

No. 2007-1542

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**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

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**NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS  
PHARMA AG, AND NOVARTIS INTERNATIONAL  
PHARMACEUTICAL LTD.,**

**Plaintiffs-Appellants,**

**v.**

**TEVA PHARMACEUTICALS USA, INC.,**

**Defendant-Appellee.**

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**Appeal from the United States District Court for the District of New  
Jersey in Case No. 05-CV-1887, Hon. Dennis M Cavanaugh**

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**DEFENDANT-APPELLEE'S OPPOSITION TO MOTION FOR  
INJUNCTION PENDING APPEAL**

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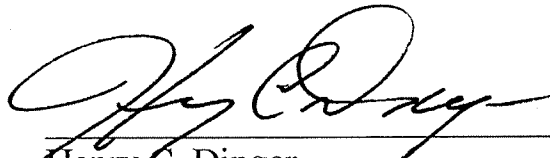
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2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:  
  
Teva Pharmaceuticals USA, Inc.
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:  
  
Orvet UK Unlimited  
Teva Pharmaceuticals Europe B.V.  
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4. All law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

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## *Introduction*

Novartis asks this Court to enjoin the sale of Teva's generic famciclovir product after failing to persuade the District Court either that it was likely to succeed on the merits or that it faced irreparable harm. Rather than explaining why the District Court's extensive decision constitutes an abuse of discretion, Novartis simply repeats the arguments it made unsuccessfully to the District Court.

But an application to an appellate court for an injunction pending appeal provides no occasion for a "do over" of the trial court's preliminary injunction proceedings. An injunction pending appeal is an extraordinary remedy that can only be sustained by showing that the District Court so botched its balancing of the pertinent factors that it abused its discretion. But Novartis does not argue that the District Court applied an incorrect legal standard or lacked evidence to support its findings. It is plainly insufficient to argue that the District Court should have rejected Teva's evidence and accepted Novartis' evidence. Nor is it enough simply to repeat epithets such as "hindsight." Novartis' motion for an injunction pending appeal offers nothing more and must be rejected.

The single patent-in-suit<sup>1</sup> — which will expire in 2010 — is directed to a compound (famciclovir), a “pro-drug” for the prior art anti-herpes agent penciclovir,<sup>2</sup> and methods of using famciclovir to treat herpes viruses. The District Court found, based on a careful analysis of an extensive record, that the prior art disclosed penciclovir as a member of a class of acyclic nucleosides that were anti-viral agents particularly effective in the treatment of herpes. Slip Op. at 12-13. It was also known that these compounds had low oral bioavailability, *i.e.*, they were not readily absorbed into the bloodstream after oral administration. *See id.* at 14; *see also* Broom Dec. ¶¶ 52-57. But skilled artisans knew how to overcome drug bioavailability problems by forming more absorbable pro-drugs that metabolized into the drug in the body. *See* Slip Op. at 14; *see also* Broom Dec. ¶¶ 52-66; Smee Rpt. 10-12, 40-50. Indeed, a single prior art reference taught how to convert the two closest prior art acyclic nucleoside analogs of penciclovir, to orally absorbable pro-drugs. Beecham<sup>3</sup> merely copied that methodology to convert

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<sup>1</sup> U.S. Patent No. 5,246,937 (the ‘937 patent”).

<sup>2</sup> A “pro-drug” is a compound converted in the human body to a medically active compound. Here, famciclovir converts to penciclovir after ingestion. The use of pro-drugs to deliver compounds not themselves readily absorbed after oral administration was well-known in many areas, including specifically the delivery of acyclic nucleoside analogs such as penciclovir. *See* Broom Dec. ¶¶ 6, 58-59.

<sup>3</sup> Beecham Group was the original assignee of the ‘937 patent. Novartis obtained the patent from GlaxoSmithKline which had earlier acquired Beecham.

penciclovir into famciclovir, and, predictably, famciclovir turned out to be an orally absorbable pro-drug of penciclovir. *See* Slip Op. at 14 (citing Koval Dec. Confidential Exs. 9-10).

Based on this evidence, the District Court found Novartis unlikely to prevail on obviousness. *See* Slip Op. at 18, 30. The evidence amply supported the District Court's conclusion that a person of skill in the art would have combined familiar elements (penciclovir) according to known methods (the prior art methods of optimizing the penciclovir analogs) to yield a predictable result (an orally absorbable pro-drug) and thereby obtained famciclovir. *See* Broom Dec. ¶¶ 58-66; Smee Rpt. 35-50. As the Supreme Court recently ruled, such a combination "is likely to be obvious." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007).

