UNITED STATES OF AMERICA
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

TO: The Honorable D. Michael Chappell
Administrative Law Judge

AVENTIS PHARMACEUTICALS, INC.'S STATEMENT OF THE CASE

I. INTRODUCTION

On January 31, 1996, Hoechst Marion Roussel, Inc. ("HMR"), a predecessor of Respondent Aventis Pharmaceuticals Inc. ("Aventis") and Carderm Capital, L.P. ("Carderm") filed a patent infringement action against Andrx Pharmaceuticals Inc. ("Andrx") alleging Andrx's generic formulation of HMR's successful Cardizem® CD product Andrx infringed one of HMR's patents. In September 1997, following substantial discovery by both sides and the filing of four separate dispositive motions with the trial court, HMR, Carderm and Andrx entered into a Stipulation and Agreement, in which Andrx agreed to refrain from marketing the

infringing product until the Court ruled on the merits of the action in exchange for HMR's agreement to pay a stipulated amount of money to Andrx to compensate for lost profits in the event that Andrx ultimately prevailed in the litigation. In addition, HMR agreed to make certain payments *pendente lite* to Andrx during the life of the Stipulation, which would either be deducted from the lost profits payment in the event Andrx won, or recovered by HMR under a licensing arrangement in the event HMR prevailed.

Shortly after the Stipulation and Agreement took effect, Andrx advised HMR that it had "invented around" the patent and sought FDA approval to market its reformulated product. HMR investigated Andrx's new claim, and, when it was satisfied that the reformulated product did not infringe the patent, agreed to dismiss the patent litigation and terminate the Stipulation and Agreement contingent upon the FDA approving the reformulated product and Andrx agreeing not to market its original infringing formulation. On June 8, 1999, Andrx received FDA approval for its reformulated product, the parties settled the patent litigation, the Stipulation and Agreement ended and Andrx commenced marketing its reformulated generic product.

On March 22, 2000, the Federal Trade Commission filed a Complaint against HMR, Carderm Capital, L.P. and Andrx alleging that the Stipulation and Agreement injured competition by preventing or discouraging the earlier entry of generic forms of Cardizem® CD into the marketplace. (Compl. ¶¶ 29, 30.) The FTC also claimed that provisions which relieved HMR of its obligations to make the lost profits payments were Andrx to enter the market with an alternative generic formulation or to sell its FDA application for its generic product (called an abbreviated new drug application ("ANDA")), or any rights pertaining thereto, to another party constituted an unreasonable restraint of trade. (Compl. ¶¶ 32, 33, 36.) Finally, the FTC alleged that HMR enjoyed monopoly power in a relevant market, had the specific intent to preserve its

monopoly in that market and, by the way it handled its patent claims with Andrx and others, created a dangerous probability that it would accomplish its monopolistic objectives in violation of Section 5 of the Federal Trade Commission Act ("FTC Act"). (Compl. ¶¶ 37, 38.) FTC's claims have no basis in fact or in law.

To establish a Section 5 violation, Complaint Counsel must demonstrate that the Stipulation and Agreement produced "substantial anticompetitive effects." Aventis respectfully submits that Complaint Counsel will not be able to make this threshold and indispensable burden. While the FTC alleges that the Stipulation and Agreement delayed the market entry of a non-infringing generic version of Cardizem® CD, to date, despite Aventis' repeated requests for clarification of Complaint Counsel's theory of its case, Complaint Counsel has not offered any evidence to support the allegations. Nor can it. The evidence in this case will indisputably show that the first non-infringing generic version of Cardizem® CD approved for sale by the U.S. Food and Drug Administration ("FDA") went on sale the day FDA approval was obtained. Accordingly, entry of the Stipulation and Agreement produced no "substantial anticompetitive effect" and the FTC's naked allegations to the contrary will fail.

The FTC's charges of monopolization and monopolistic behavior fare no better. As a threshold matter, the evidence will show that the FTC's allegation of a once-daily diltiazem-only market (Compl. ¶ 12) is artificially narrow. HMR's Cardizem® CD and other diltiazem-based products compete in a broader market which is minimally defined by a class of anti-hypertension products known as calcium channel blockers, a market in which Cardizem® CD claims only a modest market share.

The FTC also fails to acknowledge and makes no effort to distinguish between the legitimate exercise of the rights of exclusivity enjoyed by a patent holder and the improper and

illegal conduct of a monopolist. To sustain a charge of monopolistic behavior, Complaint Counsel must prove HMR acted in an unreasonably exclusionary manner and that HMR's challenged practice yielded unreasonable anticompetitive effects. As a patent holder, however, HMR has every right to enforce its patents and prevent the sale of infringing goods. Conduct reasonably incidental to the exercise of patent rights does not constitute an act of monopolization. Unless Complaint Counsel reverses its position and now argues that HMR's efforts to enforce its Cardizem® CD-related patents constituted nothing more than a sham or that the Stipulation and Agreement was but a pretext for cloaking anticompetitive behavior, the charge of monopolization cannot stand.[1]

Moreover, the FTC may but the Court cannot ignore that the Stipulation and Agreement is wholly dependent upon and inextricably intertwined with the underlying patent infringement case. Indeed, the patent case defines the scope and duration of the Agreement and the allocation of benefits and obligations among the parties. Since the Stipulation and Agreement is incidental to the patent litigation, it is presumptively protected from antitrust scrutiny by the *Noerr-Pennington* doctrine. To overcome *Noerr-Pennington* immunity, Complaint Counsel must plead and prove facts sufficient to show that the Stipulation and Agreement was not incident to valid petitioning activity. HMR respectfully submits Complaint Counsel will be unable to meet this burden as a matter of law.

In this regard, Aventis notes the Stipulation and Agreement was an effort by parties to a hotly contested and vigorously pursued patent infringement case to preserve the

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1. See FTC's Answer to Respondent Aventis Pharmaceuticals, Inc. Request for Admission No. 10 where Complaint Counsel stated "Compliant Counsel does not contend, however, that HMR's assertion of infringement was objectively baseless."

status quo pending the final resolution of their case. Its provisions are typical of preliminary injunction practice in patent actions. Such injunctions frequently require the patent holder to post a bond or otherwise agree to make good lost profits in the event that the party enjoined ultimately prevails in the litigation. The provision for *pendente lite* payments is also not unprecedented, particularly where, as here, the continuing costs of litigation are substantial and there exists a substantial disparity in terms of the financial wherewithal of the parties.

The fact that the parties reached this interim result by stipulation, as opposed to litigating a motion for a preliminary injunction, is both reasonable and efficient in light of the fact that the court presiding over that action had, up to that point, utterly failed to move the proceedings forward – even to the point of denying the parties' applications for a scheduling order – thereby leaving HMR in a quandary arising out of its good-faith concern that Andrx might attempt to enter the market with an infringing product after expiration of the statutory stay but well before a court decision vindicating its patent rights. The further fact that the Stipulation conserved the scarce resources of the Article III court to resolve the substantive issues presented by the patent dispute, including those raised in the several dispositive motions then pending, merely augmented the procompetitive efficiencies of the transaction.

Finally, the FTC alleges that certain conduct by Aventis separate and apart from the Stipulation and Agreement constitute unfair methods of competition. As explained in more detail below, the evidence will show that FTC's arguments are specious and substantially premised on the false testimony of Aventis' longtime adversary, Biovail Corporation. Aventis submits that the evidence will show that Biovail has engaged in "rent seeking," and that is presence in this matter is but a small part of an overall and well-orchestrated plan to pressure Aventis to make valuable commercial concessions in its behalf. Far from being a hapless

victim, the evidence will also show that Biovail was an active instigator who proposed anticompetitive transactions to both Aventis and Andrx which were manifestly anticompetitive.

II. FACTUAL BACKGROUND

Andrx filed an application with the U.S. Food and Drug Administration (ANDA 74-752) for permission to manufacture and market a generic form of HMR's Cardizem® CD on September 22, 1995. Unbeknownst to Andrx, at the time of the filing HMR recently obtained a new patent, United States Patent No. 5,470,584 (the "'584 Patent"), that claimed certain dissolution characteristics of HMR's Cardizem® CD. On December 30, 1995, as required by the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act (the "Hatch-Waxman Amendments" or "Hatch-Waxman"),[2] Andrx filed a Certification of Non-Infringement with HMR, in which it certified that its product did not infringe any of the patents listed by HMR in support of Cardizem® CD, including the '584 patent.

On January 31, 1996, HMR filed a patent infringement lawsuit against Andrx in response to Andrx's certification alleging Andrx's generic version of HMR's Cardizem CD infringed the '584 Patent. *See Hoechst Marion Roussel, Inc., et al. v. Andrx Pharmaceuticals, Inc.,* No. 96-06121 (S.D. Fla.). Immediately following the filing of the lawsuit, the parties moved aggressively into discovery. Beginning in April, HMR issued the first of 11 document production requests and took the depositions of two key Andrx witnesses. Andrx countered with four document requests that yielded 60 boxes of materials, while deposing seven key HMR witnesses between February and August of 1996. On August 23, 1996, Andrx filed a motion to dismiss, followed, on December 12, by the first of what would be three motions for summary

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2. 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.

judgment.[3] On January 24, 1997, HMR filed its own motion for summary judgment in which it argued that Andrx's product exhibited dissolution profiles at or near 45% release after 18 hours, and therefore infringed the '584 Patent either directly or through the doctrine of equivalents. Thus, the central issue in the patent case was the question of whether the dissolution profile of Andrx's product at 18 hours brought it within the claims of the '584 Patent.

