IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. FOOD AND DRUG ADMINISTRATION 5600 Fishers Lane Rockville, MD 20857; MARGARET HAMBURG Commissioner of Food and Drugs 5600 Fishers Lane Rockville, MD 20857; and KATHLEEN SEBELIUS Secretary of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20204. Defendants.	Case No. 1:10-cv-01611-JDB

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR A TEMPORARY
RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") submits this memorandum of law in support of its motion for a temporary restraining order and preliminary injunction requiring the Food and Drug Administration ("FDA") to withdraw or suspend its September 14, 2010 approval of Abbreviated New Drug Application ("ANDA") No. 78-278 filed by Watson Laboratories, Inc. ("Watson") with respect to famciclovir tablets.

PRELIMINARY STATEMENT

Novartis is the holder of NDA No. 20-363 for famciclovir tablets which Novartis sells under the brand name Famvir®. Novartis is the assignee of U.S. Patent No. 5,246,937 (the "'937 patent") which includes compound claims directed to the active ingredient famciclovir and

method of use claims directed to the use of famciclovir to treat viral infections. Although the expiration date for the '937 patent was September 21, 2010, the FDA's Orange Book reflects that, pursuant to 21 U.S.C. § 355a, the FDA granted Novartis a six month pediatric extension of its exclusivity under the '937 patent until March 21, 2011, in view of the fact that, at the FDA's request, Novartis conducted clinical trials with respect to the use of famciclovir in children.

The FDA's approval of Watson's ANDA plainly violated the Food Drug & Cosmetic Act, 21 U.S.C. § 301, *et seq*. and the Administrative Procedure Act, 5 U.S.C. § 500, *et seq*. in that:

1. Watson's ANDA was ineligible for FDA approval because it did not contain a Certification against the drug product claims in the '937 patent as required under 21 U.S.C. § 355(j)(2)(A)(vii); and

2. The FDA was precluded, under 21 U.S.C. § 355a(c)(1)(B)(i), from approving Watson's ANDA until the period of pediatric exclusivity for the '937 patent expired on March 21, 2011.

As also shown below, the FDA's approval of ANDA No. 78-278 was inconsistent with prior determinations by the FDA, in which the FDA has ruled that, for patents like the '937 patent which contain both drug product claims and method of use claims, the ANDA filer must file appropriate certifications with regard to both types of claims. Hence, the FDA's approval of ANDA No. 78-278 was arbitrary and capricious and contrary to law.

A temporary restraining order and preliminary injunctive relief are urgently needed and warranted here. Clearly, Novartis will likely succeed on the merits as the FDA's approval of Watson's ANDA indisputably was a violation of statute and FDA's own practice and procedure. Moreover, absent such relief, Novartis will be irreparably harmed. Currently, the

only two sellers of famciclovir tablets are Novartis and Teva Pharmaceuticals USA, Inc. ("Teva") which sells a generic under license from Novartis. Thus, Novartis derives profits from its own sales of its Famvir® branded product and receives a substantial royalty on Teva's sales of its generic famciclovir. If Watson enters the market, as it has stated to Novartis that it intends to do, Novartis will lose substantial royalties under its license with Teva in three respects: (i) under Novartis's license agreement with Teva, the entry of a second generic famciclovir product will cause the royalty rate paid by Teva on its famciclovir sales to drop significantly; (ii) Teva will lose generic sales to Watson; and (iii) the second generic entrant on the market will drive down the price for generic famciclovir and, in turn, the amount of the royalties paid by Teva to Novartis. Even if Watson is on the market only briefly, based on the historical practices of generic drug companies, it will likely flood the market with generic tablets making the impact irreversible.

Even if the damages to Novartis could be calculated, the harm to Novartis will, by definition, be irreparable, because the FDA is protected by sovereign immunity and will not make Novartis whole with respect to the consequences of the FDA's improper approval of Watson's ANDA. Furthermore, Novartis will not have a patent infringement claim against Watson under the '937 patent because the '937 patent has expired. The pediatric exclusivity extension until March 21, 2011, extends only the period during which the FDA is barred from approving an NDA filed by competing drug manufacturers, *see Mylan Labs. v. Thompson*, 389 F.3d 1272, 1275-76 (D.C. Cir. 2004) -- which the FDA has violated.

The equities here decidedly favor an injunction. The Hatch-Waxman Act reflects a delicate balance between the rights of research-based pharmaceutical companies and generics. Having invested heavily in Famvir® and having conducted pediatric studies at the FDA's

request, the equities favor protecting the full extent of the rights afforded Novartis under the FDCA. The public interest also favors the correct and consistent application of the law by the FDA and the protection of Novartis's rights under the FDCA. In addition, because Teva is already selling a generic famciclovir product, a brief delay in the approval of Watson's ANDA will have no adverse impact on the public.