Moreover, the District Court recognized that to overcome *eight* obviousness rejections during the prosecution of the '937 patent, the applicants repeatedly told the examiner that the "prior art as a whole" taught that methylene compounds such as penciclovir were not "effective" and "should not work." Slip Op. at 19; *see also* Koval Dec. Ex. 7. When they made these representations, the applicants concealed prior art references that taught precisely the opposite, i.e., that penciclovir and similar methylene compounds had strong antiviral activity. *See* Slip Op. at 19, 22. They also

submitted a declaration that stated that penciclovir was not toxic in MRC-5 cells and they argued that this was “surprising and unexpected.” *See* Broom Dec. Ex. 18. But they concealed that penciclovir’s non-toxicity in such cells was in fact disclosed *in Beecham’s own published prior art patent application*. *See* Slip Op. at 23; *see also* Broom Dec. ¶¶ 35- 38, 83, 121.

The high level of materiality of these misrepresentations, known to the applicants, coupled with the absence of any credible legitimate explanation for them, amply supported the District Court’s inference of intent to deceive and its finding that Novartis was unlikely to prevail on inequitable conduct.

Novartis also failed to show that it would suffer any irreparable harm from Teva’s sale of generic famciclovir products. To be sure, Novartis faced the economic harm that any monopolist faces from the introduction of competition: the prospect of lower sales or reduced profit margins. But the District Court correctly recognized such harm is reparable by an award of money damages in the event that Novartis prevails in this case. *See* Slip Op. at 27; *see also* Leffler Dec. ¶¶ 11-17.

Indeed, in this case only the *grant* of an injunction pending appeal can give rise to harm that is truly irreparable. If Novartis prevails, an award of damages for patent infringement will make it whole. But if the District Court is correct that the ‘937 patent is invalid and unenforceable, then

enjoining Teva from competing with Novartis takes money from patients and their insurers and transfers it to Novartis as unwarranted monopoly profits. Even with a sizable bond — which would be warranted under Fed. R. App. P. 8(a)(2)(E)<sup>4</sup> — there is no easy way to restore *to the public* the monopoly profits that Novartis would have extracted.

### *Argument*

#### **I. Standards governing injunctions pending appeal**

An injunction pending appeal under Fed. R. App. P. 8(a) turns on four factors: (i) likelihood of success on the merits of the appeal, (ii) irreparable injury in the absence of an injunction, (iii) effect of the injunction on the non-moving party and other persons, and (iv) the public interest. *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990). While similar to the preliminary injunction standard under Fed. R. Civ. P. 65, the merits question here is not whether Novartis is likely to prevail in the lawsuit (as it was in the District Court), but rather whether Novartis is likely to prevail in its appellate challenge to the District Court's denial of a preliminary injunction. Since that decision is reviewed under an

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<sup>4</sup> If the Court intends to grant an injunction pending appeal, Teva requests an opportunity to make a further submission on the size of the injunction bond. Since the current annual sales for Famvir®, Novartis' famciclovir product, is currently about \$160 million (Novartis Mot. at 3), a very large bond would be required.

abuse of discretion standard, Novartis faces the difficult task on appeal of demonstrating that the District Court “made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings.” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997).

Novartis never acknowledges that it must establish an abuse of discretion, and does not seriously attempt to do so. It identifies no errors of law committed by the District Court. Novartis cites its own evidence and contends that that evidence supported a finding that the ‘937 patent was valid and enforceable. But that is not enough. As this Court very recently stressed, appellants “do not inform us why the district court was not entitled to rely on the evidence favorable to [Teva] or demonstrate that the evidence favorable to them heavily outweighed the evidence favorable to [Teva.]” *Forest Laboratories, Inc. v. IVAX Pharmaceuticals, Inc.*, No. 2007-1059, Slip op. at 9 (Fed. Cir. Sept. 5, 2007). As explained below, Novartis has not established an abuse of discretion.

**II. The District Court did not abuse its discretion or clearly err in finding Novartis unlikely to succeed on the merits of its claim.**

**A. *The District Court did not abuse its discretion or clearly err in finding that Teva had raised a substantial question concerning the validity of the ‘937 patent.***