Despite the constant urging of the parties, the District Court took no action on any of the motions and refused to consider the parties' March and April 1997 applications to schedule these dispositive motions for argument or resolution. The Court's failure to take control of the case presented a very real problem for HMR. Under the Hatch-Waxman Amendments, in the event a drug innovator (Aventis) commences patent litigation against a generic drug applicant (Andrx), the FDA is prohibited from granting final approval for the generic product for a period of 30 months from the date that the innovator receives the generic applicant's patent certification. 21 U.S.C. § 355(j)(5)(B)(iii). Congress believed that this automatic stay would provide patent litigants with sufficient time in which to try their infringement cases. *See* Remarks of Sen. Hatch, Cong. Rec., Aug. 10, 1984, S10504.

The establishment and operation of this 30-month period are premised on the assumption that both the parties and the courts would expedite the handling of these cases.[4] By

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3. All together, four dispositive motions were filed by the parties between August 23, 1996 and February 14, 1998. These motions were: (1) Defendant's Motion to Dismiss for Lack of Subject Matter Jurisdiction (August 23, 1996); (2) Defendant's Motion for Summary Judgment on the Issue of Non-Infringement (December 12, 1996); (3) Plaintiff's Motion for Summary Judgment on the Issue of Infringement (January 24, 1997); and (4) Defendant's Motion on the Issue of Invalidity (February 14, 1997).

4. *See, e.g.*, 21 U.S.C. § 355(j)(5)(B)(iii) (requiring that in a patent infringement action filed pursuant to Hatch-Waxman, "each of the parties shall reasonably cooperate in expediting the action" and permitting court to extend or shorten the 30-month statutory stay "because either party to the action failed to reasonably cooperate in expediting the action"); H.R. Rep. No. 98-857, pt. I, at 27 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2660 ("Each party to the action has an affirmative duty to reasonably cooperate in expediting the action.").

July 1997, however, with the expiration of the statutory stay less than one year away, HMR became concerned that the District Court was unlikely to resolve the substantive issues within the period of the statutory stay and that Andrx might enter the market with an infringing product. While such concerns would normally be tempered by the knowledge that any harm caused by the sale of an infringing product could be remedied by an award of damages,[5] Andrx simply did not have the financial resources to make good the losses that HMR would suffer by the sale of an infringing product. HMR was keenly aware by marketing an infringing product, Andrx would effectively destroy the value of Cardizem® CD and leave HMR with nothing but the prospect of a pyrrhic victory in its infringement case.[6]

Consequently, HMR began exploring the possibility of reaching an agreement that would maintain the *status quo* between the parties during the pendency of the action. The product of these discussions was the Stipulation and Agreement. Consistent with preliminary injunction practice in patent cases, the Stipulation and Agreement provided that HMR would make good Andrx's reasonable lost profits -- to the stipulated amount of $100 million per year -- in the event that Andrx were to agree to defer the sale of its allegedly infringing product until the

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5. Among other things, the Patent Act provides for the recovery of treble damages in instances of willful infringement. 35 U.S.C. § 284. Of course, this remedy is meaningless if the infringer, after having damaged the value of the patent, lacks the wherewithal to compensate the prevailing patent holder at the conclusion of infringement litigation. *See Eli Lilly & Co. v. Premo Pharm. Labs., Inc.,* 630 F.2d 120, 137 (3d Cir. 1980) (finding irreparable harm for purposes of preliminary injunction standard where "damages could very conceivably run beyond [defendant's] ability to pay them").

6. Courts have recognized that a potential infringer's marketing of its product during the pendency of infringement litigation can lead to the destruction of the value of the patent, thereby inflicting immediate and continuing harm on a patent holder that can be difficult to fully quantify and even more difficult to fully recover. *See Ortho Pharm. Corp. v. Smith,* 15 U.S.P.Q.2d 1856, 1990 WL 18681, at *9 (E.D. Pa. Feb. 23, 1990) (one factor court should consider in determining whether sufficient irreparable harm exists to support preliminary injunction is "the fact that by the time the litigation is finished, it is entirely possible that the value of the patent will be gone," in part due to resulting loss of market share, which "is so difficult to recover," to an infringing product (citations and internal quotations omitted)).

resolution of the patent infringement case *and* were to ultimately prevail in that case. (*See* Stipulation ¶ 3.) These "lost profits" payments were designed to strike a balance between compensating Andrx for the likely profit potential of a non-infringing Cardizem® CD generic in the event that Andrx were to prevail in the district court and preserving Andrx's incentives to bring a non-infringing reformulated product to market. As a result, the payments were calculated to be less than the actual profits that a non-infringing generic product was anticipated to earn, a point that even the Complaint appears to concede. (*See* Compl. ¶ 30.)[7]

Having effectively posted a bond worth tens of millions of dollars to compensate Andrx for any profits lost as a result of deferring market entry until the resolution of the patent case in the event that Andrx prevailed, HMR took the reasonable steps of insuring that its obligation to pay lost profits terminated at the very moment that Andrx's risk of losing profits ended -- including situations where Andrx entered the market with a different product or where Andrx sold its product or any significant rights therein to some other party. (*See* Stipulation ¶¶ 2.A, 8.B.i.).[8]

In response to Andrx's claimed short-term need for capital, HMR agreed to make interim payments to Andrx of $10 million per quarter that would either be deducted from the lost

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7. This places the lost profits payments that Complaint Counsel challenges here in stark contrast to the substantial supracompetitive "premium" paid by Abbott to Geneva that the Commission found objectionable in its recent enforcement action against those companies. (*Compare* Abbott/Geneva Complaint ¶ 25.)

8. Paragraph 2.A provided, in pertinent part: "Pending the entry of Final Judgment, the parties agree to maintain the status quo with respect to the commercial sale of the Andrx Product in the United States. Andrx agrees not to commence the commercial sale of the Andrx Product or other bioequivalent or generic version of Cardizem® CD in the United States directly or indirectly until the entry of Final Judgment . . . . . Andrx further agrees that during the pendency of the Patent Infringement Action, it will diligently prosecute the ANDA for the Andrx Product and will not relinquish or otherwise compromise any right accruing thereunder or pertaining thereto." Paragraph 8.B.i provided, in pertinent part: "In the event that Andrx violates its obligations under Paragraph 2 . . . . Andrx shall pay HMRI an amount equal to the amount of all payments that have been paid to Andrx pursuant to this Stipulation and Agreement, and this Stipulation and Agreement shall be terminated."

profit payments if Andrx won the litigation or recovered by HMR by way of enhanced licensing fees and royalty rates in the event Andrx lost.[9] (*See* Stipulation ¶¶ 3.B, 4, 7.)

Importantly, the Stipulation and Agreement did not lock Andrx into its original infringing formulation. Paragraph 8.B.iv of the Stipulation and Agreement expressly recognized Andrx's right to make such modifications to its ANDA as it might deem necessary and appropriate without losing any rights to the lost profits and interim payments that Andrx might otherwise enjoy under the Stipulation and Agreement. In this manner, the Stipulation and Agreement created a positive incentive for Andrx to invent around HMR's patent claims if it could.[10]

The Stipulation was signed on September 24, 1997. It was only scheduled to take effect if the patent case remained pending upon the expiration of the 30-month stay (July 9, 1998) and was to end upon the resolution of the patent infringement suit or on January 2000

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9. Although Paragraph 4.A of the Stipulation describes these interim payments as "nonrefundable," this statement, taken in isolation, is misleading. To understand Paragraph 4.A, the provision must be read in the context of the entire agreement. The Stipulation clearly provides for the refunding of the interim payments in the event that Andrx chooses to disturb the *status quo* as it existed at the commencement of the litigation and at the effective date of the Stipulation, or in the event that Andrx attempts to assign the licensing rights to the '584 Patent contemplated by the Stipulation. (*See* Stipulation ¶ 8.B.i.) Moreover, in the event that HMR ultimately prevailed in the patent litigation and Andrx exercised its rights under the Stipulation to license HMR's '584 Patent, Andrx would pay significantly enhanced royalties and license fees, the purpose being to permit HMR to recoup the interim payments provided during the pendency of the litigation. (*See* Stipulation ¶ 7.) Even if HMR had lost the underlying action, the Stipulation permitted it to offset the value of the interim payments against the value of the lost profits liquidated damages payment contemplated by the Stipulation. (*See* Stipulation ¶ 3.B.) Thus, the Stipulation did in fact provide for the recoupment of the supposedly "nonrefundable" interim payments. As testimony at trial will demonstrate, the parties adopted this somewhat complicated structure for payment and recoupment of the interim payments solely to accommodate Andrx's stated business concerns that it be able to account for the interim payments as income for balance sheet purposes.

10. Andrx had no other generic Cardizem® CD to bring to market, and as a practical matter, in light of the expense and effort required to develop an entirely new product, it was more economical and more efficient for Andrx to concentrate its efforts on reformulating its existing product to render it non-infringing. Finally, as described more fully below and as the evidence will demonstrate at trial, there existed no eligible suitor or partner who could have used Andrx's 180-day exclusivity rights to expedite the entry of another generic product, either alone or in partnership with Andrx, at any time that the Stipulation was in existence.

regardless of the status or outcome of the case at which time Andrx had the right to license HMR's technology. (*See* Stipulation ¶¶ 5, 6.). On the day that the Stipulation and Agreement was signed, both HMR and Andrx issued press releases generally describing its terms and conditions. The Federal Trade Commission requested copies of the document from both Andrx and HMR shortly after it was signed, and copies were delivered to the Commission in November 1997, more than eight months prior the date upon which the agreement was scheduled to take effect.