STATEMENT OF FACTS

Famciclovir is a pharmaceutical sold for treatment of herpes. (Exhibit A, Catalano Decl. ¶ 4.) Novartis is the holder of NDA No. 20-363 for famciclovir tablets, which Novartis sells under the brand name Famvir®. (*Id.* ¶ 12.) The only famciclovir tablets currently marketed in the United States are sold by Novartis or by Teva under license from Novartis. (*Id.* ¶ 21.)

Novartis is also the assignee of the '937 Patent which contains both compound claims directed to famciclovir and method of use claims directed to the use of famciclovir to treat viral infections. (*Id.* ¶ 12.)

At the FDA's request, Novartis conducted studies with respect to the use of famciclovir to treat children. (*Id.* ¶11.) Although the original expiration date of the '937 patent was September 21, 2010, pursuant to 21 U.S.C. § 355a(c), the FDA granted a six month pediatric extension of Novartis's exclusivity under the '937 patent until March 21, 2011. (*Id.* ¶13.) The FDA's Orange Book thus identifies March 21, 2011 as the expiration date for the '937 patent. (*Id.*)

Pursuant to section 505(b)(1) of the FDCA, 21 U.S.C. § 355(b)(1), information regarding the '937 patent was submitted to the FDA for listing in the FDA's Orange Book.

Prior to the September 21, 2010 expiration of the '937 patent, Watson filed an abbreviated new drug application, ANDA No. 78-278, pursuant to section 505(j) of the FDA

Act, 21 U.S.C. § 355(j), seeking to market famciclovir tablets that were generic versions of Novartis's Famvir® tablets. (*Id.* ¶ 22.)

Pursuant to the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii), an ANDA applicant generally must submit to the FDA a certification with respect to each patent which claims the drug for which the applicant seeks approval, stating:

> (I) that such patent information has not been filed;
>
> (II) that such patent has expired;
>
> (III) of the date on which such patent will expire; or
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted.

However, Watson filed no such certification with ANDA No. 78-278. Instead, Watson filed only a statement, pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) (a "section viii statement"), that it was not seeking approval for a method of use claimed by the '937 patent. Significantly, an ANDA filer making a "Paragraph IV" certification must provide notice to the NDA holder and, because a Paragraph IV certification is an act of patent infringement under 35 U.S.C. § 271(e)(2), the NDA holder may file suit within 45 days of such notice and obtain a 30 month stay of FDA approval of the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). In contrast, an ANDA filer making only a "section viii statement" does not provide notice to the NDA holder, and the NDA holder does not receive the attendant procedural protections of a Paragraph IV certification.

On September 14, 2010, the FDA approved Watson's ANDA No. 78-278, notwithstanding the FDA's extension of Novartis's exclusivity rights under the '937 until March 21, 2011. Watson has stated that it intends to launch its generic famciclovir tablets prior to expiration of Novartis' pediatric exclusivity period. (*Id.* ¶ 24.)

FDA's approval letter to Watson states that Watson's "ANDA contains statements under section 505(j)(2)(A)(viii) of the Act indicating that the '937 patent[] [is] a method of use patent, and that [this] patent do[es] not claim any proposed indication for which [Watson is] seeking approval under [its] ANDA." (A copy of the FDA's approval letter to Watson is annexed as Exhibit B.) However, Watson's statement to the FDA regarding the '937 patent ignores the fact that nine of the claims of the '937 patent, including the first seven claims, are directed to pharmaceutical compounds and compositions -- not methods of use. As such, Watson was obligated to file with the FDA either a "Paragraph III" certification (that it would await expiration of the '937 patent, including the expiration of the pediatric exclusivity period), or a "Paragraph IV" certification that would provide notice to Novartis and would give Novartis the opportunity to sue Watson for patent infringement prior to any FDA approval of Watson's ANDA.

Two other ANDA filers for famciclovir, Teva and Roxane, Laboratories, Inc. ("Roxane"), filed Paragraph IV certifications with respect to the '937 patent, which resulted in patent infringement actions brought by Novartis against both Teva and Roxane.

In the litigation against Teva, Teva stipulated to infringement of the '937 patent and a jury returned a verdict in favor of Novartis on the issues of validity and unenforceability. (Exhibit A, Catalano Decl. ¶ 18.) Novartis subsequently licensed Teva under the '937 and other patents in return for a substantial royalty on Teva's sales of famciclovir. (*Id.* ¶ 19.) Significant here, Teva's royalty payments to Novartis will greatly decrease upon the entry of second generic product. (*Id.* ¶ 27.)

