No. 07-912

IN THE

Supreme Court of the United States

APOTEX, INC. and APOTEX CORPORATION,

Petitioners,

v.

ABBOTT LABORATORIES,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Circuit correctly ruled that, even where no contempt sanction could properly be imposed against petitioners, the district court did not abuse its discretion by conducting proceedings to examine whether its prior injunction had been violated, by making factual findings incident to that inquiry, and by modifying its injunction according to those findings to prohibit petitioners' new infringing activities, which involved using another corporation as a "subterfuge" and "stalking horse" for performing the same activities previously enjoined.

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

There is no public corporation that owns 10% or more of the stock of respondent Abbott Laboratories.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT ii

TABLE OF AUTHORITIES v

BRIEF IN OPPOSITION 1

STATEMENT 2

I. Abbott's Patents 2

II. Litigation History 2

A. The Apotex ANDA Litigation 2

B. The Nu-Pharm ANDA Litigation 4

1. Petitioners Enlist Nu-Pharm In Their Effort To Avoid The 2004 Injunction 4

2. Acting Through Nu-Pharm, Apotex Succeeded In Provoking New Litigation With Abbott 6

C. The Enforcement Proceedings Before Judge Posner And Subsequent Appeal 8

D. Nu-Pharm Sues The FDA 10

REASONS FOR DENYING THE WRIT 11

CONCLUSION 19

TABLE OF AUTHORITIES

Page

Cases

Abbott Labs. v. TorPharm, Inc.,
503 F.3d 1372 (Fed. Cir. 2007) 7
Abbott Labs. v. TorPharm, Inc.,
122 F. App'x 511 (Fed. Cir. 2005) 4
Abbott Labs. v. TorPharm, Inc.,
300 F.3d 1367 (Fed. Cir. 2002) 2, 3
Abbott Labs. v. TorPharm, Inc.,
455 F. Supp. 2d 831 (N.D. Ill. 2006) 4, 7
Abbott Labs. v. TorPharm, Inc.,
309 F. Supp. 2d 1043 (N.D. Ill. 2004) 3
Abbott Labs. v. TorPharm, Inc.,
156 F. Supp. 2d 738 (N.D. Ill. 2001) 3
Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc., 154 F.3d 1345 (Fed. Cir. 1998) 12
Cal. Artificial Stone Paving Co. v. Molitor,
113 U.S. 609 (1885) 13, 14
Collins v. Barry,
841 F.2d 1297 (6th Cir. 1988) 15
Conoco, Inc. v. Energy & Envtl. Int'l, L.C.,
460 F.3d 1349 (Fed. Cir. 2006) 13
Cooke v. United States,
267 U.S. 517 (1925) 14
Decade Indus. v. Wood Tech., Inc.,
145 F. Supp. 2d 1075 (D. Minn. 2001) 13
Doe v. Bush,
261 F.3d 1037 (11th Cir. 2001) 16
Ex parte Fisk,
113 U.S. 713 (1885) 14
FTC v. Enforma Natural Prods., Inc.,
362 F.3d 1204 (9th Cir. 2004) 15

TABLE OF AUTHORITIES
(Continued)

Page

FTC v. Kuykendall,
371 F.3d 745 (10th Cir. 2004) 15
Ferrell v. U.S. Dep't of Hous. & Urban Dev.,
186 F.3d 805 (7th Cir. 1999) 15
Fonar Corp. v. Deccaid Servs., Inc.,
983 F.2d 427 (2d Cir. 1993) 15
Hicks v. Feiock,
485 U.S. 624 (1988) 14
Imageware, Inc. v. U.S. W. Commc'ns,
219 F.3d 793 (8th Cir. 2000) 15
KSM Fastening Sys., Inc. v. H.A. Jones Co.,
776 F.2d 1522 (Fed. Cir. 1985) 12, 13, 14
Karaha Bodas Co. v. Perushaan Pertambangan Minyak Dan Gas Bumi Negara, 335 F.3d 357 (5th Cir. 2003) 15
Proctor v. State Gov't of N.C.,
830 F.2d 514 (4th Cir. 1987) 15
Rufo v. Inmates of Suffolk County Jail,
502 U.S. 367 (1992) 13
Shepherd v. Am. Broad. Cos.,
62 F.3d 1469 (D.C. Cir. 1995) 15
United Elec., Radio & Mach. Workers of Am. v. 163 Pleasant St. Corp., 960 F.2d 1080 (1st Cir. 1992) 16
United States v. Johnston,
268 U.S. 220 (1925) 18
United States v. Spectro Foods Corp.,
544 F.2d 1175 (3d Cir. 1976) 15