Notwithstanding the entry of the Stipulation and Agreement, both parties continued their intensive discovery efforts and trial preparations and also continued to push the Court to rule or hear argument on the pending summary judgment motions. Unfortunately, the 30-month statutory stay expired without action by the court to resolve any of the substantive issues in the case, and the Stipulation and Agreement came into effect on July 9, 1998. On October 7, 1998, less than three months following the effective date of the Stipulation, HMR received notice from Andrx that Andrx had invented around the '584 Patent and filed a supplement to its generic drug application that embraced this new, allegedly non-infringing formulation. Andrx advised HMR that its new product exhibited a dissolution profile with "not less than 65%" release after 18 hours, which would not infringe the 45% dissolution value claimed by the '584 Patent.

Upon learning of Andrx's reformulation, HMR undertook an examination of the new product to determine whether its patent infringement claim could properly reach the reformulated product. Based on this evaluation, HMR concluded that Andrx's reformulated product would not likely infringe HMR's patent so long as the reformulated product maintained the dissolution characteristics represented by Andrx and confirmed by HMR. HMR concluded that this development left it with no reasonable basis for continuing its patent infringement

lawsuit so long as Andrx's product remained within the non-infringing dissolution parameters exhibited by its reformulated version. As a result, following HMR's evaluation, the parties entered into negotiations to define precise values for Andrx's dissolution claims that could provide a basis for settling the lawsuit.[11] Ultimately, HMR and Andrx conditionally agreed to a Stipulation and Order in which HMR would dismiss its patent infringement case in exchange for Andrx's agreement that it would market only the reformulated product and manufacture that product in a manner that achieved a dissolution profile of not less than 68% at 18 hours.

On June 8, 1999, Andrx received the FDA's approval to market the reformulated product, and the parties executed the Stipulation and Order, thereby ending the patent dispute and terminating the Stipulation and Agreement. Andrx immediately began accepting orders for its new product, Cartia XT. The District Court entered an Order formally dismissing the patent infringement case on June 24, 1999.

III. THE CONDUCT AT ISSUE DOES NOT CONSTITUTE AN UNLAWFUL RESTRAINT OF TRADE AS DEFINED BY SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

In assessing Complaint Counsel's antitrust claims, this Court should approach the allegations of the Complaint with caution and care, keeping in mind that "[a]ntitrust allegations are not lightly sustained, . . . and the burden of proof on all material elements of an antitrust claim rests with the party asserting the claim." *Darda Inc. USA v. Majorette Toys (U.S.) Inc.,*

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11. The fact that the parties here terminated the Stipulation and Agreement as the result of procompetitive developments in the industry – namely, Andrx's reformulation of its original product to avoid HMR's patent claims – is yet another fact that distinguishes this case from the Commission's recent action against Abbott and Geneva, in which the parties there determined to "cancel" the challenged agreement only after becoming aware of the Commission's investigation of that agreement. (*See* Abbott/Geneva Complaint ¶ 33.)

627 F. Supp. 1121, 1141 (S.D. Fla. 1986), *aff'd in part, rev'd in part on other grounds,* 824 F.2d 976 (Fed. Cir. 1987). In order to establish an unlawful restraint of trade under Section 5 of the FTC Act, Complaint Counsel must first demonstrate that the acts or practices that it seeks to challenge produced a substantial anticompetitive effect in a properly defined market. *California Dental Ass'n v. FTC,* 526 U.S. 756, 774-75 & n.12 (1999) (requiring demonstration of anticompetitive effects in Section 5 restraint of trade case); *see United States v. Arnold, Schwinn & Co.,* 388 U.S. 365, 374 & n.5, 382 (1967), *overruled on other grounds by Continental T.V., Inc. v. GTE Sylvania Inc.,* 433 U.S. 36 (1977) (under Rule of Reason evaluation of alleged restraint of trade, court "must look to the specifics of the challenged practices and their impact upon the marketplace," looking at "the product market as a whole" rather than merely effects on intra brand competition, and "[t]he burden of proof in antitrust cases remains with the plaintiff"). In the event that Complaint Counsel satisfies this threshold burden, the burden then shifts to Respondents to show that any anticompetitive effect established by Complaint Counsel is offset by such procompetitive benefits as may be produced by the transaction. *NCAA v. Board of Regents,* 468 U.S. 85, 113 (1984).

A. No Evidence Suggests That the Stipulation and Agreement Produced Any Significant Anticompetitive Effect.

The Complaint states a case under the Rule of Reason. The starting point in the evaluation of a challenged practice under the Rule of Reason is a showing by the proponent of the claim – Complaint Counsel here – that the practice in fact produced substantial anticompetitive effects. As the Seventh Circuit concluded:

> It is by now well established that any rule of reason analysis requires a showing of anticompetitive market effect. To hold otherwise would ignore the very purpose of the antitrust laws

> which were enacted for the protection of competition, not competitors.

Lektro-Vend Corp. v. Vendo Co., 660 F.2d 255, 268 (7th Cir. 1981). Moreover, "[i]t is the plaintiffs' burden" to adequately plead and "to prove the adverse effect on competition." *Id.* at 269 n.15. The fact that the violation is urged by the Federal Trade Commission under Section 5 of the FTC Act or that the Commission seeks only injunctive relief does not modify or alter this essential element of proof. *Boise Cascade Corp. v. FTC,* 637 F.2d 573 (9th Cir. 1980); *In re General Foods Corp.*, 103 F.T.C. 204, 364-65 (1984); *In re General Motors Co.*, 103 F.T.C. 641, 701 (1984).

The anticompetitive effects attributed to the practice must be substantial (*Dunafon v. Delaware McDonald's Corp.*, 691 F. Supp. 1232, 1241 (W.D. Mo. 1988) ("Congress did not intend to prohibit contracts that cause an insignificant restraint of trade," citing *Northern Pac. Ry. Co. v. United States,* 356 U.S. 1, 5 (1958)), real and certain, and not merely the theoretical creation of imaginative lawyering. *California Dental Ass'n,* 526 U.S. at 775 n.12 ("[B]efore a theoretical claim of anticompetitive effects can justify shifting to a defendant the burden to show empirical evidence of procompetitive effects, . . . there must be some indication that the court making the decision has properly identified the theoretical basis for the anticompetitive effects and considered whether the effects actually are anticompetitive. Where, as here, the circumstances of the restriction are somewhat complex, assumption alone will not do."). Finally, the obligation residing in Complaint Counsel to allege and demonstrate that a substantial anticompetitive effect flowed from this transaction cannot be discharged by generalized and conclusory assertions. *See, e.g., 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 conclusory, insufficient to defeat motion for summary judgment, and "what modicum of factual elements could be extracted from the conclusory pleadings did not support an antitrust cause of action").

In its Complaint, the Commission alleges that the Stipulation and Agreement prevented the early entry of a generic version of Cardizem CD to the market. According to the Commission, three companies would have entered the market with generic versions of Cardizem CD but for the entry of the Stipulation and Agreement: Andrx, Fauldings and Biovail Corporation. Thus, the Commission argues the Stipulation and Agreement had a substantial anticompetitive impact. The evidence adduced to date has shown, however, that none of these entities were impacted by the Stipulation and Agreement and that each entity brought its non-infringing product to market as soon as it was legally able to do so.

1. It Was Not Reasonably Probable That Andrx Would Enter the Market With Its Original Generic Formulation

Aventis submits the record will overwhelmingly show that Andrx's original generic product infringed HMR's patent and HMR was well within the realm of reasonableness in asserting its claims against that product.[12] In addition to HMR's own evaluation of the Andrx product, the facts will show that third parties were also of the view that Andrx's initial

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12. This is arguably the most fundamental distinction between the conduct challenged in the Complaint in this matter and the conduct censured in the Abbott/Geneva enforcement action. The Stipulation in the present case was intended to protect HMR's valid and valuable patent rights from an infringing product. In reformulating its original product, Andrx acted in a way that cast doubt on its appraisal of the chances of its product to prevail in the patent litigation. Having successfully reformulated its product, Andrx abandoned its original product to market its non-infringing reformulation. By contrast, in the Abbott/Geneva patent litigation, Geneva apparently remained confident that its product would survive the infringement litigation (*see* Abbott/Geneva Complaint ¶ 20), and its confidence proved justified when the court vindicated its product against Abbott's challenge (*id.* ¶ 31), yet Geneva continued to withhold its product from the market long after its vindication by the court. (*id.* ¶¶ 32-33.)

formulation infringed HMR's patents. Further, the evidence shows that once it learned of HMR's '584 patent, Andrx invested a substantial amount of time, money and effort in an ultimately successful attempt to "invent around" the '584 claims -- an unusual investment of resources for a party supposedly confident in the ability of its product to withstand an infringement challenge or lulled into complacency by an alleged scheme to restrain competition. These facts coupled with Andrx's more recent assertions that it had no intention to market the infringing product all weigh heavily against the Commission's naked assertion that Andrx would have gone to market with its infringing product but for the Stipulation and Agreement.[13]

2. The Stipulation And Agreement did not Interfere With or Delay the Entry of an Alternative Generic Cardizem® CD Product Manufactured by Andrx

The Commission's claim that the Stipulation and Agreement interfered with Andrx's development and introduction of an alternative, non-infringing generic version of Cardizem® CD (*See* Compl. ¶ 32.) is also baseless. It is undisputed that Andrx ultimately avoided HMR's patent claims by inventing around them, a process which was available under the Stipulation and Agreement. (*See* Stipulation ¶ 8.B.iv.) There is no basis from which Complaint Counsel can argue that the Stipulation and Agreement delayed the introduction by Andrx of an alternative, non-infringing generic version of Cardizem® CD. While the Supplement to ANDA 74-752 was pending before the FDA, HMR undertook an examination of the reformulated product to determine whether it was prepared to continue the patent litigation in light of the new product. Nothing in the Stipulation and Agreement interfered with this process

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13. Regardless of Andrx's intent, the fact remains the antitrust laws do not confer a right upon an infringer to bring an infringer product to market or a right on the public to acquire infringing goods. Thus even if the Complaint Counsel could somehow demonstrate that Andrx would have entered the market with its original formulation "but for" the Stipulation and Agreement, it remains incumbent upon the Complaint Counsel to explain just how it was in the public interest for an infringing product to enter the market.

and the parties were able to negotiated an end to their patent dispute while the FDA review was underway. The fact that Andrx was able to offer its non-infringing, reformulated Cardizem® CD generic for sale on the very day that the reformulated product was approved for sale by the FDA demonstrates that the Stipulation and Agreement did not interfere with Andrx's ability to develop and enter the market with a non-infringing generic product.

