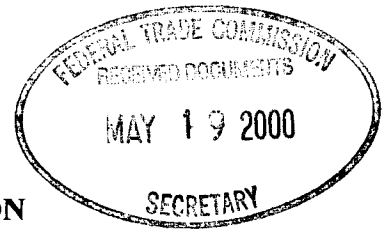

UNITED STATES OF AMERICA

BEFORE FEDERAL TRADE COMMISSION

In the Matter of

HOECHST MARION ROUSSEL, INC., a corporation,

CARDERM CAPITAL L.P., a limited partnership,

and

ANDRX CORPORATION, a corporation.

Docket No. 9293

RESPONDENT ANDRX CORPORATION'S MEMORANDUM IN OPPOSITION TO COMPLIANT COUNSEL'S MOTION TO STRIKE CERTAIN AFFIRMATIVE DEFENSES

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RESPONDENT ANDRX CORPORATION'S MEMORANDUM IN OPPOSITION TO COMPLAINT COUNSEL'S MOTION TO STRIKE CERTAIN AFFIRMATIVE DEFENSES

Pursuant to § 3.22 of the Federal Trade Commission's Rules of Practice, respondent Andrx Corporation ("Andrx") submits this Memorandum in Opposition to Complaint Counsel's Motion to Strike Certain Affirmative Defenses.

Preliminary Statement

Complaint Counsel's motion to strike is addressed to nine affirmative defenses asserted by Andrx. These defenses pertain to, among other things, the statutory and regulatory justification of Andrx's challenged conduct; the serious improprieties in the process by which the FTC staff acted in collaboration with Andrx's alleged competitor to create a basis for bringing these proceedings; and the total absence of any injury to any consumer or to competition by reason of Andrx's conduct. We demonstrate below that the motion should be denied because it has no basis in law. Indeed, the only support cited for the motion are portions of inapposite decisions, taken largely out of context, that do not relate at all to the circumstances pleaded in the affirmative defenses here. To bolster its motion, Complaint Counsel raises purported "practical concerns" about the scope of discovery (Moving Mem. at 4). That argument, however, is unavailing. Even if "practical concerns" alone were sufficient to strike the defenses (and they are not), the motion still serves no useful purpose since respondents will need to obtain the same discovery in any event. Given the extraordinary time pressure respondents are under to ready this matter for trial in only six months, this motion should be seen as an unnecessary distraction created by Complaint Counsel which is much further along in its trial preparation, having had the benefit of the FTC staff's 2+ years of investigation into this matter.

The Complaint in this proceeding focuses on a Stipulation pendente lite, which arose out of then-ongoing patent infringement litigation brought by Hoechst Marion Roussel, Inc. ("HMR") against Andrx in federal court in the Southern District of Florida, captioned Hoechst Marion Roussel, Inc. v. Andrx Pharmaceuticals, No. 96-06121 (the "Patent Action"). The Patent Action was brought under the complex and interconnected series of statutes known as the Hatch-Waxman Act, formally, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, codified at 21 U.S.C. §355(j). The statute was enacted to coordinate patent law, drug law, and competition policy with respect to generic pharmaceuticals in the United States. In the context of that statutory and regulatory scheme, the Stipulation was lawful and procompetitive in both purpose and effect. Reviewing the very Stipulation and very conduct at issue here, the Federal District Court for the District of Columbia held that, pursuant to the applicable statutory and regulatory scheme, Andrx's conduct was "permit[ted]" and "protect[ed]." Andrx v. Friedman, 83 F.Supp.2d 179, 185-186 (D.D.C. 2000). The Stipulation served to advance competition, not hinder it.

In challenging a Stipulation that terminated a year ago, Complaint Counsel presses a Complaint short on specifics. Nowhere, for example, does (nor can) Complaint Counsel describe how consumers were harmed as a result of respondents' conduct. Nor does (or can) Complaint Counsel identify a single competitor excluded from or delayed in entering the market by the Stipulation. Tellingly, the Complaint does not allege that the Stipulation actually restrained trade; rather, it alleges that the Stipulation had the "tendency or capacity" to do so (Cmplt., ¶ 29) -- whatever that means. That, however, fundamentally misstates Complaint Counsel's burden, which is not to demonstrate that respondents' conduct merely had a theoretical "tendency or capacity" or "was likely" to

restrain trade but that it, in fact, had a concrete anticompetitive effect -- a showing Complaint Counsel cannot make, and fails even to plead that it can.

This is a tribunal sophisticated and informed about the relevant antitrust jurisprudence and practice. This, therefore, is not a case in which Complaint Counsel can rely on snippets or soundbites to gloss over the absence of any injury whatsoever to either consumers or to competition. Andrx is also entitled to rely on this tribunal to protect it against abuses by the government in bringing baseless claims -- the defense of which is requiring Andrx to expend substantial sums, which benefits an alleged competitor that the FTC staff, for wholly illegitimate reasons, has decided to prefer.

Complaint Counsel claims it wants to get to the heart of the matter. So does Andrx. To that end, it is critical to examine how Andrx came to be named as a respondent when it did what Congress under the Hatch-Waxman Act granted it a right to do and when -- after two and a half years of investigation -- the FTC cannot identify a single consumer harmed. We intend to prove at the trial of this action that Andrx finds itself here because of a gross perversion in the FTC process initiated by a company, Biovail Corporation International ("Biovail"), who claims to be a competitor. Biovail first co-opted the former Senior Deputy Director of the Bureau of Competition, hiring George Cary as its outside counsel to petition his former colleagues at the FTC at a time when doing so violated federal statutes, FTC regulations, and common sense notions of conflict of interest. See 18 U.S.C. §207; 16 C.F.R. 4.1. Biovail then coupled that improper engagement with improper dealings with members of the FTC staff. Together with its outside counsel and public relations consultants, Biovail impermissibly influenced the purportedly non-public FTC investigation as well as orchestrated a publicity campaign and a series of private lawsuits against Andrx and HMR.

As part of the effort to assist the former Senior Deputy Director and his client, various members of the FTC staff engaged in numerous leaks of confidential information to Biovail, into the public domain, and elsewhere during the investigation concerning the Stipulation. These leaks were in clear violation of the FTC's rules and procedures. The leaks created an atmosphere in which the Commission concededly felt compelled to file charges. Indeed, Robert J. Pitofsky, the Chairman of the FTC, advised Andrx that the FTC had to act because of the extensive publicity generated about the Stipulation. We intend to prove that, since the FTC staff along with Biovail, by way of improper leaks and other misconduct, improperly created that very publicity, there was no legitimate basis for the bringing of this action.

By its motion, Complaint Counsel seeks to immunize from attack many of the deficiencies in its case. Specifically, Complaint Counsel seeks an Order striking the following of Andrx's affirmative defenses: numbers 2, 7, 8, 12, 14, 15, 17, 18, and 19. Falling essentially into five categories, these defenses are all valid and properly pleaded.

First, Andrx asserts, as an affirmative defense, that its activities with respect to entering and implementing the Stipulation were authorized by federal statute and regulation. See Andrx's Aff. Defenses, Nos. 2, 14. At the end of its brief, Complaint Counsel contends that the overall statutory and regulatory framework "has no bearing whatsoever on the legality of respondents' conduct" (Moving Mem. at 9). That remarkable assertion is wrong. The legal context that Complaint Counsel seeks to ignore is essential for understanding that the Stipulation and Andrx's conduct were lawful and procompetitive. Specifically, two statutory schemes are directly relevant to determining the propriety of the conduct here. The first involves the patent laws, which protected HMR by granting it a lawful monopoly over its brand drug. The HMR patents by law are

presumed valid, and no court ever found otherwise. Pending a determination as to the scope and validity of the HMR patents, neither Andrx nor any other competitor had a legal basis to market a generic version of the HMR product. The second aspect of the relevant legal context involves the Hatch-Waxman Act, which protected Andrx by permitting it to defer marketing its generic product until it had an opportunity to adjudicate the patent issues.

