

United States Court of Appeals
for the
Federal Circuit

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS PHARMA AG and
NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.,

Plaintiffs-Appellants,

– v. –

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF NEW JERSEY IN CASE NO. 05-CV-1887,
JUDGE DENNIS M. CAVANAUGH

**PLAINTIFFS-APPELLANTS' EMERGENCY MOTION FOR AN
INJUNCTION PENDING APPEAL**

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I. INTRODUCTION

Plaintiffs Appellants respectfully submit this emergency motion for an injunction pending resolution by the Court of Novartis' appeal of the district court's denial of Novartis' motion for a preliminary injunction to prevent defendant-appellee from launching "at risk" its generic famciclovir product.¹

Teva is poised to flood the market with a generic copy of Novartis' successful Famvir® product (branded famciclovir) that Teva concedes will infringe Novartis' patent for that compound. In fact, having been told yesterday that Novartis would make the present motion, Teva has now proceeded with its launch of generic famciclovir. Thus, the status quo will be irretrievably changed and Novartis will be irreparably injured. Precedent shows that a generic can sell months worth of product within days.

The facts of this case precisely parallel those of the Plavix litigation² in which the trial court held an evidentiary hearing, granted a preliminary injunction, and this court affirmed. Here, as in that case, the defendant admitted infringement and asserted obviousness based on prior art that had been fully considered by the patent examiner and arguments that were inconsistent with what had happened in the real world. Here, as in that case, evidence from a renowned

¹ Novartis submits with this motion the declarations filed with the district court that support the underlying facts. Two of those declarations have been minimally redacted to protect sensitive, current Novartis financial information. The Court has been provided unredacted confidential versions of those declarations.

² Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368 (Fed. Cir. 2006).

economics expert established that the patent owner would suffer immediate and irreparable harm if the generic was not enjoined. In fact, the balance of harm here tips even more strongly in favor of the patentee, because Teva, unlike Apotex in the Plavix case, had not yet triggered the 180 days of marketing exclusivity prior to the district court's decision, so that an injunction, even if improvidently granted, would merely delay for a short period its sales and profits.

Despite the compelling parallel to Sanofi, the trial court here did not hold an evidentiary hearing, heard no live testimony, denied the motion for a preliminary injunction at the close of a 1-1/2 hour argument and, when Novartis sought to make an application for an injunction to maintain the status quo until it could apply to this court for interim relief, summarily ruled that the application was deemed to have been made and denied.³

Novartis respectfully requests this Court to issue an injunction pending resolution of Novartis' appeal. Further, to preserve the status quo, Novartis requests that the Court immediately issue a temporary injunction lasting only until the Court issues its decision on this motion. Novartis has discussed this motion with Teva, which objects. Novartis is committed to pursue the appeal on an expedited basis to minimize any potential harm to Teva.

The invention in issue here – the medicine that Teva concedes was a novel compound when it was made by Beecham – is an “acyclic nucleoside” that

³ This order will be submitted to this Court as soon as it issues.

Beecham created by making two critical chemical modifications to a known compound, penciclovir. Unlike penciclovir, famciclovir is a safe and effective oral medicine used successfully (with annual sales of \$160 million) to treat infections caused by HSV-1, HSV-2 and herpes, sexually transmitted diseases and shingles.

Famciclovir itself has no antiviral activity. It is a successful oral drug because it is converted by the body in a unique, three-step, unpredictable way, into the active entity, penciclovir and, importantly, without creating other metabolic products that produce undesired side-effects.

II. ARGUMENT

An applicant for an injunction pending appeal under FRAP 8(b) must demonstrate the following factors: (1) likelihood of the success on appeal; (2) whether the applicant will otherwise suffer irreparable harm; (3) whether the injunction will substantially injure the adverse party; and (4) the public interest. E.I. DuPont de Nemours & Co. v. Phillips Petroleum, 835 F.2d 277, 278 (Fed. Cir. 1987). Each factor, however, need not be given equal weight. See Providence Journal Co. v. Federal Bureau of Investigation, 595 F.2d 889, 890 (1st Cir. 1979) (granting stay pending appeal). As Novartis will show, all four factors weigh strongly in favor of the grant of provisional injunctive relief here.