TABLE OF AUTHORITIES
(Continued)

Page

Statutes

21 U.S.C. § 355(b)(2)(A)(iv) 6
21 U.S.C. § 355a(c)(1)(B) 2, 18
35 U.S.C. § 271(e)(2) 3
35 U.S.C. § 271(e)(4) 16

BRIEF IN OPPOSITION

Respondent Abbott Laboratories respectfully requests that this Court deny the petition for a writ of certiorari for three basic and fundamental reasons:

First, the decision below presents no conflict among the circuits, and is perfectly in keeping with this Court's decisions. The Federal Circuit did no more than follow the sound and established law recognizing that a trial judge has the inherent authority to modify an injunctive order where the facts warrant such an action, regardless of whether a contempt sanction ultimately is imposed for violation of the original order. Contrary to petitioners' suggestion, the modification of an injunction, and the factual findings that undergird such a modification, are not "contempt remedies" that are forbidden if unaccompanied by an ultimate contempt sanction.

Second, once petitioners' misconception of the law is cleared away, all that remains is the Federal Circuit's decision—rendered after a decade of fierce litigation between the parties, including three appeals—that the trial court did not abuse its discretion in modifying an injunction to capture petitioners' proposed infringing product, where the record established that the product proposed to be manufactured under the new Abbreviated New Drug Application (ANDA) was identical to an ANDA product previously adjudged infringing and enjoined after a trial. Such a factbound decision scarcely warrants this Court's attention.

Third, there is little, if anything, at stake here. The patents-in-suit have expired, and this matter unquestionably will become moot no later than July 30, 2008, when Abbott's statutory period of pediatric

exclusivity comes to an end. Even setting aside the other significant reasons to deny review, the procedural posture and imminent mootness of the dispute renders this case an exceedingly poor vehicle to resolve the questions presented.

STATEMENT

Petitioners' recitation of the facts is highly selective, and in many respects incomplete and materially inaccurate. The facts germane to the issues presented to this Court are as follows:

I. Abbott's Patents

Abbott owns two patents that cover divalproex sodium, the active ingredient in Depakote®—a product widely prescribed in treatment of epilepsy, bipolar disorder, and migraine headaches. The patents have been adjudged valid and enforceable. *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1381 (Fed. Cir. 2002) (*Abbott II*). Both patents expired on January 29, 2008. Having completed extensive pediatric studies, Abbott has been awarded an additional period of regulatory exclusivity by the U.S. Food and Drug Administration (FDA) that will prevent final approval of any generic divalproex sodium products until after July 29, 2008. *See* 21 U.S.C. § 355a(c)(1)(B).

II. Litigation History

A. The Apotex ANDA Litigation.

In April 1997, petitioners (through a division formerly known as TorPharm, Inc.) submitted Abbreviated New Drug Application No. 75-112 (the Apotex ANDA) to the FDA, seeking approval to market a generic copy of Depakote® prior to the expiration of Abbott's patents. *Abbott Labs. v.*

TorPharm, Inc., 156 F. Supp. 2d 738, 739-40 (N.D. Ill. 2001) (*Abbott I*); *Abbott Labs. v. TorPharm, Inc.*, 309 F. Supp. 2d 1043, 1044 (N.D. Ill. 2004) (*Abbott III*). Abbott sued for patent infringement under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), and secured summary judgment on all issues before the United States District Court for the Northern District of Illinois. *See Abbott I*, 156 F. Supp. 2d at 747-49.

In the first of three appeals to the Federal Circuit, the court upheld summary judgment in Abbott's favor as to all issues save one, remanding the case for trial with respect to infringement of a single claim limitation (whether petitioners' product was an "oligomer"—a molecule comprised of a relatively small number of repeating units joined together). *See Abbott II*, 300 F.3d at 1381.

After a trial on the merits, Circuit Judge Richard A. Posner, sitting by designation in the district court, ruled that petitioners' product was infringing. *See Abbott III*, 309 F. Supp. 2d at 1054. On March 31, 2004, he issued an injunction order directing that:

> [Defendants], and their respective affiliates, successors in interest, and assigns are enjoined from commercially manufacturing, using, selling, or offering to sell generic divalproex sodium which the Court has found to be infringing within the United States, or from importing such product into the United States, until Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326 expire and defendants have received final approval from FDA to market generic divalproex sodium.
>
> The effective date for any approval by FDA of ANDA No. 75-112, *or any other application*

> *concerning defendants' generic divalproex sodium which the Court has found to be infringing*, shall be no earlier than January 29, 2008, the date of expiration of Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326.