Second, Andrx asserts an affirmative defense predicated on its conduct in vigorously prosecuting the Patent Action. Only after the court in that action refused to resolve the patent issues, discovery issues, and even scheduling issues, Andrx entered into the Stipulation as an equivalent to a stipulated preliminary injunction. See Andrx's Aff. Defense, No. 15. The defense pertaining to the Patent Action is not only proper but critical. The activities of the parties in pressing to resolve the Patent Action, both judicially and through Andrx's reformulating its product, demonstrate that the Stipulation did not have any anticompetitive design or effect. In addition, the Stipulation was incidental to the litigation and, as such, constitutes protected conduct immune from antitrust liability. The Stipulation was the equivalent of a preliminary injunction and, therefore, does not give rise to antitrust liability because it duplicates what a court otherwise predictably would have done. It resolved preliminary injunction issues voluntarily -- which is consistent with the public policy of encouraging settlement.

Third, Andrx asserts affirmative defenses challenging the determination, as required under §5 of the FTC Act, 15 U.S.C. §45(b), that this action is "to the interest of the public" and that "reason to believe" exists that respondents' conduct violated the antitrust laws. See Andrx Aff. Defenses, Nos 7,8,18-19. Complaint Counsel seeks to insulate that determination from review, arguing that "[t]his is not the forum" to

"question the integrity" of the FTC process (Moving Mem. at 5). But if not here, then where? If not now, when? The law does not treat the FTC's decision making in this regard as unreviewable. Indeed, there is no other appropriate forum, and Complaint Counsel does not offer any other, to scrutinize the procedure and merits of the FTC's determination. Nor is this simply a matter of Andrx questioning the FTC's exercise of discretion. To the contrary, there is hard evidence that the FTC staff engaged in improper dealings with Biovail and repeatedly leaked confidential information into the public domain during a supposedly non-public investigation concerning the Stipulation. It was the FTC staff itself that thereby improperly created the very environment that the Chairman of the FTC believed made it necessary for the FTC to take action.

Fourth, Andrx asserts an affirmative defense challenging this proceeding because it constitutes selective enforcement of the antitrust laws. See Andrx's Aff. Defense, No. 12. Complaint Counsel resorts to arguing that it has unfettered discretion in picking its targets. The law, however, is otherwise, prohibiting the FTC from acting arbitrarily and discriminatorily. In any event, this is not a situation where Andrx simply is claiming that it was singled out among a host of wrongdoers. Rather, Andrx will demonstrate that the ancillary provisions of the Stipulation being challenged by Complaint Counsel are commonplace in the industry and, when understood in light of the business environment and governing statutory and regulatory framework, were procompetitive and beneficial to consumers. Particularly where, as here, conduct is subject to a "rule of reason" analysis, evidence of industry practices and other deals is essential to assessing the competitive nature of the conduct.

Fifth, Andrx asserts an affirmative defense challenging the FTC's conduct on the grounds of laches, waiver, and unclean hands. See Andrx's Aff. Defense, No. 17.

Such "equitable" defenses are properly pleaded against the FTC, amply supported by the allegations, and surely are relevant to the equitable relief being sought by Complaint Counsel. For example, having investigated the Stipulation when it was signed in 1997, the FTC knowingly delayed challenging the Stipulation until after the Patent Action was settled and dismissed, at a time when it was too late for the judge in the Patent Action to approve or consider it. Yet with exquisite unfairness, the FTC now claims the Stipulation is improper because it was never brought to the court's attention in the Patent Action. In addition, the equitable-type defenses also arise from the FTC's conduct in, among other things, approving or condoning other business deals similar to the Stipulation, creating adverse publicity about the Stipulation by leaking confidential information, and engaging in improper dealings with Biovail during the investigation.

Complaint Counsel seeks to avoid having to address the merits of Andrx's affirmative defenses, and argues -- incorrectly -- that the defenses risk leading to a "fishing expedition" during discovery. That tired complaint is just a smoke-screen to conceal the serious deficiencies in Complaint Counsel's case, including improprieties within the FTC. Andrx already possesses documents and other credible evidence substantiating its defenses, and it sought to present, as part of this motion, that evidence to the Court. Much of the evidence, however, was not included -- shockingly -- in the documents produced by the FTC in this case but by third parties in other actions subject to confidentiality restrictions. The claims of confidentiality for these documents are bogus, but Andrx is scrupulously abiding by the terms of the restrictions in opposing this motion.

BACKGROUND

In brief, the gravamen of Complaint Counsel's case is that the Stipulation may have had the potential or capacity to restrain trade because, according to the theory, there was a delay in Andrx's marketing of its generic product. Given the statutory and regulatory framework, there are only two possible means by which that might have occurred: first, if Andrx itself remained out of the market because of the Stipulation; or second, if others were kept out by it. Thus, at the very least, Complaint Counsel will need to prove that Andrx would have marketed sooner but for the Stipulation or that the Stipulation precluded others from entering the market. Complaint Counsel will not be able to show either of those effects. On the very first page of its brief on this motion Complaint Counsel is sensitive to this vulnerability and asserts incorrectly that "[t]he purpose of the proceeding is to determine whether Respondents' conduct . . . was likely to restrain significant competition" (Moving Mem. at 1). That is an insufficient basis for finding antitrust liability.

A. The Parties

HMR manufactures and markets Cardizem® CD, a widely-prescribed drug taken once daily for treatment of hypertension and angina. Andrx was the first to obtain FDA approval to market a generic version of the drug. HMR holds certain patent rights covering Cardizem® CD. To this day those rights have never been successfully challenged. They are presumed valid under the federal patent laws. See 35 U.S.C. § 282.

B. The Federal Regulatory Scheme

The Hatch-Waxman Act authorizes generic manufacturers such as Andrx to seek regulatory approval of a generic product based on an abbreviated new drug application ("ANDA"), by which the bioequivalency of the product to the band name

version is assessed without the need for extensive clinical trials. By permitting manufacturers to rely on studies previously performed for drugs already on the market, the Hatch-Waxman Act enables relatively quicker FDA approval for generic forms of those drugs.

The Act, however, also permits brand name manufacturers such as HMR to delay regulatory approval of the generic product, if there is a belief that the generic infringes patents covering the brand name product. The Act accomplishes this by requiring a generic manufacturer filing an ANDA for a drug protected by patents to notify the patent holder and to make a "certification" concerning the patents (21 U.S.C. §355(j) (2) (A) (vii)).

The type of certification relevant to this matter is known as a "Paragraph IV" certification, in which the applicant certifies that its product will not infringe the patents covering the innovator drug or that those patents are invalid and unenforceable (§355(j) (2) (A) (vii) (IV)). The Hatch-Waxman Act expressly permits a manufacturer that receives a Paragraph IV certification to initiate a patent infringement action against the applicant.

To create an incentive for the company that first steps up to challenge a brand name manufacturer and its patents, the Hatch-Waxman Act provides the first applicant filing a Paragraph IV certification 180 days of market exclusivity, during which it is the sole authorized marketer of the generic product (§355(j) (5) (B) (iv)). This 180-day exclusivity period begins on the earlier of (1) the date of a final decision in favor of the ANDA files in the patent litigation (§355(j) (5) (B) (iv)) or (2) the date upon which the first ANDA applicant begins to market its product (such as in the case where the applicant has not been sued) (§355(j) (5) (B) (iv) (I)).