3. The Stipulation And Agreement did not Interfere With or Delay the Entry of an Alternative Generic Cardizem® CD Product Manufactured by Third Parties.

The Commission also alleges that the Stipulation and Agreement interfered with or delayed the introduction of generic Cardizem® CD manufactured by others and that, either acting alone or in combination with Andrx, one or more of these third parties could have reached the market sooner with a generic product had the Stipulation and Agreement not been in effect. (*See* Compl. ¶¶ 31, 33.) Again, Aventis respectfully submits that Complaint Counsel can present no evidence to support these bare allegations. Faulding Inc. and its subsidiary, Purepac Pharmaceutical Co. (collectively, "Faulding"), the first generic applicant in line behind Andrx, was embroiled in its own patent infringement litigation with HMR throughout the term of the Stipulation and Agreement. Regardless of any assessment of its risks, Faulding could not have entered the market any earlier than May 31, 1999, the date that the 30-month statutory stay under Hatch-Waxman corresponding to the HMR/Faulding litigation expired. Ultimately, the source of Faulding's marketing handicap was more fundamental than the operation of Hatch-Waxman, however; in the settlement which terminated that litigation, Faulding admitted that its generic

product infringed HMR's patent and was forced to take a license from HMR in order to gain access to the market.[14]

The evidence will also show that the generic product for which Biovail Corporation International ("Biovail") filed an application was not approved for sale by the FDA until late October 1999, some five months after the Andrx reformulated product actually reached the market. Thus, Biovail's entry into the market was not impacted by the Stipulation and Agreement and, even if Andrx had any interest in selling its 180-day exclusivity period[15] rights to Biovail (*see* Compl. ¶ 33), the effect of such sale would have served no purpose *other than to delay* the introduction of generic Cardizem® CD by nearly five months.

While Complaint Counsel may not have been privy to the facts which cripple its "anticompetitive effect" claims at the time the Complaint was filed, it is clear from the record adduced to date that Complaint Counsel is aware of these facts today. Complaint Counsel is thus left with conclusory assertions of anticompetitive effect and, unless counsel comes up with some novel arguments or unknown facts, this case simply cannot go forward under any reasonable application of well-established principles of law.

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14. The facts adduced at trial will demonstrate that no other party had a non-infringing, FDA-approved generic Cardizem® CD product that could have the market while the Stipulation was in effect if only such product could have "piggybacked" on Andrx's 180-day exclusivity rights. This manifestly is *not* a case like the one confronted by the Commission in the Abbott/Geneva enforcement action, in which "at least one other generic manufacturer had satisfied the FDA's requirements for approval and was barred from entering the market because [a respondent's] 180-day Exclusivity Period had not begun to run." (*See* Abbott/Geneva Complaint ¶ 38.) To the contrary, as described more fully below, only two other companies were prosecuting ANDAs for generic Cardizem® CD during the period that the Stipulation was in effect, and of those two companies, one did not receive FDA approval until well after the Stipulation had terminated and the other was embroiled in patent litigation that it ultimately settled with an admission of infringement and that had triggered a Hatch-Waxman 30-month statutory stay that was in effect during the relevant period.

15. Hatch-Waxman provides the first generic applicant to file an ANDA and a patent certification for a new generic drug with 180 days of market exclusivity, beginning from the earlier of (1) the date on which the first applicant begins selling its generic product, or (2) the date on which the pioneer manufacturer's patent is held to be invalid or not infringed in any patent challenge. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

B. The Procompetitive Benefits Associated with the Stipulation and Agreement are Substantial.

As noted above, if and only if Complaint Counsel comes forward with adequate proof of actual, concrete and substantial anticompetitive effects that are causally related to the challenged practices, then the burden shift to Respondents to demonstrate the procompetitive efficiencies of those practices. *Dunafon,* 691 F. Supp. at 1242 (if a plaintiff fails to prove that a challenged practice "has a substantial adverse effect on competition," "it is unnecessary for the defendant to establish economic justifications for the restriction as an affirmative defense"). The amount of evidence of procompetitive efficiencies that a respondent must show will, of necessity, vary with the quantum of proof of substantial, concrete anticompetitive impact established by a plaintiff in the first instance. Once a respondent has produced evidence of the procompetitive efficiencies of a challenged practice,

> a court generally will be required to analyze "the facts peculiar to the business, the history of the restraint, and the reasons why it was imposed." If, on analysis, the restraint is found to have legitimate business purposes whose realization serves to promote competition, the "anticompetitive evils" of the challenged practice must be carefully balanced against its "procompetitive virtues" to ascertain whether the former outweigh the latter. A restraint is unreasonable if it has the "net effect" of substantially impeding competition.

Smith v. Pro Football, Inc., 593 F.2d 1173, 1183 (D.C. Cir. 1978); *see California Dental Ass'n v. FTC,* 128 F.3d 720, 727 (9th Cir. 1997) (Rule of Reason analysis under both Sherman Act Section 1 and FTC Act Section 5 "requires balancing the anticompetitive effects and possible efficiency gains or business justifications of the challenged practice"), *rev'd on other grounds*, 526 U.S. 756, 774 (1999) (requiring more detailed Rule of Reason inquiry than that undertaken

by Court of Appeals and FTC, and describing practice proscribed following application of Rule of Reason as one having a "net anticompetitive effect").

Assuming *arguendo* that Complaint Counsel could meets its obligation of demonstrating an anticompetitive effect sufficient to shift to Respondents the burden of demonstrating the Stipulation's procompetitive efficiencies, the evidence will show that the procompetitive benefits flowing from the transaction more than offset any potential anticompetitive effects.

First, the transaction is procompetitive because its overriding purpose and effect were to preserve and protect HMR's lawful patent rights. The fact that patents and the proper exercise of intellectual property rights benefit the public is recognized in the Intellectual Property Guidelines[16] and rests on a solid foundation of well-established legal principle and precedent.[17]

Second, where, as here, it is clear that HMR's patent claims were at least well-founded, it is in the interest of both the parties and the public for the parties to take such steps as

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16. "The intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare. The intellectual property laws provide incentives for innovation and its dissemination and commercialization by establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression. In the absence of intellectual property rights, imitators could more rapidly exploit the efforts of innovators and investors without compensation. Rapid imitation would reduce the commercial value of innovation and erode incentives to invest, ultimately to the detriment of consumers." U.S. Dep't of Justice & Federal Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* §1.0 (1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132, at 20,734.

17. *See, e.g., Abbott Labs. v. Brennan,* 952 F.2d 1346, 1355 (Fed. Cir. 1991) ("Analysis under the rule of reason takes into consideration the policy underlying the patent grant and the national interest served; for the public purpose of the patent grant as an incentive to invention, investment, and disclosure, is achieved solely by the statutory right to exclude."); *cf. Eli Lilly & Co.,* 630 F.2d at 137 (balance struck by Patent Act to "sacrific[e] short-term price competition in order to foster creativity and improvement of products in [the] long-run is particularly applicable to the pharmaceutical industry"; in light of substantial investments required for drug development, "[u]nless this type of an investment of human and capital resources is rewarded by some form of patent protection, [pharmaceutcial] companies . . . might well choose not to undertake such large expenditures and instead devote themselves to other endeavors," thereby "divert[ing] [resources] from activity that is socially beneficial – the development of new drugs").