A. Novartis Has Established The Necessary Likelihood Of Success

A stay pending appeal is appropriate when a movant's appeal involves serious and substantial questions going to the merits of the decision and the movant

will suffer irreparable harm absent a stay. See Arkansas Peace Ctr. v. Arkansas Dep't of Pollution Control, 992 F.2d 145, 147 (8th Cir. 1993). It does not require a showing that “ultimate success by the movant is a mathematical probability.” Washington Metro. Area Transit Comm'n v. Holiday Tours, 559 F.2d 841, 843 (D.C. Cir. 1977) (rejecting the view that “50% plus probability is required”). Indeed, when harm to an applicant is great enough, a court will not require “a strong showing” that the applicant is “likely to succeed on the merits.” Hilton v. Braunskill, 481 U.S. 770, 776 (1987); William Inglis & Sons Baking Co. v. ITT Continental Baking Co., 526 F.2d 86, 88 (9th Cir. 1975).

Novartis plainly demonstrates here that it is entitled to the requested injunction pending appeal. The district court clearly erred on each of the two bases it cited for denying Novartis' preliminary injunction motion -- (1) that Teva would likely succeed in proving its defenses of obviousness and inequitable conduct, and (2) that Novartis would not suffer irreparable harm if Teva launched its generic famciclovir product now and was later enjoined.

1. The '937 Patent Is Not Invalid

a) The Applicable Law

Every patent is presumed valid and enforceable, and this presumption exists at every stage of the litigation. See 35 U.S.C. § 282; Sanofi, 470 F.3d at 1375. Teva bears the burden of proof on the obviousness issue by clear and convincing evidence. Oney v. Ratliff, 182 F.3d 893, 895 (Fed. Cir. 1999). See also, Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1358-60

(Fed. Cir. 1984). Teva's burden of proving invalidity is "especially difficult" when the supposedly invalidating prior art was before the Patent Examiner at the time the patent was allowed. E.g., Sanofi, 470 F.3d at 1375 (quoting Glaxo Group Ltd. v. Apotex Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004)); Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 1323 (Fed. Cir. 1999).

In the preliminary injunction context, only if Teva produces evidence raising a "substantial question" concerning validity, or enforceability" must plaintiffs then produce countervailing evidence demonstrating "that these defenses 'lack substantial merit.'" Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1363 (Fed. Cir. 2001); Sanofi, 470 F.3d at 1374. Therefore, Novartis' burden was only to show that it is unlikely that Teva will meet its elevated "clear and convincing" burden. See H. H. Robertson Co. v. United Steel Deck, 820 F.2d 384, 387-88 (Fed. Cir. 1987).

Obviousness is a question of law, Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561,1566-67 (Fed. Cir. 1987), based on the following factual inquiries: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, (3) the level of ordinary skill in the art, and (4) objective evidence, or "objective indicia," of nonobviousness. See Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). In determining whether an invention is obvious, Courts must also consider "objective indicia" of nonobviousness such as unexpected properties and commercial success. See Ruiz v. A.B. Chance Co., 234 F.3d 654, 667 (Fed. Cir. 2000).

For chemical compounds, the “invention as a whole” is the compound and all its properties. Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1448 (Fed. Cir. 1984) (emphasis in original); In re Papesch, 315 F.2d 381, 391 (C.C.P.A. 1963). And, in any consideration of obviousness, the Court must avoid the use of hindsight. In re Omeprazole Patent Litig., No. MDL 1291, 2007 U.S. Dist. LEXIS 39670, at *400-01 (S.D.N.Y. May 31, 2007) (emphasis added) (citation omitted) (quoting KSR Int’l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742 (2007)); see also, Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138 (Fed. Cir. 1985).

In its recent KSR decision, the Supreme Court cautioned against (1) a rigid application of the teaching, suggestion, and motivation (“TSM”) test, and (2) a rigid rejection of an “obvious to try” analysis when there is pressure to solve a problem with “a finite number of identified, predictable solutions.”⁴ The Court advocated a more “common sense” approach to determining obviousness. KSR, 127 S. Ct. at 1741-1743.⁵ “Common sense,” however, requires recognizing, in chemical cases, the almost infinite number of possible chemical modifications and the unpredictability of the result of making them.

⁴ The Court acknowledged, however, that the TSM test can provide meaningful insight and that “obvious to try” did not equate to “obvious.” KSR, 127 S. Ct. at 1741-1742.