The statute thus gives the first ANDA applicant a right to 180 days of market exclusively. Critically, the statute does not *require* the applicant to go to market at any particular time (such as when the 30-month waiting period expires). Thus, as the federal court for the District of Columbia explained in analyzing the Stipulation:

> "Andrx is free to wait until the conclusion of the Florida litigation [Patent Action] before it begins to market its generic, and indeed the statute contemplates that possibility. . . . There is the possibility that Andrx would not have gone to market even absent the agreement with HMRI, and *certainly the Hatch-Waxman amendments would permit and protect that delay until the conclusion of the patent litigation.*"

Andrx v. Friedman, 83 F.Supp.2d at 184, 186.

By protecting the first ANDA applicant's right to await the conclusion of patent infringement litigation before the commencement of marketing, the Hatch-Waxman Act does no more than acknowledge the reality of the situation. Until the patent claims are disposed of, the patent holder almost certainly would be entitled to a preliminary injunction precluding the marketing of the allegedly infringing product, and the ANDA applicant would therefore be unable to enter the market whether it wished to or not. Also, given the substantial risks of marketing an infringing product, an ANDA applicant will almost certainly refrain from marketing its product until the brand name manufacturer's patent claims were resolved. As one of the sponsors of the Hatch-Waxman Act explained at the time the statute was enacted:

> "The facts of life are that a generic drug manufacturer will await, as a practical matter, until the decision of a court on a patent challenge before that manufacturer markets a generic drug. That is the information they have given us as to their practice."

130 Cong. Rec. 24,427 (1984). As another court recently noted:

> "[S]tatements by the legislation's co-authors indicate that the final bill was intended to conform to generic manufacturers' practice of

> waiting until a litigation is "resolved" or "concluded" before bringing their product to market."

Mylan Pharmaceuticals, Inc. v. Shalala, 81 F.Supp.2d 30, 40 (D.D.C. 2000); see also Andrx v. Friedman, 83 F.Supp.2d at 179.

The FDA has repeatedly confirmed this understanding of the statute:

> "[T]he 180-day reward of exclusive marketing begins when the applicant wins the lawsuit or when the applicant actually begins marketing, "whichever is earlier." *The applicant thus does not lose any of the 180-day period by electing to stay off the market until the lawsuit is over.*"

Proposed Rules: Abbreviated New Drug Applicants, 54 Fed. Reg. 28,872, 28,894 (1989) (emphasis added); see also Abbreviated New Drug Applicant Regulations: Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,352 (1994).

In the face of these clear legislative expressions, Andrx's decision to await the conclusion of the Patent Litigation before marketing its generic product was proper under the circumstances Andrx then faced.

C. Andrx's ANDA

Andrx was the first applicant to submit an ANDA for a generic form of Cardizem® CD containing a Paragraph IV certification that its product did not infringe any of the five patents then listed by HMR as covering Cardizem® CD or that those patents were invalid. In due course notice was given to HMR. As it does with other products, Andrx believed it had successfully "invented around" the five HMR patents, which were the only patents then in existence covering Cardizem® CD.

Unbeknownst to Andrx, shortly after Andrx submitted its ANDA, HMR obtained another patent covering Cardizem® CD, known as the "'584 patent". Because that patent had not been issued when Andrx submitted its ANDA, Andrx had not been able to invent around the patent.

D. The Patent Action

Within the time period specified by the Hatch-Waxman statute, HMR filed the Patent Action alleging that Andrx's product infringed the newly-issued '584 patent. As the record of the case reflects, both HMR and Andrx litigated the Patent Action vigorously. However, the parties found themselves before a court that showed no interest in the case and gave no indication that it intended to do anything to resolve the dispute or to move the case along. No fewer than five dispositive motions were pending before the court. Any of these motions would have resolved the litigation, but all went undecided. Innumerable letters and calls to the court to prompt judicial action went unanswered. The parties were so persistent that the judge's clerk advised the parties not to contact chambers any more. In over three and a half years, the parties were never allowed to see the judge once. No scheduling order was ever entered.

E. The Stipulation Pendente Lite

By statute, FDA regulatory approval for the Andrx generic had to wait until July 1998. But even being allowed to sell under the Food and Drug laws did nothing to eliminate HMR's patent infringement litigation. Indeed, Congress understood Andrx would have been irresponsible to market in the face of such litigation. We will further amplify Andrx's reasons for waiting to market at the hearing in this matter.

Andrx did not inform HMR of its position -- the sharing of that sort of competitive information no doubt would have concerned the FTC. HMR therefore advised Andrx it intended to move for a preliminary injunction in the Patent Action, so as to preclude Andrx from marketing its generic version of the HMR product until the court finally resolved the litigation. It was in that context that the parties negotiated and signed the Stipulation. The Stipulation essentially duplicated the terms of a preliminary

injunction and was the product of arms' length negotiations between two parties locked in a vigorous patent battle. The Stipulation by its terms lasted no longer than the litigation.

Providing the same remedy as a stipulated preliminary injunction, the Stipulation required the parties to maintain the status quo pending resolution of the case, notwithstanding the possible future grant of regulatory approval to Andrx's product. If Andrx ultimately won the case, HMR would pay a stipulated amount of "lost profits" for the period during which Andrx had FDA approval to market its product but did not do so because of HMR's claims of patent infringement. The Stipulation also granted Andrx the right to obtain a license from HMR to market its generic product even if Andrx lost the case or if the case was not resolved by a date certain. In addition, the Stipulation entitled Andrx to receive "interim payments" from HMR during the period after Andrx obtained FDA approval and prior to the time the infringement claims were resolved. Whether Andrx won or lost the patent case, these payments would ultimately be repaid to HMR (if Andrx lost and paid for the license) or credited to HMR (if Andrx won and HMR paid Andrx the stipulated "success payment").

These payments were procompetitive. They enabled Andrx, at the time only five years in existence and relatively cash poor, to defend itself in the Patent Action, reformulate its product, and get its generic product to market earlier (plus obtain license rights, among other things).

Although the Stipulation was executed in September 1997, it did not take effect until July 1998. The FTC concedes it had prompt notice of the Stipulation. See Complaint Counsel's Response to Aventis' First Request for Admissions (5/15/00), Response No. 26.

F. Andrx's Successful Efforts to Develop the Reformulated Product

After the parties signed the Stipulation and continued litigating the Patent Action, Andrx intensified its efforts to reformulate its product to avoid the HMR patents. These efforts were begun long before the 1997 Stipulation was executed and were pursued over the course of more than a year afterward. The efforts involved internal research, extensive regulatory submissions, and, after Andrx had largely succeeded in both of these respects, communications with HMR leading it to determine not to press its infringement claims against the reformulated product. During that same period, Andrx solved significant technical and manufacturing difficulties it was having in scaling up manufacture of its generic product -- difficulties, of course, that Andrx never told HMR about.

G. The Settlement of the Patent Action

Having studied samples, HMR determined not to sue Andrx on the reformulated product. Andrx received FDA approval to market its reformulated product in June 1999. On that same day, HMR and Andrx settled the Patent Action, the Stipulation by its terms then terminated, and Andrx brought its generic product to market.

H. Absence of Other Generic Competitors

No manufacturer other than Andrx had final FDA approval to market a generic Cardizem® CD prior to the expiration of Andrx's period of statutory exclusivity. In the Complaint, Complaint Counsel alleges that, well after Andrx filed its ANDA for generic Cardizem® CD, two other companies, Faulding, Inc. and Biovail, filed their own ANDAs for what they asserted were bioequivalent formulations of Cardizem® CD. The recent interrogatory responses from Complaint Counsel confirm that it has no basis to

assert -- and does not do so -- that either of these parties could have entered the market with a generic product prior to the end of Andrx's statutory exclusivity period -- irrespective of the Stipulation. See, e.g., Complaint Counsel's Responses to Andrx's First Set of Interrogatories (5/15/00), Response No. 15; Complaint Counsel's Response To Aventis' First Request for Admissions (5/15/00), Response Nos., 50, 59. Complaint Counsel concedes that Faulding is not relevant because it admitted that its product infringed the HMR patents. See Complaint Counsel's Response to Aventis' First Request for Admissions, Response No. 56. It therefore had no right to market its generic product.

