of Reason, Respondents are entitled to take discovery of information in the Commission's possession, including information and documents relating to the conduct of other companies caught up in comparable cases and situations, which might show the reasonableness of Respondents' actions.

Even in instances where Complaint Counsel's objections under the first (*i.e.*, materiality) prong of the *Dura Lube* test for motions to strike might appear stronger, the element of prejudice, defined by the potential expansion of the scope of discovery, remains elusive. For example, even if one were to accept Complaint Counsel's arguments as to the applicability of the defenses of laches, waiver, estoppel and unclean hands[19] (Pl.'s Br. at 7), it remains that the

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19. Respondents do not concede Complaint Counsel's arguments as to the applicability of these equitable defenses. In the *Walerko Tool* case cited by Complaint Counsel, for example (*see* Pl.'s Br. at 2), a federal district court, after carefully reviewing the law applicable to the equitable defenses of estoppel, release, waiver and laches, rejected government counsel's argument that "common law equitable defenses cannot be asserted against the United States when the federal government acts in its sovereign capacity to protect the public welfare," held that these equitable "defenses are not foreclosed as a matter of law," and denied the government's motion to strike defendant's equitable affirmative defenses. *Walerko Tool & Eng'g Corp.*, 784 F. Supp. at 1388-90. *See also RTC v. Gregor,* 1995 WL 931093, at *4 (denying government's motion to strike equitable defenses on grounds similar to those asserted by Complaint Counsel, court finds that "[b]ecause of the uncertainty of the authority, the viability of laches and estoppel/waiver defenses in this context is an open and disputed question of law that the Court declines to decide on this motion"); *EEOC v. Times Mirror Magazine, Inc.*, No. 86 Civ.
(continued...)

Commission staff was in possession of the HMR/Andrx Stipulation and Agreement for nearly 20 months before the patent infringement litigation was dismissed by the District Court. An issue squarely presented under the Commission's Complaint is whether Respondents behaved reasonably by electing not to present the Stipulation and Agreement to the District Court. The fact that the Commission staff also chose not to communicate its views to the District Court during that 20-month time span suggests that the Respondents' decision regarding the need to and advisability of approaching the Court may not have been as unreasonable as Complaint Counsel now claims. Moreover, where the relief sought by Complaint Counsel includes a requirement that would compel Respondents to notify the Commission prior to entering into any comparable stipulated preliminary injunction in the future (*see* Notice of Contemplated Relief ¶¶ 2-4), it is legitimate to inquire as to whether the proposed remedy will serve any purpose given that the Commission staff was given comparable notice in this case and elected not to present its views to the District Court. *See, e.g., Kroger Co.,* 1977 FTC Lexis 70, at *4 (Oct. 18, 1977) (refusing to strike affirmative defense that might be relevant to the nature and scope of any remedy in the proceeding). Thus, any evidence which might come into play under Respondent Andrx's affirmative defense is already properly in play by virtue of the facts and contentions of this case.

In sum, Complaint Counsel has failed to demonstrate that any of the Affirmative and Additional Defenses raised by the Respondents would expand the scope of discovery to any appreciable degree and thus, under the rules governing motions to strike, Complaint Counsel's

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19. (...continued)
1120(CBM), 1986 WL 13015, at *2 (S.D.N.Y. Nov. 13, 1986) (on motion for summary judgment, court notes, without analysis, that the defense of laches "is clearly available against the E.E.O.C.").

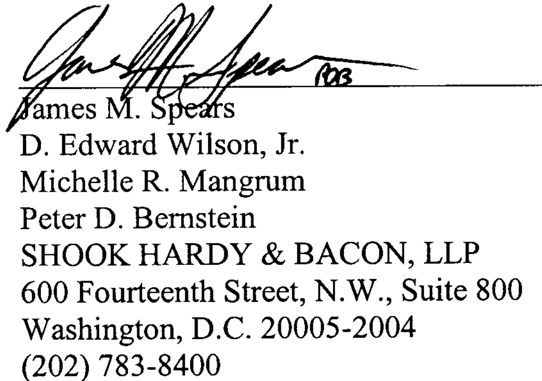
motion should fail. *See Synchronal Corp.*, 1992 FTC Lexis 61, at *1 (denying motion to strike affirmative defense where "[c]omplaint counsel fail[ed] to show any prejudice which would result in the continuation of this affirmative defense").

**CONCLUSION**

WHEREFORE, for the reasons set forth herein Respondent HMR respectfully requests that this Court deny Complaint Counsel's motion to strike Respondents' Affirmative Defenses in its entirety, and grant such other and further relief as the Court may deem just and proper.

Dated: May 19, 2000

Respectfully Submitted,



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

| | |
|---|---|
| In the Matter of<br><br>**Hoechst Marion Roussel, Inc., et al.,**<br><br>**Respondents** | Docket No. 9293 |

## ORDER

This matter came before the Court on Complaint Counsel's Motion to Strike Certain Affirmative Defenses Set Forth in Respondents' Answers. Complaint Counsel has asked the Court to enter an Order striking Additional Defenses Nos. 2 and 13 of Respondent Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc. ("HMR"), as well as Respondent Andrx Corporation's Affirmative Defenses Nos. 2, 7, 8, 12, 14, 15, 17, 18 and 19, and Respondent Carderm Capital L.P.'s Affirmative Defenses Nos. 2 and 13. Respondents have opposed Complaint Counsel's motion. Upon consideration of the briefing submitted,

IT IS ORDERED that Complaint Counsel's Motion to Strike Certain Affirmative Defenses Set Forth in Respondents' Answers is hereby DENIED in its entirety.

Dated: May __, 2000

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D. Michael Chappell
Administrative Law Judge

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

| In the Matter of<br><br>**Hoechst Marion Roussel, Inc., et al.,**<br><br>**Respondents** | Docket No. 9293 |
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## CERTIFICATE OF SERVICE

I, Peter D. Bernstein, hereby certify that on May 19, 2000, a copy of Respondent Aventis Pharmaceuticals, Inc.'s Opposition to Complaint Counsel's Motion to Strike Certain Affirmative Defenses Set Forth in Respondents' Answers, memorandum in support thereof, and proposed order, to be served upon the following persons by hand delivery and/or Federal Express as follows:

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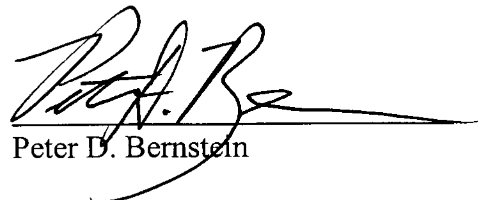

Peter D. Bernstein