⁵ Importantly, KSR concerned relatively predictable technology, namely a brake pedal combined with a position sensor.

In Takeda Chem. Indus., Ltd. v. Alphapharm Pt., Ltd., No. 06-1329, 2007 U.S. App. LEXIS 15349, at *4 (Fed. Cir. June 28, 2007), this court affirmed a finding on non-obviousness where the defendant's arguments relied on a hindsight reconstruction that disregarded the real world events. The Court explained that, consistent with KSR, there must be a showing that the prior art "suggested" both the choice of a starting point and making the molecular modifications at issue. The Court then held that the claimed compound would not have been obvious because the solutions identified in the prior art were numerous and unpredictable. Id. at *21.

b) Famciclovir Was Plainly Not Obvious

Teva's obviousness attack is based entirely on hindsight. Teva and its experts started with the structure and properties of famciclovir, worked backward along the path the inventors ultimately took, and then, with the perfect clarity of hindsight, now argue that this pathway was obvious. But there was nothing obvious about the inventors' choices -- not to mention the outcome -- of the chemical modifications the inventors made to penciclovir to make famciclovir. This is particularly true given the extraordinarily large number of directions the inventors could have taken.

Teva predicates its argument on five steps, each of which Teva claims supports the obviousness of famciclovir:

- It was obvious to choose penciclovir as a starting point for antiviral research (i.e., penciclovir was an obvious "lead compound");

- It was obvious that penciclovir needed to be converted into a prodrug before it was useful;
- It was obvious what chemical modifications would make that conversion;
- It was obvious that those chemical modifications would work; and
- It was obvious what famciclovir's resulting properties would be (i.e., its properties were not unexpected).

Every one of Teva's obviousness steps is wrong. Every one is inconsistent with the prior art as a whole and what happened in the real world when the inventors made famciclovir. For example, according to Teva's expert Dr. Broom, "everyone" got into the field of making antiviral compounds after Burroughs Wellcome's development of acyclovir. Yet out of Teva's "everyone", only four companies even bothered looking at penciclovir as a starting point for research. After a short time three of them dropped it. That left only Beecham, who did not abandon hope for some use of penciclovir. Beecham found the answer in famciclovir.

c) Penciclovir Was Not An Obvious Lead Compound

Teva argues that it was obvious to start with penciclovir, and that it was only one of five possible lead compounds. Teva's theory is not surprising since Teva worked backwards to arrive at penciclovir. Novartis demonstrated that based on Teva's prior art references alone, there were dozens of possible lead compounds meeting Teva's criteria. (Bartlett Decl. ¶¶ 64, 114, 118). The court nevertheless concluded there were only five possible antiviral lead compounds.

This conclusion totally ignores the evidence presented by Novartis and totally ignores the real world facts above concerning the small number of companies looking at penciclovir.

**d) It Was Not Obvious To Modify
Penciclovir to Make an Effective Prodrug**

There is no dispute that penciclovir was a known compound with antiviral activity. The Patent Examiner was fully aware of that fact -- Beecham had already cited the Tippie reference disclosing that. But penciclovir was useless as an oral medicine because it was not absorbed by the human body from the gastrointestinal tract. Yet Teva concludes that everything one needed to know to convert penciclovir into an effective orally-absorbed prodrug was in the prior art. Indeed, Teva says that the “roadmap” for such conversion was set forth in just one reference -- the GB '204 patent. But then why did all of the other companies that were looking for a successful and profitable antiviral drug ignore Teva's roadmap to famciclovir? All of Teva's prior art was certainly available to those companies.

But more than that, it was simply not obvious that the chemical modifications that the inventors made to penciclovir to make famciclovir would have worked to make a safe and effective prodrug. Both Teva and the trial court ignored the uncontested fact that small changes in a chemical compound can have radical changes in how that compound behaves in the human body. The following facts belie Teva's argument:

- The Beecham inventors tried many different variations and modifications to the 2- and 6-position of the penciclovir 6-membered

ring and the penciclovir side chain. Each of these modifications were also “suggested” in the prior art but those modifications did not work on penciclovir. (Jarvest Decl. ¶¶ 18-21; Bartlett Decl. ¶¶ 123-26).