As for Biovail, it was unable to secure even tentative FDA approval for its product on a timely basis because of medical and scientific issues surrounding its formulation. Indeed, even after Biovail finally received tentative approval in October 1999 (shortly before the end of Andrx's exclusivity period), the FDA continued to accept and consider material relating to whether or not Biovail's product was safe enough to substitute for Cardizem® CD. Biovail did not receive final marketing approval until December 23, 1999, which was *after* the expiration of Andrx's 180 days of statutory exclusivity.

This of course means that by definition the Stipulation did not delay other manufacturers from entering the market. It is for this reason that Complaint Counsel presses its hypothetical claim that, even if the Stipulation did not impede competition, it potentially might have.

I. The FTC Staff's Complicity In Biovail's Coordinated Regulatory Attacks, Litigation and Public Relations Campaign Against Andrx and HMR

With the complicity of various members of the FTC staff, Biovail, along with its outside counsel and public relations consultants, implemented a Machiavellian strategy to attack Andrx. The strategy pursued by Biovail included the improper collaboration with the FTC staff, vexatious litigation, and a self-serving public relations campaign.

To influence the FTC staff, Biovail hired the former Senior Deputy Director of the Bureau of Competition, George Cary of the Cleary, Gottlieb firm, as its outside counsel at a time when he was prohibited from dealing with the FTC on this matter. Nonetheless, Mr. Cary communicated with the FTC staff in violation of these conflict of interest restrictions. In particular, David Balto, Assistant Director of the Bureau of Competition, engaged in secret exchanges with Mr. Cary about the non-public investigation and provided confidential information to Mr. Cary. In turn, Mr. Cary used the information gained from Mr. Balto and other FTC officials in preparing, on Biovail's behalf, submissions to the FTC criticizing the Stipulation.

Such conduct on the part of Mr. Cary was in clear violation of 18 U.S.C. § 207, and 16 C.F.R. 4.1. Mr. Cary worked at the FTC until March 1998; however, he was actively involved on Biovail's behalf by January 1999.

The extent of communications between Messrs. Cary and Balto and other FTC staff members must be explored fully. Andrx calls to the Court's attention that specific documents exist in the FTC's files demonstrating the leaking of non-public information about the investigation. In this way, government officials secretly collaborated with Biovail, a private party, in developing the very arguments then relied

on by the government officials to claim unlawful conduct on the part of respondents. Then, the government officials sought to cover up these dealings. Indeed, after Andrx expressed outrage at the leaks of confidential information about the investigation, senior staff at the FTC made reckless denials about the sources of the leaks. See Letter, dated January 13, 2000, from Richard A. Feinstein to Louis M. Solomon.[1]

J. Further Improprieties In The Commission's Investigations

The FTC staff, by the Health Care Division of the Bureau of Competition, first investigated the Stipulation in 1997, in connection with its review of a planned acquisition by one of Andrx's shareholders, Watson Pharmaceuticals, Inc., of The Rugby Group, Inc., File No. 981-0006. The FTC resolution authorizing process specifically stated the investigation related to, among other things, "any stipulation or agreement between [HMR] and Andrx." In the course of that investigation, Andrx cooperated fully with the Bureau Staff and provided substantial volumes of material relating to the Patent Action and the Stipulation. Andrx fully explained the Stipulation, including voluntarily appearing for interviews. Having fully investigated the matter, in 1998 the FTC advised Andrx that the matter was closed. The FTC never raised any issue concerning the Stipulation, never advised Andrx that it believed that that there was anything wrong with the Stipulation, and never suggested that Andrx should seek the court's approval or consideration of the Stipulation in the Patent Action.

The same Health Care Division then recommenced its investigation in October 1998, this time after the importunings of Biovail and its counsel. That

[1] In addition to its own misconduct, Biovail instigated a number of class actions, purportedly brought on behalf of consumers, retailers and/or wholesalers, against Andrx and HMR. Biovail actively searched for cooperative counsel to bring the class actions and was the source of information for developing the pleadings in those actions. Biovail also retained the public relations firm of Sitrick & Company, which has engaged is

investigation again focused on the dealings between HMR and Andrx, including the Patent Action and the Stipulation. During this phase, the FTC staff acted in violation of the FTC's rules and procedures in a number of instances. In addition to the communications between Mr. Cary and Mr. Balto, there were a number of leaks of confidential information into the public domain. For example:

- On December 10, 1998 -- well over a year before the Commission issued the complaint in this action -- the Wall Street Journal reported that the FTC is "investigating charges that Hoechst AG engaged in anti-competitive behavior center[ing] on an agreement between Germany's Hoechst and a small U.S. drug company, Andrx Corp., that is allegedly shielding one of the Hoechst's biggest sellers, heart drug Cardizem CD, from generic competitors, and, in effect, fixing prices. As for the source of its information, the Journal pointed to "people familiar with the investigation."

- On September 30, 1999 -- over five and a half months before the Commission issued the complaint in this matter -- USA Today reported that "Federal antitrust enforcers plan to recommend an antitrust lawsuit against brand-name drugmaker Hoechst Marion Roussel." The article also quoted George Cary, former Deputy Director of the FTC's Bureau of Competition, who commented on the likelihood that the Commission would take action against HMR and Andrx.

- On October 10, 1999 -- over five months before the Commission issued the complaint in this matter -- the German periodical Die Welt [extract] reported that "[t]he U.S.A.'s anti-trust authority is considering legal action against Hoechst and Andrx Corp., a U.S. pharmaceuticals group, due to illegal price agreements for Hoechst's heart drug, Cardizem." The article then elaborated: "According to the U.S. Federal Trade Commission, both

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ongoing efforts to persuade news organizations to feature stories critical of the

groups reached an agreement which was aimed at keeping the price of the drug artificially high. The anti-trust authority claims that Hoechst's annual payments of $100 million dollars to Andrx violate U.S. competition laws. In return for the payments, Andrx, a specialist in generic drugs, guarantees the Frankfurt-based group that it will not start producing a generic drug for Cardizem." (emphasis supplied)

- On or about December 17, 1999 -- some three months before the Commission issued the complaint in this matter -- David Balto, the Director of Policy and Planning for the Bureau of Competition, gave a speech to the Food and Drug Law Institute Educational Conference in which he commented on the Commission's ongoing investigation of the HMR/Andrx Stipulation. Shortly after that speech, Andrx representatives received several inquiries from reporters seeking comment on Balto's disclosures. When Andrx subsequently requested from the Commission a copy of Balto's speech, that request was denied on the grounds that the speech discussed ongoing, nonpublic investigations.

- On January 7, 2000 -- more than two months before the Commission issued the complaint in this matter -- Bloomberg News reported that Commission staff lawyers were recommending suit against Abbott Laboratories and were also considering recommending suit against HMR and Andrx.

- On or about March 10, 2000 – at least five days before the Commission could have lawfully voted on the staff's recommendation to commence this proceeding -- Andrx began receiving press inquiries from reporters concerning what they characterized as the Commission's decision to sue Andrx. When asked for her sources, one reported responded that if she revealed her sources among the ranks of the FTC's legal staff, they would disappear.

Stipulation.

- On March 15, 2000, ABC News announced that "Tomorrow at 1:00 p.m. the FTC will announce" that it had authorized an action against HMR and Andrx," although Andrx was again informed that no vote by the Commission had yet taken place.

In discussions with the FTC prior to the filing of the Complaint in this proceeding, Chairman Pitofsky advised Andrx's counsel that the FTC felt compelled to bring an action because of the substantial publicity surrounding the Stipulation. That very publicity, however, was the result of leaks from the FTC's purportedly non-public investigation, which violated the FTC's own rules, and also Biovail's public relations campaign, which made use of confidential information ascertained from Mr. Balto and other FTC staff members.