may be reasonably necessary to reduce the costs of litigation and to move the case forward efficiently. Here, the Stipulation and Agreement facilitated the ultimate resolution of the case by limiting the harm that the parties faced during the pendency of the dispute and reducing the degree to which the limited resources of the court would be called upon to address issues which are ancillary to the underlying claim. With four dispositive motions already pending before the court, additional procedural motions could only distract the court from the fundamental substantive issues that the parties were urging it to decide, and thus further delay and impede the speedy resolution of the case. Again, case law recognizes the efficiencies that inhere when parties to litigation settle all or part of their differences without the court's intervention. *See, e.g., Speed Shore Corp. v. Denda,* 605 F.2d 469, 473 (9th Cir. 1979) ("It is well recognized that settlement agreements are judicially favored as a matter of sound public policy" because they "conserve judicial time and limit expensive litigation"); *Duplan Corp. v. Deering Milliken, Inc.,* 540 F.2d 1215, 1221 (4th Cir. 1976) (rejecting argument that settlement of a patent case by a party that had received a legal opinion that it might prevail in the action might provide *prima facie* showing of antitrust violation, as "contrary to sound judicial policy which requires that settlements be encouraged, not discouraged"); *Aro Corp. v. Allied Witan Co.,* 531 F.2d 1368, 1372 (6th Cir. 1976); *Procter & Gamble Co. v. Paragon Trade Brands, Inc.,* 61 F. Supp.2d 102, 108 (D. Del. 1996) ("The settlement of disputes is legitimate conduct" that is encouraged by the law, and "[t]his is especially true for patent disputes. . . . The settlement of patent disputes

should not be used to infer an agreement to fix royalty rates or to discriminatorily enforce patents to restrain competition.").[18]

Third, by defining the "Andrx Product" as any product that Andrx "intends to sell pursuant to the ANDA" (*see* Paragraph 8.B.iv), the Stipulation preserved Andrx's ability to continue working on its product, while the Stipulation as a whole preserved Andrx's incentive to do so. This flexibility provided Andrx with an opportunity to "invent around" HMR's patent claim if it had the skill, resources and determination to do so. The case law recognizes that the incentive and ability to engineer around a patent are procompetitive in that these conditions may result in the establishment of an independent competitor instead of a licensee who would remain subject to such terms and conditions as the patent monopolist might impose upon the licensing of the technology.[19]

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18. The Sixth Circuit long ago recognized many of the procompetitive efficiencies that attend full or partial settlements of patent disputes:

> Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. . . . By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes support the latter. An amicable compromise provides the more speedy and reasonable remedy for the dispute.

Aro Corp., 531 F.2d at 1372 (citing *D.H. Overmeyer Co. v. Loflin,* 440 F.2d 1213 (5th Cir. 1971).

19. *See Read Corp. v. Portec, Inc.*, 970 F.2d 816, 828 (Fed. Cir. 1992), *abrogated on other grounds by Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) ("We have often noted that one of the benefits of the patent system is the incentive it provides for 'designing around' patented inventions, thus creating new innovations. Of course, determining when a patented device has been 'designed around' enough to avoid infringement is a difficult determination to make. One cannot know for certain that changes are sufficient to avoid infringement until a judge or a jury has made that determination." (citations omitted)); *Yarway Corp. v. Eur-Control USA, Inc.*, 775 F.2d 268, 277 (Fed. Cir. 1985) ("This court has indicated that the incentive to 'design around' patents is a positive result of the patent system."); *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235-36 (Fed. Cir. 1985) ("Conduct such as [defendant's], involving keeping track of a competitor's products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made and is supposed to benefit the consumer. One of the benefits of a patent system is its so-called 'negative incentive' to 'design around' a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace."); *Baxter Diagnostics, Inc. v. AVL Scientific*
(continued...)

Fourth, had Andrx been unable to "invent around" HMR's patent, the Stipulation provided a fall-back option that promoted and facilitated Andrx's lawful entry and was procompetitive -- an irrevocable right on the part of Andrx to take a license to HMR's technology to manufacture and sell a generic version of Cardizem® CD. This is a right that HMR was otherwise under no obligation to confer on any would-be generic manufacturer.[20] In addition to providing Andrx with a profitable alternative way to enter the market, this license would insure that generic competition would occur by no later than January 2000, regardless of the outcome of the HMR/Andrx litigation or the status of any other generic application.

In sum, any competitive analysis of the Stipulation must take into account the fact that its purpose and effect were to preserve and protect a valid intellectual property right while simultaneously providing Andrx with the incentive and ability to develop an independently competitive product or, failing that, with the right to enter the market with a licensed generic competitor. The parties sought to accomplish these objectives while conserving scarce judicial resources and keeping the court's focus on expeditiously resolving the substantive issues of the

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19. (...continued)
Corp., 924 F. Supp. 994, 1020 (C.D. Cal.), *order modified*, 954 F. Supp. 199 (C.D. Cal. 1996) ("Designing around patents promotes healthy competition. Competitors can design better or cheaper functional equivalents of each other's products and benefit consumers."); *see generally* 7 Donald S. Chisum, *Chisum on Patents* § 20.03[4][b][v][G], at 20-401 to 20-404 (1999) (suggesting "Courts frequently cite the infringer's 'copying' as a factor establishing or tending to show willful disregard of patent rights, but they also recognize that 'designing around' patented technology is a positive benefit of the patent system, not to be punished by multiple damage awards.").

20. *See, e.g., In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1328 (Fed. Cir. 2000), *petition for cert. filed*, 69 U.S.L.W. 3087 (U.S. July 11, 2000) (No. 00-62) (in light of Patent Act's statutory right to exclude, defendant "was under no obligation to sell or license its patented parts and did not violate the antitrust laws by refusing to do so"); *Miller Insituform, Inc. v. Insituform of North America, Inc.*, 830 F.2d 606, 609 (6th Cir. 1987) (patent holder who lawfully acquires patent can't be held liable under antitrust laws for refusing to license the patent to others); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981) ("Where a patent holder . . . merely exercises his 'right to exclude others from making, using, or selling the invention,' by refusing unilaterally to license his patent for its seventeen-year term, such conduct is expressly permitted by the patent laws." (citations omitted)).

case. These efficiency benefits would not have existed but for the Stipulation at issue here and would make it difficult to sustain any claim that the Stipulation had any net anticompetitive effects or that anticompetitive intent colored this transaction in any way.

C. Any Restraints Arising From the Transaction are Reasonable and Are Necessary to Secure the Benefits Afforded by the Transaction.

The Stipulation and Agreement arose out of HMR's concerns that Andrx lacked the financial resources to be answerable in damages in the event that it marketed an infringing product and that unforeseen events might prompt Andrx to take the risk of entering the market with a potentially infringing product. By pledging to make good Andrx's lost profits in a stipulated amount of $100 million per year, HMR sought to reassure Andrx that it would not be harmed by litigating the patent case to a final conclusion while refraining from acting in a manner that could ultimately be found to constitute willful infringement of the '584 Patent. In order to make this pledge, however, HMR needed to assure itself that this commitment could not be gamed by Andrx. Specifically, HMR sought to protect itself against a scenario in which it might be expected to make this substantial lost profits payment even after Andrx either no longer owned or controlled the product or, in order to avoid the losses contemplated by the Stipulation and Agreement, had entered the market, with either the product that was the subject of ANDA 74-752 or some other generic formulation. In other words, HMR did not want to indemnify Andrx for profits that, because of affirmative choices by Andrx, were never "lost."

The conditions that had to be satisfied before HMR would be obligated to make the lost profits payments contemplated by Paragraph 3 were set forth in Paragraph 2.A of the Stipulation and Agreement. Paragraph 2.A provides:

> Pending the entry of Final Judgment, the parties agree to maintain the status quo with respect to the commercial sale of the Andrx

> Product in the United States. Andrx agrees not to commence the commercial sale of the Andrx Product or other bioequivalent or generic version of Cardizem® CD in the United States directly or indirectly until the entry of Final Judgment, or until it obtains a license from HMRI pursuant to paragraphs 5, 6, and 7 of this Stipulation and Agreement, or until Andrx receives the notice [of HMR's intention to license its intellectual property to a third party or to utilize it to produce its own generic Cardizem® CD] required by Paragraph 5 of this Stipulation and Agreement, whichever is the first to occur. Andrx further agrees that during the pendency of the Patent Infringement Action, it will diligently prosecute the ANDA for the Andrx Product and will not relinquish or otherwise compromise any right accruing thereunder or pertaining thereto.

In the event that Andrx failed to comply with these conditions, the sole consequence would be that the Stipulation and Agreement would terminate and any funds advanced to Andrx during the course of the Stipulation and Agreement would be returned. (*See* Stipulation ¶ 8.B.i.)

While HMR believes that it was neither inappropriate nor anticompetitive for HMR *either* to pledge to make good Andrx's potential losses *or* to include in the agreement language that would prevent that pledge from being manipulated, the Complaint argues that these provisions constitute "unreasonable restraints of trade in violation of Section 5." (Compl. ¶¶ 32, 33, 36). However, even a practice that, standing alone, might be condemned as an unlawful restraint of trade may survive antitrust scrutiny where it is found to be (1) "merely ancillary to the main purpose of a lawful contract," and (2) "necessary to protect the covenantee in the full enjoyment of the legitimate fruits of the contract, or to protect him from the dangers of an unjust use of those fruits by the other party." *United States v. Addyston Pipe & Steel Co.,* 85 F. 271, 282 (6th Cir. 1898), *modified and aff'd,* 175 U.S. 211 (1899); *see also Business Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 729 n.3 (1988) (quoting *Addyston Pipe* in describing "[t]he classic 'ancillary' restraint" as an agreement that "merely enhances the value of" another, legitimate contract "or permits the 'enjoyment of [its] fruits.'").

The restraint must be reasonably necessary to the accomplishment of the larger, legitimate objective, and appropriately tailored to achieve its purposes. *See LDDS Communications, Inc. v. Automated Communications, Inc.*, 35 F.3d 198, 199 (5th Cir. 1994) (in determining enforceability of non-compete covenant in asset sale contract, "[t]he key is that such covenants must be ancillary to the sale, a reasonable protection of what was sold"); *Lektro-Vend Corp.*, 660 F.2d at 265. Such "ancillary restraints" are evaluated under the Rule of Reason, and will be upheld if their procompetitive efficiencies outweigh their putative anticompetitive effects. *See, e.g., Dunafon,* 691 F. Supp. at 1241 (noting "the rule that ancillary restraints should be evaluated under the rule of reason").