- The Beecham inventors even made acetyl esters of penciclovir’s side chain. Those modifications did not work. (Jarvest Decl., Exh. 11 at GSK from 100302-03).
- When Beecham tried the 6-deoxy modification taught by the GB ‘204 patent for acyclovir, that modification still did not provide sufficient bioavailability of penciclovir for an effective prodrug. (Jarvest Decl. ¶ 21).
- Burroughs-Wellcome’s work reported in the GB ‘204 patent turned out to be a dead end. While the ‘204 patent taught that 6-deoxy acyclovir had better bioavailability than acyclovir, nevertheless, subsequent work showed that 6-deoxy acyclovir was toxic due to incomplete metabolism in the body. (Bartlett Decl. ¶ 126).
- Beecham, in fact, did not achieve success until it had modified penciclovir in at least three different ways -- (1) making the 6-deoxy derivative (removing the oxygen at the 6 position), and (2) adding an acetyl ester group to each of the two side chain hydroxy groups. Each of these steps had a totally unpredictable outcome. (Bartlett Decl. ¶ 135).

In particular, as to the final step -- adding the two ester groups -- there was simply nothing in the prior art that taught that those particular ester modifications to penciclovir would work to improve its bioavailability. GB ‘204 does not say that. And the authors of GB ‘204 said precisely the opposite in their published article:

Considerable effort has been expended in attempts to find a prodrug that is well absorbed after oral administration and then converted to acyclovir. Esterification of the hydroxyl group of the (2-hydroxyethoxy) methyl moiety [i.e., the side chain] of acyclovir has been an approach taken by two separate laboratories (references).

Unfortunately, those esters that have been tested showed no significant improvement in absorption after oral administration (unpublished results) (emphasis added).

(Bartlett Decl. ¶ 129, Exh. 24).

Indeed, Beecham found that neither the 6-deoxy variant nor the ester addition -- done separately -- produced a viable drug. Even Beecham was surprised when the combination gave success.

Finally, it was surprising that famciclovir was both safe and effective. Unlike 6-deoxy acyclovir -- the compound Burroughs Wellcome had to abandon because of toxicity-- famciclovir is cleanly metabolized by an enzyme that is different from the one that acts on 6-deoxy acyclovir. (Jarvest Decl. ¶ 26). That was wholly unexpected and unpredictable.

2. The Claims Of The '937 Patent Are Not Unenforceable

Teva concocts two different theories for why the '937 patent was procured by inequitable conduct: (1) that applicants withheld certain references from the Patent Examiner; and (2) that applicants intentionally made false and misleading statements to the Patent Examiner about the prior art. Contrary to the district court's holding, neither theory comes close to satisfying the applicable test. Teva must show by clear and convincing evidence (1) that the patent applicant omitted material information or misrepresented material facts, and (2) that the applicant did so with the intention of misleading or deceiving the patent examiner. Monsanto Co. v. Bayer Bioscience N. V., 363 F.3d 1235, 1239 (Fed. Cir. 2004).

Once this threshold of materiality and intent is met, the court must balance the equities to determine whether the patentee has committed inequitable conduct. Id., at 1239. The applicant's conduct must be so culpable that the court determines it must hold the patent unenforceable. Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358 (Fed. Cir. 2003).

The court erred in holding that applicants intentionally and inappropriately withheld five material prior art references.⁶ These references were merely cumulative of references already before the Examiner and so cannot be material.⁷ The Court apparently gets around that inconvenient fact with respect the Larsson publication and the '190 patent by relying on Molins PLC v. Textron, Inc., 48 F.3d 1172 (Fed. Cir. 1995) suggesting that the materiality requirement can somehow be inferred where the references are buried in a multiplicity of other references. Op. at 21. But Molins makes clear that it does not make an otherwise non-material reference material. Id. at 1185. With respect to the remaining references the court says they are not merely cumulative of the Tippie article because they disclose that penciclovir has low toxicity and antiviral activity. But Tippie does show penciclovir has antiviral activity and the "low" toxicity is simply

⁶ Larsson publication; the '190 patent; the '084 patent; the '833 patent; the Greek '121 application.