The litigation against Roxane is still pending, and any FDA approval of Roxane's ANDA remains subject to the March 21, 2011 expiration of pediatric exclusivity for the '937

patent. (*Id*. ¶ 23.) Under the applicable statutory provisions, Watson's ANDA should have the same status as Roxane's. That it does not is due to the FDA's wrongful approval of Watson's ANDA.

ARGUMENT

POINT I

THE APPLICABLE LEGAL STANDARD

"The purpose of a temporary restraining order is to preserve the status quo for a limited period of time until the Court has the opportunity to pass on the merits of the demand for a preliminary injunction." *Barrow v. Graham*, 124 F.Supp.2d 714, 715-16 (D.D.C. 2000).

"The court considers the same factors in ruling on a motion for a temporary restraining order and a motion for a preliminary injunction." *See, e.g.*, *Morgan Stanley DW Inc. v. Rothe*, 150 F. Supp. 2d 67, 72 (D.D.C. 2001). Thus, it is well settled that "[i]n considering whether to grant preliminary injunctive relief, the court must consider whether: (1) the party seeking the injunction has a substantial likelihood of success on the merits; (2) the party seeking the injunction will be irreparably injured if relief is withheld; (3) an injunction will not substantially harm other parties; and (4) an injunction would further the public interest." *CSX Transp. Inc. v. Williams*, 406 F.3d 667, 670 (D.C. Cir. 2005). "The court evaluates these factors on a 'sliding scale' . . . balanc[ing] the factors against each other to determine whether the plaintiff has shown that 'all four factors, taken together, weigh in favor of the injunction.'" *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 69 (D.D.C. 2010) (internal citation omitted).

In this case, the need for, and entitlement to, a TRO and preliminary injunctive relief are clear.

POINT II

NOVARTIS WILL LIKELY SUCCEED ON THE MERITS

Based on a plain reading of the applicable statutes, supported by the FDA's own interpretation of these provisions, there can be no doubt that the FDA's approval of Watson's ANDA violated both the FDCA and the APA.

As reflected in the FDA's own Orange Book listing for Famvir®, the '937 patent was granted a six month pediatric extension of exclusivity beyond its expiration date of September 21, 2010, until March 21, 2011. Under 21 U.S.C. § 355a(c)(1)(B)(i), the FDA was prohibited from approving Watson's until after March 21, 2011: "the period during which an [ANDA] application *may not be approved* . . . section 355 (j)(5)(B)(ii) of this title s*hall be extended by a period of six months after the date the patent expires* (including any patent extensions.)" (Emphasis added.)

In addition, the FDA was prohibited - - under its own interpretation of the statutory requirements for patent certifications by ANDA applicants - - from approving Watson's ANDA because it did not include an appropriate certification with respect to the drug compound claims of the '937 patent. In a recent decision on a Citizen's Petition, the FDA reaffirmed that for an Orange Book listed patent that contains both drug product and method of use claims, "if an ANDA applicant chooses to submit a section viii statement with respect to any method-of-use claims, the applicant must also submit an appropriate certification under section 505(j)(2)(A)(vii) of the Act for any drug product claims." (Exhibit C, March 15, 2010 FDA letter, Docket No. FDA-2009-P-0411 at p. 10.) In that case, the FDA ruled that an ANDA lacking the appropriate certifications would be "ineligible for final approval." (*Id.* at 11.) This ruling is directly contrary to the FDA's final approval of Watson's ANDA.

Watson was obligated to certify against the drug compound claims of the '937 patent, just as Teva and Roxane did, and just as the FDA has ruled in similar situations. Absent the required certification, the FDA had no legal authority to grant final approval prior to expiration of the Novartis' pediatric exclusivity. It is well-settled that "'an agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so.'" *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 27-28 (D.D.C. 1997) ("'If an agency treats similarly situated parties differently, its action is arbitrary and capricious in violation of the APA.'") Here the FDA can offer no legitimate reason to excuse Watson's failure to make the appropriate certification with respect to the '937 patent and to grant an approval that deprives Novartis of its statutory entitlement to the six month period of pediatric exclusivity for the '937 patent reflected in the FDA's own Orange Book.

Based on the FDA's indisputable violation of the Hatch Waxman Act in approving Watson's ANDA, Novartis has made a clear showing that it will likely prevail on the merits.