1. The Limitations Contained in Paragraph 2.A are Ancillary to the Main Purpose of a Lawful Contract

HMR believes that the facts that will be adduced in this case will demonstrate that, to the extent that these provisions can be deemed to constitute "restraints" at all, they meet the classic definition of ancillary restraints. The principal purpose of the Stipulation and Agreement was to assure Andrx that it would not be substantially and irreparably harmed if it elected to defer the sale of its generic product during the pendency of the litigation and were ultimately deemed not to have infringed HMR's patent, while at the same time protecting HMR's patent rights from decimation prior to final judgment in the event that Andrx's product were ultimately deemed to infringe the '584 Patent. To achieve this result, HMR pledged to make good Andrx's lost profits in a stipulated amount of $100 million per year -- an amount which is less than that which Andrx would have earned had it been free to sell its product. Given that it is not uncommon in preliminary injunction practice in patent cases for the patent holder to be

required to pledge to make good the lost profits of the defendant in the event that the defendant prevails,[21] there is nothing unlawful about the underlying transaction.

Moreover, the Stipulation and Agreement was the product of, and reasonably incidental to, HMR's good faith patent litigation – which itself was nothing more than an exercise of HMR's legally protected right to exclude others from using its patent.[22] The Stipulation and Agreement had no meaning (nor any existence) outside of this litigation. It arose in a context in which the court in which the patent action was pending failed to respond to the several dispositive motions filed by the parties and refused to entertain the parties' applications for a scheduling order that might have provided for the expeditious resolution of the litigation. Had the court taken either action, the litigation could likely have been completed within the

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21. Not only are bonds typically required as a prerequisite to preliminary injunctive relief, *see* Fed. R. Civ. P. 65(c), but it is not uncommon for such bonds to be based upon or to factor in a defendant's potential lost profits where a plaintiff seeks to enjoin the defendant from marketing a product that is alleged to infringe a patent held by the plaintiff. *See, e.g., Jacobson v. Cox Paving Co.*, 19 U.S.P.Q.2d 1641, 1657, 1991 WL 328445 (D. Ariz. 1991), *aff'd*, 949 F.2d 404 (Fed. Cir. 1991) (court appearing to factor "a normal manufacturer's profit level of approximately 10% of gross income" into its determination of an appropriate bond, which the court ultimately set at an amount slightly in excess of defendant's estimated lost profits); *American Parking Meter Adver., Inc. v. Visual Media, Inc.*, 693 F. Supp. 1253, 1254-55 (D. Mass. 1987) (court apparently factoring present profit potential from defendant's business opportunity with City of Philadelphia involving allegedly infringing product in determining amount of bond to be posted as a condition to preliminary injunction); *Augat, Inc. v. John Mezzalingua Assocs., Inc.*, 642 F. Supp. 506, 509 (N.D.N.Y. 1986) (determining amount of bond based on "an estimated liberal profit margin" on "defendant's anticipated lost sales" in order "to estimate anticipated damages to defendant in the event the preliminary injunction is later found to have been issued improperly"); 5 *Intellectual Property Counseling and Litigation* § 65.12, at 65-77 to 65-78 (Lester Horwitz & Ethan Horwitz, eds., 1999) ("The size of the bond to be posted is . . . discretionary with the trial court and thus can be based on any relevant factors," including, among other things, "the estimated value of lost sales during the period of the injunction."). Moreover, it is not uncommon for courts to leave the determination of the size and form of the bond to the stipulation of the parties. *See, e.g., Ortho Pharm. Corp.*, 1990 WL 18681, at *12 (requiring defendant-movant for injunction to post corporate surety bond "in such form and amount as the parties may agree upon or, in the event of their failure so to agree, in the form and amount fixed by the Court in a subsequent Order"); *Sanofi, S.A. v. Med-Tech Veterinarian Prods., Inc.*, Civ. Action No. 83-2198, 1983 WL 417, at *9 (D. Kan. Sept. 16, 1983) (conditioning preliminary injunction on posting of a bond, the terms of which were to be established by agreement of the parties).

22. "Every patent shall contain . . . a grant to the patentee, his heirs or assigns, . . . of the right to exclude others from making, using, or selling the invention throughout the United States," 35 U.S.C. § 154, and in order to put teeth in this statutory right, the "patentee shall have remedy by civil action for infringement of his patent," 35 U.S.C. § 281.

period that Hatch-Waxman's statutorily imposed 30-month stay was in effect, and there would have been no need for the Stipulation. It was only because the case was stymied with no relief in sight and with the statutory stay dwindling away with less than one year remaining that the parties even began to consider the possible need for an agreement. And it was only when this condition of the litigation persisted at the time of the expiration of the statutory stay that the Stipulation and Agreement ultimately negotiated by the parties came into effect at all.

Conversely, while Andrx's concerns as to the potential that its initial formulation infringed the '584 Patent had already caused Andrx to commit substantial resources to an effort to invent around HMR's patent, Andrx also wanted some assurance that HMR would make good on the profits that Andrx might potentially lose in the event that it withheld its initial product from the market but ultimately prevailed in the litigation. Consequently, adopting an approach that is familiar to patent litigation, the Stipulation and Agreement required Andrx to refrain from marketing its product pending final resolution of the patent case in exchange for HMR's agreement to make good on Andrx's estimated potential lost profits.

2. The Limitations Contained in Paragraph 2.A are Necessary to Protect HMR Against the Unjust Use of the Agreement by Andrx

Not only were the putative restraints about which Complaint Counsel complains reasonably ancillary to the parties' agreement, they were also necessary to make the transaction work – in the words of former Chief Justice Taft, they were "necessary to protect the covenantee in the full enjoyment of the legitimate fruits of the contract, or to protect him from the dangers of an unjust use of those fruits by the other party." *Addyston Pipe & Steel Co.,* 85 F. at 282.

The termination triggers of Paragraph 2.A represented the kinds of safeguards that careful and prudent businessmen would be expected to include in an agreement in which each had put so much at stake. HMR had pledged a substantial amount of money[23] to make good Andrx's lost profits in the event that Andrx prevailed in the underlying litigation, but it was a reasonable and necessary predicate the payment of these sums on the fact that Andrx did , in fact, suffer a loss of profits. HMR's willingness to make good Andrx's lost profits was necessarily conditioned upon it receiving some assurances that the pledge would not be gamed.

As would be true of any similarly situated rational business, HMR would want to be relieved of its obligation to pay Andrx tens of millions of dollars for "lost profits" if Andrx were able to find some way to enter the market with a generic Cardizem® CD product and realize the profits that the parties presumed to be lost. Similarly, HMR did not want to remain potentially obligated to pay Andrx tens of millions of dollars for lost profits if Andrx were to sell or assign its equitable interest in ANDA 74-752 to some other party. As previously noted, the Stipulation was designed to protect HMR's valid patent from potential infringement and preserve Andrx's profit potential in the event of a judicial decision of non-infringement pending judicial

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23. The Stipulation's lost profits bonding provisions were intended to strike a balance between (i) retaining sufficient incentives for Andrx (depending upon Andrx's calculation of its probability of ultimate success in the patent action) to either vigorously litigate the patent case to a judicial resolution or attempt to invent around HMR's patent claims on the one hand, and (ii) fairly compensating Andrx for profits it might lose by withholding its product from the market in the event that it won a judgment from the patent court on the other hand. While it was important to make sure that the lost profits payments under the Stipulation would not exceed Andrx's likely actual profits (and thereby potentially dampen Andrx's competitive incentives), it was also important to insure that the level of stipulated lost profits would be sufficient to reasonably compensate Andrx in the event that it deferred entry with its product *and* the patent court ultimately determined that the product was non-infringing. This is consistent with judicial practice in preliminary injunction litigation, in which courts have been cautioned against "ignoring a cost [such as lost sales of the product at the heart of the litigation] that was sure to be large, even if the total was hard to determine on short notice," and in favor of "err[ing] on the high side" in determining the value of any bond to avoid placing defendants at the risk of having to "swallow substantial losses." *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 887-88 (7th Cir. 2000), *petition for cert. filed,* 69 U.S.L.W. 3087 (U.S. July 11, 2000) (No. 00-71).

resolution of the patent case, all while minimizing transaction costs (including additional court delays occasioned by a preliminary injunction application) to the court and the parties. Divestiture of Andrx's equitable interest in its ANDA would defeat each of these procompetitive purposes, and, as Andrx almost certainly would not do so without adequate compensation, would once again remove from Andrx any risk of loss of the profit potential attributable to its product. Having negotiated a stipulated lost profits figure with Andrx, which derived a significant amount of value from the 180-day market exclusivity right that Andrx acquired as the first ANDA applicant, HMR understandably did not want to be compelled to pay to Andrx the full stipulated amount in the event that Andrx had decided to sell that valuable right to another party. Under the Stipulation and Agreement, Andrx's sale of its 180-day exclusivity rights would have triggered the termination of the Stipulation and would have returned the parties to where they were before the Stipulation and Agreement took effect.

IV. THE CONDUCT AT ISSUE DID NOT CONSTITUTE AN UNLAWFUL ATTEMPT TO MONOPOLIZE A MARKET AS DEFINED BY SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT.