⁷ The Larsson publication and the '190 patent are merely cumulative of Ericson and the Oberg references. (Bartlett Decl. ¶¶ 154, 155). The '084 patent, the '833 patent and the Greek '121 application, all of which disclose penciclovir, are merely cumulative of the Tippie article. (Bartlett Decl. ¶¶ 152, 153).

not relevant to patentability of famciclovir, it was the comparable toxicity and activity of ganciclovir and penciclovir that mattered and those other references fail to provide any teaching in that respect.

Additionally, the court erroneously accepts Teva's misrepresentation of the statements made about methylene compounds to the Examiner. Applicants argued that compounds with a methylene group in the side chain is always less active than their ether analogs -- a true statement. Teva's references are irrelevant to the point applicants were making, because none of them contain comparisons between methylene and ether compounds.

Nor was the district court correct in finding that Mr. Malcolm Boyd's January 22, 1991 declaration was misleading. According to Teva, Mr. Boyd improperly stated that penciclovir was surprisingly and unexpectedly less toxic than ganciclovir. The court completely misses the point of the declaration which is purely a comparison of the relative toxicities of penciclovir and the structurally closest prior art compound having an ether linkage in the side chain. That data was absolutely correct -- even Teva does not dispute the veracity of the data contained in that declaration.

Finally, there is simply no evidence that applicants intentionally withheld any material references.⁸ The intent to deceive cannot be inferred from

⁸ The '833 patent, the '190 patent, and the '084 patent were in fact disclosed to the very same Patent Examiner in another co-pending patent application involving the same applicants as the '937 application and the substance of the Greek '121 application. (See Cudnik Decl., ¶ 24; Bartlett Decl. ¶ 152).

the failure to disclose information or from the materiality of the information, but that is exactly what the district court does. The court even goes so far as to suggest that Novartis fails to claim that any of the prior art references were unintentionally withheld, so infers the opposite, that those references were intentionally withheld. Op. at 24. There must be a factual basis for a finding of deceptive intent. In re Hayes, 982 F.2d 1527, 1546 (Fed. Cir. 1992); Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1442 (Fed. Cir. 1991). In this case there is none.

Simply put, there was no intent to deceive the USPTO in this case. Teva took the depositions of at least seven individuals involved in the prosecution of the '937 patent, including both inventors, and every prosecuting attorney that Teva requested. At the same time, Teva conducted widespread document discovery. Yet Teva is still unable to point to any evidence whatsoever that the '937 patent applicants intended to deceive the Patent Examiner by not citing references to him, or by making misleading arguments to him.

B. Novartis Will Suffer Irreparable Harm In The Absence Of A Stay

If an injunction is not granted pending appeal, Novartis will suffer several forms of irreparable harm. Because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole. Hybritech, Inc. v. Abbott Labs., 849 F.2d 1446, 1456-57 (Fed. Cir. 1988) (cited in Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 98 F. Supp. 2d 362, 398 (S.D.N.Y. 2000)),

aff'd, 237 F.3d 1359, 1363 (Fed. Cir. 2001); Atlas Powder Co. v. Ireco Chems., 773 F.2d 1230, 1233 (Fed. Cir. 1985). Because a patent has a limited term, the court cannot restore to its owner the exclusivity that it lost during the pendency of its appeal.

The injuries that Novartis will suffer based on Teva's launch would never be fully compensable, and those injuries would persist long after a judgment in Novartis' favor is entered. The facts demonstrating irreparable harm here are even stronger than those found persuasive in Sanofi.

1. Irreversible Market Share And Price Erosion Will Occur And Worsen With Time

If Teva is not preliminarily enjoined, it will likely continue to sell, and flood the market with its generic famciclovir product within a very short time. (Lemieux Decl., ¶ 29; Hausman Decl., ¶ 24). In the present case, Novartis would suffer severe irreparable harm in the form of lost market share and price erosion. When faced with Teva's premature market entry, Novartis could either maintain Famvir's[®] effective price but lose market share to the lower priced generic product, or lower the price in an attempt to maintain its market share. (Lemieux Decl., ¶ 29; Hausman Decl., ¶¶ 12,23).

Either course of action, however, leads to scenarios under which, even after a preliminary injunction is granted on appeal and Teva exits from the market, Novartis' market for Famvir[®] will remain devastated, most likely for the entirety of the remaining patent term. In addition, Famvir[®] effective pricing will remain

irretrievably depressed. (Lemieux Decl., ¶ 36; Hausman Decl., ¶ 22; Hausman Reply Decl.).