ARGUMENT

I.

UNDER THE APPLICABLE LEGAL STANDARD, COMPLAINT COUNSEL'S MOTION TO STRIKE SHOULD BE DENIED

As Complaint Counsel acknowledges, "the Federal Trade Commission's Rules of Practice are silent on the subject of motions to strike affirmative defenses" (Moving Mem. at 2). Complaint Counsel itself then cites to cases making clear that motions to strike affirmative defenses are "generally disfavored," Dura Lube Corp., 2000 F.T.C. LEXIS 1, 34 (Jan. 14, 2000) (Chappell, ALJ) (denying Complaint Counsel's motion to strike in its entirety), and are considered to be a "drastic remedy." United States v. Walerko Tool & Engineering Corp., 784 F. Supp. 1385, 1387 (N.D. Ind. 1992) (denying, in its entirety, government's motion to strike equitable defenses).

The standard to be applied in resolving a motion to strike reflects the motion's "disfavored" status. Grant of such a motion is proper only where the defense

"cannot succeed under any set of circumstances. . . [H]owever, where there is any question of fact or any substantial question of law, the Court should refrain from acting until some later time when these issues can be more appropriately dealt with." Walerko Tool, 784 F. Supp. at 1387 (emphasis added); see also Dura Lube, 2000 F.T.C. LEXIS at *32-33 (affirmative defenses should stand unless they are "obviously irrelevant or immaterial or are clearly invalid as a matter of law").

As this Court previously stated in denying a motion to strike, "a motion to strike defenses . . . will be granted only when the answer or defense (1) is unmistakably unrelated or so immaterial as to have no bearing on the issues and (2) prejudices Complaint Counsel by threatening an undue broadening of the issues or by imposing a burden on Complaint Counsel." Dura Lube Corp., 2000 F.T.C. LEXIS 1, at *34 (emphasis added). Complaint Counsel does not and cannot establish either prong, let alone both.

Here, each of Andrx's affirmative defenses is properly pleaded and well-grounded. Complaint Counsel has not met its heavy burden to strike any of Andrx's affirmative defenses.

II.

ANDRX'S "OTHER DEFENSES" ARE RELEVANT AND MATERIAL AND SHOULD NOT BE STRICKEN [Aff. Def. Nos. 2, 14]

Complaint Counsel buries the most remarkable portion of its motion at the end, where it challenges Andrx's "other defenses" relating to the statutory and regulatory scheme governing Andrx's conduct. In an extraordinary statement, Complaint Counsel asserts:

> "Whether or not respondents' conduct is consistent or inconsistent with some other federal law or regulation has no bearing

> whatsoever on the legality of respondents' conduct under Section 5 of the FTC Act."

(Moving Mem. at 9.) What Complaint Counsel seeks to do is gut one of respondents' most important defenses to this proceeding. In the context of the applicable statutory structure, the Stipulation served pro-competitive purposes and had the effect of actually facilitating the bringing of a generic product to market.

The legal structure critical to understanding the operation of the Stipulation includes the patent laws, the Hatch-Waxman Act, and the related regulations. As protected intellectual property, Cardizem® CD is different from other products. Under the patent laws, the HMR patents covering Cardizem® CD were presumed valid (35 U.S.C. § 282); indeed, despite 3½ years of litigation between Andrx and HMR and 2½ years of litigation between Faulding and HMR, no court ever determined otherwise. In turn, the HMR patents restricted the ability of Andrx, as well as any other potential generic competitor, to market a generic version of Cardizem® CD.

The Stipulation is not a creature of just the patent laws in isolation but of the intersection of the patent laws and the Hatch-Waxman Act. In recognition that a generic manufacturer, given the risks of bringing an infringing product to market, will not do so in the face of patent litigation, Hatch-Waxman does not require a generic manufacturer to market at any particular time. Indeed, the statute, applicable regulations, and case law provide that the generic with the first FDA approval does not forego its statutory exclusivity period by deferring the marketing of its product pending an opportunity to have the patent issues adjudicated.

At the trial of this matter we are entitled to show that the hypothetical effect that Complaint Counsel is concerned about -- a delay in entry of generic

competition -- came about and is protected by the statutory scheme, not Andrx's behavior. As Judge Penn determined, in ruling that Biovail could not state a claim against Andrx under the antitrust laws, Andrx was legally entitled not to market its product until the end of the patent litigation; that Andrx was not responsible for the fact that the statutory and regulatory scheme might preclude other manufacturers from marketing their products during Andrx's period of 180 days of market exclusivity; and that the Hatch-Waxman Act "permits" and "protects" Andrx's behavior. Andrx v. Friedman, 83 F.Supp.2d at 186. Because "[t]he statutory scheme precluded competition without the requisite regulatory permission", Complaint Counsel's claims -- that entry was delayed by the Stipulation -- are deficient and should be dismissed. City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 268 (3d Cir. 1998) (affirming dismissal of antitrust claims); see also Axis, S.p.A. v. Micafil, Inc., 870 F.2d 1105, 1107 (6th Cir.), *cert. denied*, 493 U.S. 823 (1989) ("The Possis and Globe patents, not the purchase of Mechaneer, foreclosed [plaintiff's] entry into the market"); United States v. Westinghouse Electric Corp., 648 F.2d 642, 649 (9th Cir. 1981) ("this is an effect which results from the monopoly granted by the patent laws and does not establish an antitrust violation"); B. Braun Medical, Inc. v. Abbott Laboratories, Inc., 124 F.3d 1419, 1428 n.4 (Fed. Cir. 1997) ("By virtue of its patent rights . . ., Braun has the right to exclude competition altogether in each of these markets. Therefore, the restricted sale does not constitute a per se illegal horizontal restraint.").[2]

[2] See also Indium Corp. v. Semi-Alloys, Inc., 781 F.2d 879, 882 (Fed. Cir. 1985) (judgment properly granted to defendant where plaintiff competitor could not have entered market regardless of defendants' behavior), *cert. denied*, 479 U.S. 820 (1986); Schuylkill Energy Resources, Inc. v. Pennsylvania Power & Light Co., 113 F.3d 405, 414-17 (3d Cir.) (affirming dismissal of antitrust claim on grounds that the relevant regulatory law, not defendant's conduct, prevented plaintiff from competing with defendant), *cert. denied*, 522 U.S. 977 (1997); United States v. Studiengesellschaft

Although consideration of the statutory and regulatory framework governing generic pharmaceuticals, including the patent laws and Hatch-Waxman, are essential to assessing why the Stipulation was proper, lawful, and procompetitive. Complaint Counsel's effort to preclude this consideration should be rejected.

III.

THERE IS NO BASIS TO STRIKE THE DEFENSES PERTAINING TO ANDRX'S ACTIVITIES IN THE PATENT ACTION [Aff. Def. No. 15]

Complaint Counsel seeks to strike defenses predicated on the activities in the Patent Action, including that Andrx acted in good faith to litigate the patent claims and acted consistently with the public policy in favor of encouraging private settlements. The Stipulation was incidental to the Patent Litigation, the significance of which ought not to be ignored. This part of the motion fails for at least two reasons:

First, Complaint Counsel does not deny that the parties vigorously litigated the Patent Action. See Complaint Counsel's Responses to Andrx's First Set of Interrogatories (5/15/00), Response No. 20. It is uncontested that the parties diligently sought to resolve the case; it certainly was no sham. In the event the Patent Action was concluded, the Stipulation by its terms also would end. The conduct of the parties in pressing for a disposition of the action is therefore relevant in showing the Stipulation was not serving any sinister purpose. Until the patent issues were resolved, Andrx's generic product potentially infringed HMR's patents, and it was reasonable in such circumstances for Andrx to remain out of the market.