In addition to charging the Respondents with engaging in acts or practices that constituted unreasonable restraints of trade, the Complaint also alleges that Respondent HMR acted with monopolistic intent in entering into the Stipulation and Agreement with Andrx and engaging in pre-litigation settlement discussions with Biovail and that, taken together, the Respondents' collective behavior constituted "overt acts" taken in furtherance of a conspiracy to monopolize a relevant market. (Compl. ¶¶ 37, 38.) Again, these charges cannot be sustained as either a matter of fact or law. The offense of monopolization consists of two elements: (1) possession of monopoly power in a relevant market, and (2) "the willful acquisition or

maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Eastman Kodak Co. v. Image Technical Servs., Inc.,* 504 U.S. 451, 481 (1992) (quoting *United States v. Grinnell Corp.,* 384 U.S. 563, 570-71 (1966)); *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.,* 472 U.S. 585, 596 n.19 (1985).

As a factual matter, HMR simply lacks sufficient market share in a properly defined market to exert monopoly power or to aspire to attain monopoly status. As a legal matter, the Complaint's charges of monopolistic behavior fundamentally fail to distinguish between legitimate behavior, undertaken in a good-faith effort to protect intellectual property rights, and illegal acts of monopolization. Because the activities challenged in this case are incidental to the good-faith prosecution of a well-grounded patent infringement action, they do not constitute acts of monopolization under Section 5 of the FTC Act.

A. HMR Lacks the Power to Control Prices or Exclude Competition in a Properly Defined Market.

The first element of the monopolization offense, monopoly power, has been defined as "the power to control prices or exclude competition." *United States v. E.I. du Pont de Nemours & Co.,* 351 U.S. 377, 391-92 (1956). This standard "has been applied principally with reference to the defendant's share of the relevant product and geographic markets." *California Computer Prods., Inc. v. IBM Corp.,* 613 F.2d 727, 735 (9th Cir. 1979); *see also Tarabishi v. McAlester Regional Hosp.,* 951 F.2d 1558, 1567 (10th Cir. 1991) ("Determination of the existence of monopoly power requires proof of relevant product and geographic markets."). Where direct evidence of market power is not available, courts may look to a defendant's market share and entry conditions in a properly defined relevant market as a proxy for such proof. *See,*

e.g., Grinnell Corp., 384 U.S. at 571 (existence of monopoly power "ordinarily may be inferred from the predominant share of the market"); *Reazin v. Blue Cross & Blue Shield of Kansas, Inc.*, 899 F.2d 951, 967-68 (10th Cir. 1990). More recently, in guidance issued by the Department of Justice and the Federal Trade Commission to assist businesses in determining whether corporate transactions may present antitrust issues, the enforcement agencies established more precise methodologies for determining the scope of a relevant product market.[24]

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24. The agencies' merger guidelines adopt the following methodology for defining a relevant product market:

> Absent price discrimination, the Agency will delineate the product market to be a product or group of products such that a hypothetical profit-maximizing firm that was the only present and future seller of those products ("monopolist") likely would impose at least a "small but significant and nontransitory" increase in price. That is, assuming that buyers likely would respond to an increase in price for a tentatively identified product group only by shifting to other products, what would happen? If the alternatives were, in the aggregate, sufficiently attractive at their existing terms of sale, an attempt to raise prices would result in a reduction of sales large enough that the price increase would not prove profitable, and the tentatively identified product group would prove to be too narrow.
>
> Specifically, the Agency will begin with each product (narrowly defined) produced or sold by each merging firm and ask what would happen if a hypothetical monopolist of that product imposed at least a "small but significant and nontransitory" increase in price, but the terms of sale of all other products remained constant. If, in response to the price increase, the reduction in sales of the product would be large enough that a hypothetical monopolist would not find it profitable to impose such an increase in price, then the Agency will add to the product group the product that is the next-best substitute for the merging firm's product.
>
> In considering the likely reaction of buyers to a price increase, the Agency will take into account all relevant evidence, including, but not limited to, the following:
>
> (1) evidence that buyers have shifted or have considered shifting purchases between products in response to relative changes in price or other competitive variables;
>
> (2) evidence that sellers base business decisions on the prospect of buyer substitution between products in response to relative changes in price or other competitive variables;
>
> (3) the influence of downstream competition faced by buyers in their output markets; and
>
> (4) the timing and costs of switching products.

U.S. Dep't of Justice & Federal Trade Comm'n, *Horizontal Merger Guidelines* §1.11 (1992), *reprinted in* 4 (continued...)

Because monopoly power is determined by reference to a relevant market, the proponent of a monopolization claim must first establish the product and geographic markets that are alleged to be affected. "The essential test for ascertaining the relevant product market involves the identification of those products or services that are either (1) identical to or (2) available substitutes for the defendant's product or service," while the relevant geographic market – "the area of effective competition" – is determined by reference to "the market area in which the seller operates, and to which the purchaser can practically turn for supplies." *Dunafon,* 691 F. Supp. at 1241-42 (quoting *White & White, Inc. v. American Hosp. Supply Corp.,* 723 F.2d 495, 500-01 (6th Cir. 1983)).

Respondent HMR believes that Complaint Counsel will not be able to sustain its burden of showing that the relevant product market can be properly confined to "once-a-day diltiazem." (Compl. ¶ 12.) Contrary to the assertions set forth in the Complaint, the evidence will show that prescribing physicians generally view calcium channel blockers as being equally efficacious and that the percentage of hypertension patients who might suffer adverse side effects from other calcium channel blockers but who might avoid such side effects by switching to once-a-day diltiazem is minor and insignificant. The evidence will also show that, contrary to the assertions set forth in the Complaint, the risks associated with switching patients from one antihypertension product to another are not significant and that prescribing physicians routinely switch their patents from one antihypertension product to another, both within and across product classes.

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24. (...continued)
Trade Reg. Rep. (CCH) ¶ 13,104, at 20,572-73.

The evidence will also demonstrate that neither buyers nor sellers of antihypertension drugs in the real world adhere to the Complaint's artificially narrow product market definition. The evidence will show that HMR targeted its sales strategies on other non-diltiazem based calcium channel blockers and that the manufacturers of these other products promoted their products against a broad range of competitors as well. The evidence will also show that the biggest buyers of pharmaceutical products -- the managed care providers and insurance companies who manage formularies and purchase a substantial share of all prescription drugs sold each year – see once-daily diltiazem formulations as but one of several therapeutic options available for physicians in the calcium channel blocker category and that many do not list any once-daily diltiazem-based products on their formulary list of "preferred" products. The evidence will also show that managed care providers and calcium channel blocker manufacturers regularly enter into incentive contracts which reward the managed care providers based upon how well that manufacturer's product sell against all other calcium channel blockers purchased by that managed care company. The Complaint's effort to confine the scope of the product market to once-daily diltiazem simply cannot be sustained.

B. HMR's Acts Constituted Legitimate Enforcement of its Intellectual Property Rights and not "Exclusionary Conduct."

The second element of a monopolization claim, willful acquisition or maintenance, is often referred to as "exclusionary conduct." To be wrongful, exclusionary conduct must be both unreasonable and produce a substantial anticompetitive effect. "At the very least, willful maintenance of monopoly power requires the plaintiff to prove that the monopolist has acted in an unreasonably exclusionary manner, that is, that the monopolist's challenged practice has yielded unreasonable anticompetitive effects." *Trans Sport, Inc. v.*

Starter Sportswear, Inc., 775 F. Supp. 536, 541 (N.D.N.Y. 1991), *aff'd*, 964 F.2d 186 (2d Cir. 1992); *see also Aspen Skiing Co.*, 472 U.S. at 605 (to determine whether conduct is exclusionary it is appropriate to examine the effect of the challenged activity on consumers, competitors and the defendant); *Fairchild v. City Management Corp.*, 142 F.3d 433, 1998 WL 136569, at *1 (6th Cir. 1998); Timothy J. Muris, *The FTC and the Law of Monopolization,* 67 Antitrust L.J. 693, 694-95, 696-98 (2000) ("Recent Supreme Court pronouncements have confirmed that no matter how bad a firm's conduct is, or how injurious to rivals, there can be no Section 2 violation without injury to competition.").

Moreover, because the exclusionary conduct element does not preclude legitimate competitive behavior, evidence of a valid business justification for the challenged conduct is relevant to any determination of whether such conduct can fairly be deemed to be exclusionary. *See Aspen Skiing Co.*, 472 U.S. at 604-05. In this regard, there is perhaps no better example of legitimate exclusionary conduct than that provided by patent laws. Even if a respondent is found to possess monopoly power, its exercise of the exclusionary power inherent in the possession of a valid patent does *not* constitute "exclusionary conduct" within the meaning of monopolization. *See, e.g., THK America, Inc. v. NSK, Ltd.*, 157 F.R.D. 660, 662-63 (N.D. Ill. 1994) ("regardless of whether THK intended any monopolistic or predatory purpose in filing [its patent infringement] suit, THK has statutory patent rights which it may protect in American courts," and "as patents are cloaked in a presumption of validity, a patent infringement suit is presumed to be brought in good faith").

1. HMR's Good Faith Efforts by HMR to Facilitate the Resolution of its Patent Infringement Case Against Andrx Does Not Constitute a Willful Attempt to Acquire or Maintain Monopoly Power.