POINT III

NOVARTIS WILL SUFFER IRREPARABLE HARM ABSENT INJUNCTIVE RELIEF

After succeeding in patent infringement litigation against Teva, Novartis licensed Teva to manufacture and sell a generic famciclovir product at a substantial royalty. (Exhibit A, Catalano Decl. ¶ 19.) The stream of income from that license currently constitutes the lion's share of Novartis's revenue from famciclovir tablets and Novartis' ability to recoup its enormous investment in Famvir® is dependent on the royalty income received from Teva. (*Id.* ¶ 20.) However, the license imposes on Novartis a severe reduction in the royalties received from Teva if a second generic famciclovir product, such as Watson's, enters the market. (*Id.* ¶ 27.)

Moreover, Watson is likely to flood the market with its generic product when it launches and to aggressively price its product below Teva's price, forcing an irreversible reduction in both the volume and the price of Teva's sales and thereby further reducing the royalty payments to Novartis. (*Id.* ¶ 28.) Novartis will therefore suffer immediate and irreparable injury due to the loss of income from the Teva license agreement.

Even if the economic injury inflicted on Novartis by the FDA's unlawful approval of Watson's ANDA does not threaten Novartis' viability, it is still irreparable because Novartis cannot recover money damages against the FDA. *Smoking Everywhere, Inc. v. U.S. Food & Drug Admin.*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010) ("Where a plaintiff cannot recover damages from an agency because the agency has sovereign immunity, 'any loss of income suffered by [the] plaintiff is irreparable *per se*.'"); *see also Clarke v. Office of Federal Housing Enterp. Oversight*, 355 F. Supp. 2d 56, 65 (D.D.C. 2004) ("[C]ourts have recognized that economic loss may constitute 'irreparable harm' where a plaintiff's alleged damages are unrecoverable.")

Moreover, since the '937 patent has expired, Novartis cannot assert it against Watson in a patent infringement litigation. The period of pediatric exclusivity only serves to bar the FDA from approving Watson's ANDA until March 21, 2011, and exclusivity which the FDA violated.

Simply put, an unlawful launch by Watson will result in substantial and irreparable injury to Novartis.

POINT IV

THE EQUITIES FAVOR GRANTING AN INJUNCTION

In contrast to the clear and irreparable harm Novartis will suffer from an unlawful product launch by Watson, Watson will, at worst, face only a temporary delay pending

a hearing on the merits. Thus, even if, *arguendo*, Watson were to ultimately prevail on the merits, it is unlikely to suffer any real harm in the relatively short period of time it will take the Court to decide what is purely a legal issue.

The FDA's wrongful approval of Watson's ANDA gives Watson the improper windfall of entering the market six months before it could legally do so. while, denying Novartis the right to obtain any compensation from Watson. The balance of hardships weighs heavily in favor of Novartis, supporting the injunctive relief sought.

POINT V

THE PUBLIC INTEREST FAVORS AN INJUNCTION

There is a strong public interest in carrying out the goals of the Hatch Waxman Act, which provides incentives to the development of new drugs and new treatments, including for pediatric patients. To this end, the Hatch-Waxman Act provides an additional six months of exclusivity to an NDA holder who at the FDA's request conducts tests to determine the suitability of a drug for pediatric patients. The FDA's wrongful approval of Watson's ANDA undermines this public interest which can only be preserved by the injunctive relief sought here.

Moreover, the public interest strongly favors the faithful and consistent application of the FDCA. *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997); *see Whitaker v. Thompson*, 248 F. Supp. 2d 1, 16 (D.D.C. 2002) ("[I]t is clearly in the public interest to ensure that governmental agencies, such as FDA, fully comply with the law..."); *Bracco*, 963 F. Supp. at 30 ("[T]here is a strong public interest in requiring [FDA] to act lawfully, consistent with its obligations under the APA, and to treat all similarly situated and regulated parties equally.") The public interest therefore favors the grant of an injunction in this case.

Finally, since Teva is currently marketing a generic famciclovir product, the public interest will not be adversely affected by a brief delay in Watson's entry with a second generic product pending a decision on the merits.

CONCLUSION

Based on the foregoing, Novartis's motion should be granted in all respects.

September 23, 2010

Respectfully submitted,

/s/ David O. Bickart
Sylvia M. Becker #412094
David O. Bickart Bar #355313
KAYE SCHOLER LLP
901 15th Street, N.W.
Washington, DC 20005
(202) 682-3500

Aaron Stiefel
David Barr
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
(212) 836-8000

Attorneys for Plaintiff
Novartis Pharmaceuticals Corporation