Kohle, m.b.H., 670 F.2d 1122, 1131 (D.C. Cir. 1981) (noting lack of authority finding antitrust violation where only restraint on competition was "imposed by the patent itself or by exercise of legal rights corollary to those created by the patent").

Second, Complaint Counsel acknowledges the public policy in favor of private settlements (Moving Mem. at 8). The Stipulation, fairly characterized, was equivalent to a stipulated preliminary injunction, allowing the parties to bypass the time, expense, and risks of having to litigate a preliminary injunction application. As such, it is protected from antitrust scrutiny under the *Noerr-Pennington* doctrine. See Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc. 365 U.S. 127 (1961); United Mine Workers v. Pennington, 381 U.S. 657 (1965). For example, if HMR obtained a preliminary injunction, it would have needed to post a bond to cover the damages it might later be required to pay to Andrx and been required to make interim payments to Andrx. See, e.g., United States v. Bedford Associates, 618 F.2d 904, 919-20 (2d Cir. 1980); CBS, Inc. v. ASCAP, 320 F.Supp. 389, 392 (S.D.N.Y. 1970); United States v. Price, 688 F.2d 204, 212-13 (3d Cir. 1982). Under the Stipulation, HMR made interim payments directly to Andrx in lieu of obtaining, and paying for, a bond. If Andrx won the patent case, the interim payments would be credited against the $100 million per year "success payment" from HMR. And if Andrx lost the litigation, the interim payments would be used to pay for a license.

The Stipulation was a proper settlement of the preliminary injunction aspect of the patent dispute. As is well-settled, settlement of disputed patent litigation alone cannot violate the antitrust laws. See, e.g., Duplan Corp. v. Deering Milliken, Inc., 540 F.2d 1215, 1220 (4th Cir. 1976); Procter & Gamble Co. v. Paragon Trade Brands, Inc., 61 F.Supp.2d 102, 108 (D. Del. 1996); Polo Fashions, Inc. v. Fashion Associates, Inc., 1986 WL 1176. *3 (S.D.N.Y. 1986). "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." Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir.), *cert. denied*, 429 U.S. 862 (1976).

IV.

ANDRX'S CHALLENGE TO THE COMMISSION'S "PUBLIC INTEREST" DETERMINATION IS GROUNDED IN VENERABLE SUPREME COURT JURISPRUDENCE AND THE COMMISSION'S OWN PRECEDENTS [Aff. Def. Nos. 7-8, 18-19]

Under Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), two of the elements that are essential for any Commission proceeding are (1) that "reason to believe" exists that the defendants have violated the law; and (2) that a proceeding "would be to the interest of the public". Although Complaint Counsel argues the FTC has unfettered discretion whether to commence enforcement proceedings, the case law is to the contrary and holds that decisions about "public interest" and "reason to believe" are subject to review. See Federal Trade Commission v. Klesner, 280 U.S. 19 (1929) (Brandeis, J.); Moretrench v. Federal Trade Commission, 127 F.2d 792, 795 (2d Cir. 1942) (Hand, J.) (The Supreme Court in Klesner "did indeed decide that the public interest in the controversy was a justiciable issue"); Block Drug Company, Inc., 1976 FTC LEXIS 552 (February 6, 1976) *5 ("As a matter of proper pleading, respondents should not be denied the opportunity of demonstrating the lack of public interest"); American Family Publishers, Inc., 1991 FTC LEXIS 177 *1 (May 6, 1991) (denying motion to strike affirmative defense "pertaining to the alleged lack of public interest in the prosecution of this Complaint").

In Klesner, the FTC concluded that respondent had engaged in an "unfair method of competition" and issued a cease and desist order against him. Klesner, 280 U.S. at 23. The United States Supreme Court vacated the cease and desist order, holding

that the complaint was improper and exceeded the lawful scope of the Commission's authority:

> "While the Federal Trade Commission exercises under § 5 the functions of both prosecutor and judge, the scope of its authority is strictly limited. A complaint may be filed only 'if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public' . . . . [T]he Commission's action in authorizing the filing of a complaint, like its action in making an order thereon, is subject to judicial review. The specific facts established may show, as a matter of law, that the proceeding which it authorized is not in the public interest, within the meaning of the Act. If this appears at any time during the course of the proceeding before it, the Commission should dismiss the complaint. If, instead, the Commission enters an order, and later brings suit to enforce it, the court should, without enquiry into the merits, dismiss the suit."

Id. at 27, 30 (emphasis supplied).

Consistent with the holding in Klesner, the Commission has observed that, in appropriate circumstances, the determination as to whether an enforcement proceeding "would be to the interest of the public" is subject to challenge. See e.g. Boise Cascade, 97 F.T.C. 246 n. 3 (March 27, 1981) (approving review of the "reason to believe and public interest determinations"); TRW, Inc., 88 F.T.C. 544 (October 13, 1976) (recognizing that "the Commission will review its determinations that it has reason to believe . . . that a proceeding would be in the public interest"); Pepsico, Inc., 83 F.T.C. 1716 (May 14, 1974) (same). Indeed, the Commission has dismissed complaints on this very basis. See, e.g., Wildroot Co, Inc., Docket No. 5928 (June 30, 1953); Denver Chemical Mfgr. Co., Docket No. 5755 (March 25, 1954); Metal Lath Mfgrs. Ass'n, Docket No. 5449 (1954). Were this not the case, and "the basic issue of public interest can be removed from the hearing table and determined by the Commission, as plaintiff instead of judge, upon the basis of information contained in secret files, so can any other

issue." Florida Citrus Mutual, 50 F.T.C. 959 (May 10, 1954) (Chairman Howery, dissenting).

In arguing otherwise, Complaint Counsel ignores all of the above authority and instead relies on a long quote from Exxon Corporation, 83 F.T.C. 1759 (June 4, 1974). Not only is the decision wholly inapposite but it does not even purport to take issue with the well-settled jurisprudence approving review of public interest determinations. The particular question presented in Exxon was whether the FTC investigation was "prompted" by "communications received by [the FTC] from any member of Congress"; in its ruling, the court found that nothing about the congressional communications were "remotely of the character deemed improper by the courts." Id. at *1. Beyond that, the decision contained no discussion of the factual circumstances pleaded by respondents; it therefore bears no relevance to the sufficiency of Andrx's allegations. Even, however, Complaint Counsel's own cases find that, at the very least in "extraordinary circumstances" the Commission will "review its reason to believe any public interest determination." Boise Cascade Corp., 97 F.T.C. 246 (March 27, 1981) *2 n. 3. Unlike in Boise Cascade, where "[r]espondent . . . made no showing" (id.) of appropriate circumstances, here Andrx does.[3]

Andrx's allegations establish circumstances that, if proven, would demonstrate that the Commission acted improperly and in excess of its statutory authority by bringing this action. Prompted by, and surely with assistance and encouragement from, Biovail, FTC staff members collaborated with complaining witness to fashion the

[3] The other decisions cited by Complaint Counsel are similarly irrelevant to Andrx's defenses. E.g., Synchronal Grp., 1992 FTC LEXIS 61 (March 5, 1992) (no reference even to public interest defense); Metagenics, Inc., 1995 FTC LEXIS 2 (January 5, 1995) (no discussion of circumstances).

very claim later relied upon by the staff. This constitutes a gross abuse of governmental power and is unconstitutional. Then, to make matters worse, staff members leaked details of its investigation -- details which, according to the FTC Act and the Commission's own policy manual, were supposed to remain confidential.

Andrx contends that Biovail -- through its well-connected counsel -- fostered these leaks so that the Commission would be forced, due to excessive publicity, to commence this enforcement proceeding. Biovail's strategy was effective. On February 18, 2000, Federal Trade Commission Chairman Robert Pitofsky stated that, given the public's awareness of the Commission's investigation, a decision not to proceed against Andrx "would send the wrong signal." The significance of Chairman Pitofsky's statement is unmistakable: because of the excess publicity, the Commission was forced to commence a proceeding to justify the protracted and high profile investigation.