The patent laws confer upon the patentee the exclusive right to make, use or sell the patented invention during the patent term, and authorize the patentee to exclude others – for example, by the initiation of infringement litigation – from manufacturing, using and/or selling the invention during the patent term. *See* 35 U.S.C. §§ 154, 271, 281.[25] "[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws." *SCM Corp.*, 645 F.2d at 1206. More specifically, a patent holder who holds a valid, lawfully acquired patent cannot be deemed to be unlawfully preserving monopoly power simply by exercising the right to exclude others from making, using or selling the patented invention. *Miller Insituform, Inc.*, 830 F.2d at 609 ("A patent holder who lawfully acquires a patent cannot be held liable under Section 2 of the Sherman Act for maintaining the monopoly power he lawfully acquired by refusing to license the patent to others."); *see Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999) ("the antitrust laws do not negate the patentee's right to exclude others from patent property").

In prosecuting the infringement litigation against Andrx and entering into the Stipulation as a reasonable incident thereof, HMR's did no more than to exercise its lawful right to exclude an infringer from trespassing upon its valid patent. An agreement such as the Stipulation does not violate the antitrust laws where any restrictions allegedly imposed by the

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25. Section 271(d) of the Patent Act, for example, provides that "[n]o patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . sought to enforce his patent rights against infringement or contributory infringement." 35 U.S.C. § 271(d).

agreement actually resulted from a patent rather than the agreement. *See United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 649 (9th Cir. 1981).

2. HMR's Good Faith Efforts to Settle a Series of Outstanding Legal Disputes with Biovail do not Constitute a Willful Attempt to Acquire or Maintain Monopoly Power

In addition to the allegations concerning the Stipulation, FTC further claims that HMR's effort to resolve existing and reasonably anticipated disputes with Biovail, in conjunction with its efforts to develop a new indication for Probucol, an HMR product in which Biovail had expressed interest, constituted additional acts of monopolization by HMR. (Compl. ¶ 21.) As the evidence will demonstrate at trial, these allegations have no basis in fact.

Evidence will show that Biovail expressed interest in pursuing the development of a new indication for Probucol prior to the meeting cited in the Complaint. HMR and Biovail met in August 1997 to discuss three primary issues: (1) Biovail's expressed interest in participating in an effort to obtain FDA approval for the use of Probucol for the prevention of restenosis following angioplasty; (2) the ongoing dispute between Biovail and HMR regarding the terms and scope of a right of reference that HMR provided to Biovail under an FTC consent order which had become the subject of a lawsuit by Biovail against HMR in the District of New Jersey; and, (3) Biovail's desire to file both an NDA and an ANDA covering its generic version of Cardizem® CD.

The evidence will show that the August 1997 meetings were undertaken in an effort to resolve these issues so the parties could focus again on their core businesses. The

evidence will also show that both parties negotiated hard for a global settlement of these concerns at that time and in discussions which continued over well into 1998.[26]

With regard to Biovail's ANDA application for a generic version of Cardizem® CD, evidence will show that Biovail refused to provide access to the materials HMR needed to make an informed decision regarding whether the Biovail product infringed any patent owned or controlled by HMR. Thus, Biovail was attempting to prevent HMR from filing a patent infringement action within the initial window allowed by Hatch-Waxman. The discussions in early August 1997 were an attempt on the part of both companies to reach settlement of these existing issues, including a deal on Probucol, and head off any potential patent infringement action related to Biovail's generic version of Cardizem® CD. This was appropriate, legitimate conduct and Complaint Counsel has not elaborated on how these allegations amount to an act of monopolization.

V. THE STIPULATION AND AGREEMENT WAS REASONABLY ATTENDANT UPON LEGITIMATE PETITIONING ACTIVITY AND WAS THEREFORE PROTECTED FROM ANTITRUST SCRUTINY BY THE *NOERR-PENNINGTON* DOCTRINE.

As noted above, at the core of the practices about which Complaint Counsel now complains lies a dispute between HMR and Andrx over whether Andrx's original formulation of a Cardizem® CD generic infringed HMR's '584 Patent. The '584 Patent is, and is presumed to be, valid, and HMR was legally entitled to enforce its rights in the '584 Patent against an Andrx product that HMR believed in good faith would infringe this patent. 35 U.S.C. §§ 281, 282.

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26. The evidence will show that contrary to passive picture painted by the Complaint, Biovail was an active participant in these settlement discussion. In fact, the evidence will show that Biovail's last proposal contemplated a scheme in which a "reformulated" version of Cardizem® CD would be brought to the market in order to frustrate and forestall the generization of the Cardizem® CD brand. The evidence will show that it was HMR, and not Biovail, who refused to participate in this anticompetitive scheme

Ultimately, HMR did just that, filing suit to protect its valuable patent rights against infringement in January 1996. It is undisputed that HMR's action in bringing suit in federal court was a protected form of governmental petitioning that is normally immune from antitrust scrutiny under the *Noerr-Pennington* doctrine.[27] *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56-57 (1993).

It is well-established that *Noerr-Pennington* immunity shields from antitrust scrutiny not only good faith litigation itself, but also any conduct that is "reasonably and normally attendant upon effective litigation." *McGuire Oil Co. v. Mapco, Inc.*, 958 F.2d 1552, 1560 (11th Cir. 1992) (quoting *Coastal States Marketing, Inc.*, 694 F.2d at 1366). Consequently, *Noerr-Pennington* immunity has been held to extend to such ancillary conduct as threatening litigation,[28] making public statements about the lawsuit aimed at an opposing party's customers,[29] and sending demand letters prior to litigation.[30] On the same rationale, *Noerr-Pennington* immunity has been extended to interim agreements adopted by parties to a dispute that seek to manage the risks posed by the ongoing prosecution of the underlying case. Thus, in *McGuire Oil Co.*, the Eleventh Circuit held that an interim stipulation entered into by opposing parties in ongoing litigation was protected by *Noerr-Pennington* immunity. 958 F.2d at 1555. Similarly, the *Noerr-Pennington* doctrine has been found to immunize settlements of litigation from

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27. *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965).

28. *McGuire Oil Co.*, 958 F.2d at 1560.

29. *AirCapitol Cablevision, Inc. v. Starlink Communications Group, Inc.*, 634 F. Supp. 316, 324, 326 (D. Kan. 1986).

30. *Barq's Inc. v. Barq's Beverages, Inc.*, 677 F. Supp. 449, 452 (E.D. La. 1987). *See also Modesto Irrigation Dist. v. Pacific Gas & Elec. Co.*, 61 F. Supp. 2d 1058, 1070-73 (N.D. Cal. 1999) (defendant's refusal to grant request to provide transmission service to a substation was incidental to its filing of a Federal Energy Regulatory Commission petition and fell within the scope of *Noerr-Pennington* immunity).

antitrust scrutiny[31] – even settlements comparable to that effected by the Stipulation and Agreement and without regard for whether the particular settlement was ever filed with or approved by the court in the underlying action.[32]

There is no question but that the Stipulation and Agreement is reasonably attendant to this litigation. Not only does the Stipulation and Agreement draw upon the litigation to determine its effective date, terms, duration and ultimate termination, but its purpose and effect were to facilitate the ultimate resolution of the dispute. The Stipulation represented the parties' settlement of a significant ancillary issue to this litigation, namely the issue of how the parties would bear the risks of potential infringement and potential lost profits as the underlying patent infringement lawsuit proceeded.[33] Under any standard, the Stipulation and Agreement was reasonably and normally attendant upon effective litigation of the patent case and is immune from the antitrust laws under the *Noerr-Pennington* doctrine. *Noerr Motor Freight, Inc.*, 365 U.S. at 144; *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 512 (1972).[34]

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31. *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) ("A decision to accept or reject a settlement offer is conduct incidental to the prosecution of the suit" and is therefore immunized); *Forces Action Project LLC v. California,* No. C 99-0607 MJJ, 2000 WL 20977, at *8 (N.D. Cal. Jan. 5, 2000) ("litigation settlements are also within the ambit of the immunity conferred" by *Noerr*); *Hise v. Philip Morris Inc.*, 46 F. Supp. 2d 1201, 1206-07 (N.D. Okla. 1999), *aff'd,* 208 F.3d 226 (10th Cir. 2000) (holding that the *Noerr-Pennington* doctrine immunizes non-sham settlements).

32. *See Columbia Pictures Indus., Inc.*, 944 F.2d at 1528-29 ("A decision to accept or reject an offer of settlement is conduct incidental to the prosecution of a suit and not a separate and distinct activity which might form the basis for antitrust liability.").

33. The Stipulation and Agreement also resolved with finality Andrx's antitrust and unfair competition counterclaims against HMR. (*See* Stipulation ¶ 2(C).)

34. The sham exception to the doctrine does not apply since Complaint Counsel properly recognized that Aventis' patent infringement action was not objectively baseless. *See* note 1, *supra*; *Professional Real Estate Investors, Inc., supra.*

CONCLUSION

Aventis respectfully submits that the issues presented and discussed above will need to be addressed by this tribunal during the course of this proceeding.

Dated: September 13, 2000

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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

CERTIFICATE OF SERVICE

I, Peter D. Bernstein, hereby certify that on September 13, 2000, a copy of Aventis Pharmaceuticals, Inc.'s Statement of the Case was served upon the following persons by hand delivery and/or Federal Express as follows:

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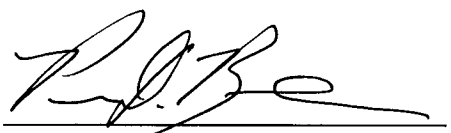

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