Irretrievable loss of market share and price erosion are recognized forms of irreparable harm that have served to support preliminary injunctive relief in cases similar to this. Purdue, 237 F.3d at 1368 ; Sanofi, 470 F.3d at 1382-83; Glaxo Group Ltd. v. Apotex, Inc., 64 F. App'x 751, 756 (Fed. Cir. 2003).⁹

2. Irreparable Harm Will Result From The Suspension of Clinical Research

Novartis has ongoing clinical trials in which it currently is committed to invest large sums of money. At the F.D.A.'s request, Novartis is undertaking to study the effects of Famvir® treatment on the African American population, in addition to ongoing pediatric clinical trials designed to establish safe and effective antiviral treatments for babies and children under the age of 12. (Lemieux Decl., ¶ 13). The loss of these research opportunities, which are jeopardized by Teva's premature generic launch, will result in irreparable harm. Sanofi, 470 F.3d at 1382-83; Pharmacia, 274 F. Supp. 2d at 614, aff'd, 85 F. App'x 205 (Fed. Cir. 2003).

⁹ See also, Pharmacia & Upjohn Co. v. Ranbaxy Pharms. Inc., 274 F. Supp. 2d 597, 614 (D.N.J. 2003), aff'd, 85 F. App'x 205 (Fed. Cir. 2003) (harm from "irretrievable price and market erosion"); Abbott Labs. v. Sandoz, Inc., No. 05 C 5373, 2007 U.S. Dist. LEXIS 28185, at *88-92 (N.D. Ill. Apr. 16, 2007) (harm from loss of market position); Dusa Pharms. Inc. v. River's Edge Pharms., LLC, No. 06-1843, 2006 U.S. Dist. LEXIS 29852, at *23 (D.N.J. May 15, 2006), injunction vacated on other grounds, 2007 U.S. Dist. LEXIS 16005 (D.N.J. Mar. 6, 2007) (harm from market erosion caused by generic product).

3. A Launch Enjoined Only After The Appeal Will Irreparably Impair Plaintiffs' Goodwill

The delay of injunctive relief until after the appeal will inevitably generate ill-will among those who understandably grew accustomed to lower prices for famciclovir because of Teva's unlawful, but unenjoined, course of conduct. Those losses are not quantifiable, but are certain to increase the longer its generic product remains on the market. (Lemieux Decl., ¶¶ 22, 29, Lemieux Reply Decl. ¶ 3). See Sanofi-Synthelabo v. Apotex, No. 02 Civ 2255, 2006 U.S. Dist. LEXIS 65127, at *72 (S.D.N.Y. Aug. 31, 2006); see also, Sanofi, 470 F.3d at 1382-83; Syntex (USA) LLC v. Apotex Inc., No. 01-02214, 2006 U.S. Dist. LEXIS 34608, at *8-9 (N.D. Cal. May 18, 2006). Moreover, the appearance and disappearance of Teva's generic product if an injunction is not granted until after the appeal would also result in substantial confusion in the minds of both doctors and patients, contributing further to the diminution of Novartis' goodwill. (Lemieux Decl., ¶¶ 41; Lemieux Reply Decl. ¶ 3).

Also, it is highly likely that Teva will flood the market with generic famciclovir which wholesalers will stockpile, and which will supply the market for a long time to come (Lemieux Decl. ¶¶ 29; Hausman Dec. ¶ 24). Because the '937 patent expires in September 2010, it likely will have only about two and one half years of remaining life following resolution of the appeal to this Court. Thus, because of the substantial inventory "overhang" of generic famciclovir, even when this court reverses the court below, the patent term remaining at that point will be rendered worthless. Indeed, in Sanofi, Apotex reported that it sold 6 months

supply of generic product in only 23 days on the market. See 470 F.3d 1368 at 1373, 1383; Hausman Reply Decl. ¶ 6.