In an attempt to escape from the embarrassing revelation of serious improprieties, Complaint Counsel argues that "[t]his is not the forum for respondents to . . . call[ ] into question the integrity of the Commission's mental deliberations and procedures" (Moving Mem. at 5). Contrary to what Complaint Counsel argues, this is the proper forum, and the issue of the integrity of the internal FTC process directly relates to whether a proper basis existed for bringing the charges. Indeed, there is no other appropriate forum to explore the issue. If, as Chairman Pitofsky acknowledged, the FTC concluded that the publicity surrounding its non-public investigation of the Stipulation is what made the case satisfy the "to the public interest" element, the basis for the publicity is put at issue - - and the basis was leaks and other misconduct on the part of the FTC and Biovail. Likewise, insofar as Biovail exerted improper influence on the FTC process, by

having its outside counsel communicate with FTC staff in disregard of conflict of interest restrictions and make submissions based on leaks from the FTC, the basis of the case is subject to challenge.

The important role of an ALJ in an administrative proceeding to scrutinize the integrity of the agency process was recognized in State of North Carolina Policy Institute v. E.P.A., 881 F.2d 1250 (4th Cir. 1989), which involved claims that "alleged ex parte communications between EPA officials and certain 'interested parties' . . . might [have] tainted" the process. Id. at 1253-54. The court expressed the view that "the means and the obligation to protect against the possibility of taint by ex parte communications are . . . present in the ongoing administrative proceeding" before the ALJ. The Fourth Circuit approved the ALJ's order to the "EPA to disclose all alleged ex parte communications" and his "indicat[ion] that if the material disclosed suggested that a broader inquiry were warranted, he would order an evidentiary hearing." Id. at 1258.

Not wanting to reveal the perversions of the FTC process, Complaint Counsel argues that Andrx's affirmative defenses "could lead to discovery that would substantially burdened burden and prejudice complaint counsel". Without any basis, Complaint Counsel raises the hypothetical spectre that

> "[o]pening up the Commission's non-public and highly confidential investigatory files for respondents' 'fishing expedition' could compromise the integrity of the FTC investigative process and may have a 'chilling' effect on third-parties' willingness to provide confidential information in the future."

(Moving Men. at 6.) It is the height of hypocrisy for Complaint Counsel to express concern for the "integrity" of the investigation at issue here, given the numerous leaks and other misconduct that, to Andrx's prejudice, has been characteristic of the investigation. Beyond that, there is no merit to Complaint Counsel's claims about

unnecessarily "opening up" discovery. The discovery pertaining to the FTC staff's improprieties and violations of rules is directly relevant and material to assessing the basis for bringing the charges. In any event, Complaint Counsel does not and cannot make any concrete showing as to hardship or prejudice with respect to any anticipated discovery. Not only is the discovery issue pure conjecture, but the appropriate means for dealing with abusive or improper discovery is not to strike allegations or defenses. Rather, the procedural rules govern objections to discovery and the methodology for handling discovery disputes.

Because Andrx's challenge to the Commission's "public interest" determination is well-grounded in both Supreme Court jurisprudence and Commission precedent, and because striking Andrx's affirmative defenses at this preliminary stage of the proceeding would preclude Andrx from developing an appropriate administrative record, Andrx's public interest defenses should be permitted to stand.[4]

V.

ANDRX'S DEFENSE OF DISCRIMINATORY ENFORCEMENT IS WELL-GROUNDED IN BOTH FACT AND LAW [Aff. Def. No. 12]

Complaint Counsel seek to strike Andrx's Twelfth Defense, namely, that the FTC is "acting unlawful and arbitrarily in attempting to single out Andrx for challenge with respect to . . . commonplace provisions" such as the ancillary provisions

[4] In a footnote (Moving Mem. at 3 n.3), Complaint Counsel argues that the fact that the Stipulation "is over" is irrelevant to its public interest analysis. However, Complaint Counsel's own cases hold otherwise. E.g., The Kroger Company, 1977 F.T.C. LEXIS 70 at *3 (Oct. 18, 1977) (the defense of "discontinuance" of the "challenged conduct . . . may nevertheless be relevant to the nature and scope of the remedy in this proceeding, and for this reason should not be stricken"). Another case cited by Complaint Counsel merely states that the cessation of conduct "did not render the controversy moot", not that the issue was irrelevant to the action. FTC v. Goodyear Tire & Rubber Co., 304 U.S. 257, 260 (1938).

of the Stipulation. Complaint Counsel misapprehends the law on the affirmative defense of "discriminatory prosecution".

Andrx's defense does not simply assert that the FTC has singled it out for prosecution under Section 5. Andrx believes that the Stipulation, the existence of which forms the basis of the FTC's complaint, is not anticompetitive in the context of the statutory structure and commonplace practices in the pharmaceutical industry. That is, these agreements are in fact procompetitive when viewed in the totality of circumstances. Furthermore, Andrx believes that the FTC knows that such provisions are widely used in the industry, and that there are numerous other "deals" with similar provisions, which the FTC either specifically approved or does not plan to challenge.[5] Thus, Andrx is not asserting that the FTC should have proceeded on an "industry-wide" scale (as was the basis of the decision for denying judicial review – not the question here -- of a cease and desist order) in Moog Industries v. FTC, 355 U.S. 411 (1958), upon which the Commission places much emphasis), but rather, that the challenged provisions of the Stipulation are of the type regularly used in the industry and necessary to achieve the procompetitive benefits that Congress intended with respect to the generic drug industry. Particularly in situations, such as here, where a rule of reason analysis is being applied, industry-wide practices are necessary to understand and, therefore, essentially the same discovery regarding general practices would occur even absent the affirmative defense.

[5] For example, as stated in Andrx's Answer, there is a March 31, 1998 agreement between Abbott Laboratories and Zenith Goldline Pharmaceuticals, with very the same provisions as Complaint Counsel challenges in the Andrx/HMR Stipulation. The Commission has publicly indicated that it will take no action against the Zenith Goldline agreement. Moreover, Complaint Counsel's self-serving assertion that the allegation "the Commission arbitrarily singled out Andrx is also inconsistent with the facts" (Moving Mem. at 5 n.5) requires discovery to assess – we obviously dispute it.

To put the Stipulation in the context of accepted industry practices, Andrx will prove that Biovail, among other entities, has participated in the same sort of transactions. Yet, Biovail -- represented by the former Deputy Director of the Bureau of Competition -- is not prosecuted, only respondents.

The FTC's discretion in proceeding against one competitor is "not unlimited and may be 'overturned . . . [for] a patent abuse of discretion.'" Encyclopaedia Britannica, Inc. v. FTC, 605 F.2d 964, 974 (7th Cir. 1979) (quoting Moog Industries, *supra*), cert. denied, 445 U.S. 934 (1980). Furthermore,

> "If the Commission elects to litigate against similarly situated competitors, for example, it cannot place one competitor at a competitive disadvantage by arbitrarily treating one violator different from another. Encyclopaedia Britannica at 974; see also Garrett v. FCC, 513 F.2d 1056 (D.C.Cir. 1975)."