The harms Novartis will suffer from Teva's launch are strikingly similar to the harms that this Court found recently determined are irreparable in Sanofi including:

- Irreversible price erosion (470 F.3d at 1382)
- Potential discontinuation of clinical trials (470 F.3d at 1381, 1383)
- Loss of good will due to generic entry (470 F.3d at 1381, 1383)

C. Granting An Injunction Would Serve The Public Interest And Would Not Significantly Harm Teva

The enforcement of the intellectual property rights of innovator pharmaceutical companies is an essential component of efforts to discover new, useful compounds. It has been estimated that for every 5,000 compounds tested, only one is approved by the FDA.¹⁰ These oft-cited statistics underscore how critical to the process of drug discovery is the protection of patents, without which recovery of the costs of laboratory and clinical research would be impossible. See Eli Lilly & Co. v. Premo Pharm. Labs., Inc., 630 F.2d 120, 137 (3d Cir. 1980); Ortho Pharm. Corp. v. Smith, 15 U.S.P.Q.2d 1856, 1863 (E.D. Pa. 1990).¹¹

¹⁰ Dep't of Health & Human Srvs., Nat'l Insts. of Health, A Plan to Ensure Taxpayers Interests Are Protected (July 2001), http://www.ott.nih.gov/policy/policy_protect_text.html

¹¹ See Sanofi, 470 F.3d at 183-84 (Court credited testimony of Novartis' expert Dr. Hausman on this issue). See also, Pfizer, Inc. v. Teva Pharms USA, Inc., 429 F.2d 1364, 1382 (Fed. Cir. 2005); Pharmacia, 274 F. Supp. 2d at 614.

Novartis faces no difficulty in filling orders for Famvir[®], and there is no risk of patients being faced with shortages of supply if Teva's products are enjoined (Lemieux Decl., ¶¶ 42)¹²

Had Teva agreed to forbear from selling for the short time required for this Court to decide the motion for an injunction pending appeal, any prospective harm to it would have been de minimis. By choosing to initiate its launch, despite being informed of Novartis' intention to seek interim relief, Teva knowingly put its potential for 180 days of marketing exclusivity in jeopardy, and this court should give no credence to that self-inflicted harm. Sanofi 470 F.3d at 1383. In any event, any harm to Teva here (if it ultimately succeeds at trial) would be purely monetary, easily calculated and fully protected by an injunction bond. Thus, the disparity between the hardship to Teva and the substantial, irreparable hardship to Novartis weighs in favor of the relief Novartis now seeks. Sanofi, 470 F.3d at 1383.

Moreover, any potential damages would also be minimized by Novartis' undertaking to seek expedited resolution of its appeal -- it commits to file all its papers on an expedited basis and will not seek any extensions of time.

¹² Indeed, the public interest would be harmed by the type of market disruption resulting from Teva's premature entry in the market now, only to be removed from the market following a trial on the merits. Solarex Corp. v. Advanced Photovaltaic Sys. Inc., 34 U.S.P.Q.2d 1234, 1241 (D. Del. 1995). The longer Teva is allowed to sell its product, the more disruption will occur when Novartis ultimately succeeds at trial, and Teva's product is then taken off the market. See Critikon, Inc. v. Becton Dickson Vascular Access, Inc., 28 U.S.P.Q.2d 1362, 1371 (D. Del. 1993).

D. Teva Should Be Required To Recall Product Already Sold

Because Teva has begun to ship famciclovir, it is apparent that an injunction that merely enjoins further sales and allows existing supplies to pass through the streams of commerce uninterrupted will not afford Novartis the full measure of relief to which it is entitled. For that reason, Novartis respectfully requests that the court include in its injunction a provision that commands a recall of the product already sold.

Under circumstances such as these, in which a defendant has already sold infringing products by the time an injunction is entered, courts do not hesitate to order the defendant to recall the infringing product. See Perfect Fit Indus. v. Acme Quilting Co., 646 F.2d 800, 805 (2d Cir. 1981); Rohm & Haas Co. v. Cumberland Chemical Corp., No. H-82-1241, 1983 U.S. Dist. Lexis 19879 at *17-*18 (S.D. Tex. 1983); Cybermedia, Inc. v. Symantec Corp., 19 F. Supp.2d 1070, 1079 (N.D. Cal. 1998) (recall ordered as “the only effective remedy,” the absence of which would cause the allegedly infringing product to continue to be sold in direct competition with the plaintiff’s).

III. CONCLUSION

This Court should enter an injunction pending appeal and order a recall of product already sold.

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