In Ford Motor Co. v. FTC, 547 F.2d 954 (6th Cir. 1976), the court held that "[t]he Commission's obligation to protect the public interest carries with it a concomitant responsibility to regulate similarly situated competitors in the same industry in a fair, equal and even-handed manner. Id. at 958. Andrx is entitled to prove that the Commission has clearly failed to do that in this case.[6]

Complaint Counsel asserts that there are cases that question the circumstances of applying judicial review to an agency's determination to proceed against one firm in an industry. Those cases, however, base their holding on the fact that "the question [of discriminatory prosecution] ha[d] not been raised before the Commission," see, e.g., Moog Industries, Inc. v. FTC, *supra*, at 414. Here, Andrx has

[6] Nor is it proper for the FTC to engage in rulemaking for industry-wide practices by targeting a select entity to prosecute. See, e.g., Ford Motor Co. v. FTC, 673 F.2d 1008 (9th Cir.), cert. denied, 459 U.S. 999 (1982). Where, as here, "industry practice has been to do what [respondent] does," the court in Ford found that the issue had "widespread application" and therefore "the matter should be addressed by rulemaking." Id. at 1010.

done precisely that: it has raised the question by means of an affirmative defense, and it has the right to adduce evidence to support that defense. In circumstances such as here, there is no basis to strike an affirmative defense that alleges discriminatory enforcement. For example, in Revlon, Inc., F.T.C. Docket No. 9231, (September 28, 1990), ALJ Lewis Parker specifically declined to strike the respondent's affirmative defenses that had asserted discriminatory enforcement, finding that "respondents should be given the opportunity to offer evidence in support of the claims made in those defenses." Similarly, in Dura Lube, *supra*, ALJ D. Michael Chappell denied the FTC's motion to strike respondent's affirmative defenses, which included a defense that the Commission "has been investigating manufacturers and marketers of various engine treatments and has consented to levels of substantiation with respect to their advertising claims" and therefore, that the Commission's decision to proceed only against Dura Lube was "arbitrary and capricious, in excess of the Commission's authority, manifestly unfair and inequitable, and a violation of Respondent's rights, including due process rights." Similarly, Andrx has alleged, in part, that the Commission has acted in an arbitrary and capricious manner with regard to this prosecution, and it has offered evidence to support these allegations.[7]

[7] In fact, in Synchronal Corporation, 1992 F.T.C. Lexis 61 (March 5, 1992), upon which Complaint Counsel rely, the ALJ held that the respondent's discriminatory enforcement claim in part failed because it "d[id] not establish the bad faith upon which this affirmative defense must rest." Id. at 2. Andrx has clearly alleged that certain conduct on the part of the FTC staff has been in bad faith. Additionally, Complaint Counsel's other cases deal with wholly inapposite circumstances having nothing to do with the allegations here (or are completely silent on the circumstances) and, therefore, do not provide any relevant precedent for this case. E.g., The Kroger Company, 1977 F.T.C. LEXIS 70 (October 18, 1977) (involving retail food outlets and advertising guides); Rush-Hampton Industries, 1984 LEXIS 94 (April 6, 1984) (in context of respondent's own particular "line of business," no discussion of facts pleaded and court states "[d]efenses do not contain enough facts"); Warner-Lambert Company, 82 F.T.C. 749

Complaint Counsel argues that, since a defense of selective enforcement "could lead to discovery that would substantially burden and prejudice" it, the defense should be stricken. Not only is there no basis to the claim of burden and prejudice, that is no reason, standing alone, to strike the defenses. Complaint Counsel has offered nothing whatsoever to suggest that the defense is irrelevant or unrelated or "so immaterial as to have no bearing on the issues," see Dura Lube at 33 (October 28, 1999). As such, Andrx is entitled to adduce evidence in support of its defense. Any concern that discovery will be broadened as a result of letting the defense stand is "best...dealt with through the Commission rules on discovery." Id. In any event, as noted above, the same evidence concerning industry practices and other deals will be adduced, whether or not the defense remains as pleaded, because such evidence is necessary to assess the Stipulation under a "rule of reason" analysis.

Andrx's Twelfth Affirmative Defense is well-grounded and should be allowed to stand.

VI.

ANDRX'S "EQUITABLE DEFENSES" ARE PROPER IN LIGHT OF THE SPECIFIC FACTS OF THIS CASE [Aff. Def. No. 17]

Complaint Counsel attacks Andrx's Seventeenth Affirmative Defense, which pleads that this proceeding is barred under the doctrines of laches, waiver, estoppel, and unclean hands. The contention that such "equitable" defenses cannot be properly pleaded against the FTC is wrong, particularly where, as here, equitable relief is

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(March 2, 1973) (addressing unrelated issue of alleged FTC "harassment" where FTC proceeded against predecessor entity 19 years earlier).

being sought, and Andrx has alleged affirmative misconduct on the part of the FTC in bringing this action.

First, Complaint Counsel cites primarily to cases involving the equitable defense of laches, while wholly failing to address Andrx's defenses of waiver, equitable estoppel. Even the cases Complaint Counsel does cite are predicated on a demonstration that the proceeding has been brought in the "public interest," an allegation that here is hotly disputed. See, e.g., FTC v. North East Telecommunications, Ltd., 1997 U.S. Dist. LEXIS 10531 at *9 (court's analysis assumed action brought by the government in a civil suit to protect a public interest), citing U.S. v. Summerlin, 310 U.S. 414 (1940), in support of that proposition; Horizon Corp., 97 F.T.C. 464 (court's analysis assumed action was in the public interest). Furthermore, the doctrine of laches is not barred as an affirmative defense against the government where, as here, the particular facts of the case indicate that that there may have been affirmative misconduct on the part of the government. See FTC v. Hang-Ups Art Enterprises, Inc., 1995 WL 914179 at *4 (C.D.Cal. 1995) (holding that respondent's affirmative defense of laches would not be stricken, and "the facts of the case should decide whether there has been affirmative misconduct by the government such that laches might apply").[8]

Second, notwithstanding Complaint Counsel's wish to the contrary, "courts undeniably have the power to estop the government" and equitable estoppel defenses can be asserted against the government. E.g., Best v. Stetson, 691 F.2d 42 (1st Cir. 1982) (setting forth a four factor test for considering estoppel as "(1) the statements

[8] Complaint Counsel's reliance on Kiefer-Stewart Co. v. Joseph E. Seagram & Sons, 340 U.S. 211 (1951) (which was overruled on other grounds, 467 U.S. 752 (1984)), and Apex Oil Co. v. DiMauro, 713 F. Supp. 587 (S.D.N.Y. 1989) is misplaced in that both cases involve disputes between two private parties, not between the government and a private party.

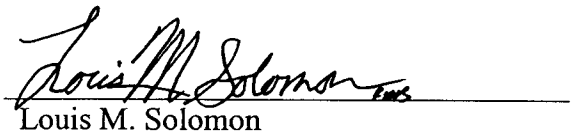
or actions of the government officials; (2) reliance to one's detriment; (3) the reasonableness of the reliance; and (4) the risk, through estoppel, that a government official will, in effect, "waive" congressionally enacted public policy"). Here, Andrx should not be barred from proving its defense that these elements or from arguing that the FTC should be estopped from pressing this case or should be severely circumscribed in obtaining any relief because of equitable considerations. For example, the FTC first investigated the Stipulation in 1997 and then advised Andrx's counsel that the matter was closed. The FTC thereafter waited almost two years before resuming an investigation into the Stipulation. In reliance on the completion of the initial investigation, Andrx was prejudiced because it proceeded to operate under the Stipulation. The FTC waited until after the Patent Action settled before challenging the Stipulation, and now contends that the Stipulation is not protected from antitrust scrutiny since the judge did not approve it. Beyond that, the FTC's unclean hands and other inequitable conduct involves, among other things, its dealings with Biovail and leaking confidential information during the non-public investigation.

It is not the office of this motion to strike to determine whether Andrx can prevail in its defenses. Complaint Counsel has offered no reason why Andrx should be deprived of its right to try.

CONCLUSION

For the foregoing reasons, Complaint Counsel's motion to strike certain of Andrx's affirmative defenses should be denied in its entirety.

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP

By 

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CERTIFICATE OF SERVICE

I, Hal S. Shaftel, hereby certify that on May 19, 2000, I caused a copy of Respondent Andrx Corporation's Opposition to Complaint Counsel's Motion to Strike Certain Affirmative Defenses to be served by hand delivery on the following:

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