Pet. App. 4a-5a (emphasis added). In the second appeal, the Federal Circuit affirmed in all respects. *Abbott Labs. v. TorPharm, Inc.*, 122 F. App'x 511 (Fed. Cir. 2005) (*Abbott IV*).

B. The Nu-Pharm ANDA Litigation.

1. Petitioners Enlist Nu-Pharm In Their Effort To Avoid The 2004 Injunction.

Even before the conclusion of the trial before Judge Posner, petitioners feared a loss and therefore put in motion plans to submit a new ANDA, hoping to provoke new litigation against Abbott and to secure different rulings from a new judge. *Abbott Labs. v. Apotex, Inc.*, 455 F. Supp. 2d 831, 835 (N.D. Ill. 2006) (*Abbott V*). Petitioners' CEO, Barry Sherman, revised the manufacturing processes for making the divalproex sodium product that was adjudged to be infringing and enjoined. Despite Sherman's express belief that the revised product might be even "more likely to infringe" Abbott's patents than the product already enjoined, petitioners did not commission a single scientific test to determine whether the revisions to the manufacturing process actually resulted in a different product. Pet. App. 34a. Nevertheless, within weeks of the 2004 injunction order, Sherman directed that his revised product be submitted for approval in a new ANDA.

However, there remained the question of who would actually be the applicant for the new ANDA.

Apotex, the applicant for the earlier ANDA, is the largest generic pharmaceutical manufacturer in Canada, and among the largest in the world. *See* Pet. App. 43a. The company admittedly had no need for outside assistance to prepare or submit the new ANDA, nor to market the revised product were it to be approved by FDA. Because of the existing injunction, however, Apotex was concerned about filing the new ANDA in its own name. Instead, Apotex determined that the new ANDA would be submitted in the name of Nu-Pharm, Inc.—a six-person company formerly owned by Apotex, and whose sole business is to market and sell re-labeled Apotex products in Canada. Pet. App. 30a-31a.

Although petitioners claim that Nu-Pharm "took on the R&D costs" associated with the revised product as part of some arrangement with petitioners (Pet. 8), that is false. Nu-Pharm's president has sworn that his company's only role in this process was (i) to receive ANDA documents prepared by petitioners, print them on Nu-Pharm letterhead, and sign as instructed by petitioners; and (ii) to fund new litigation against Abbott. C.A. App. A2161, 2164-65, 3375-80, 3899, 3902-04. Nu-Pharm thus served only as a nominal ANDA applicant: It has no ownership rights in the product; had nothing to do with the development or biotesting of the product; and did not participate in any way (other than printing and signing) in the preparation or submission of the ANDA. Indeed, Nu-Pharm was not even told that it would serve as the ANDA applicant until months after the decision was made at Apotex. C.A. App. A2159-60, 2177, 3527.

There is no contract or license between Nu-Pharm and Apotex relating to this product (C.A. App. A2110-11, 2163), despite the fact that, had it been approved, it would have been the first generic version of a drug (Depakote®) with annual sales revenues topping $1 billion. When asked why petitioners would even consider sharing this opportunity with Nu-Pharm, Apotex CEO Sherman testified that, "I am giving them money. They are taking on the litigation [against Abbott], and they are earning it." Because Apotex, not Nu-Pharm, owns the product, Sherman reasoned that, if the product were ever marketed, "we will get our profit out of it, anyway." C.A. App. A2108.

2. Acting Through Nu-Pharm, Apotex Succeeded In Provoking New Litigation With Abbott.

In March 2005, petitioner Apotex Corp. submitted (on behalf of Nu-Pharm) ANDA No. 77-615 (the Nu-Pharm ANDA) to the FDA, seeking approval of Apotex's "redesigned" divalproex sodium product. The Nu-Pharm ANDA included a Paragraph IV certification, *see* 21 U.S.C. § 355(b)(2)(A)(iv), attesting that the product described in the ANDA would not infringe Abbott's patents, and thus should be approved by FDA prior to the patents' expiry.

Petitioners state that Nu-Pharm made an "independent assessment" of infringement prior to submitting that certification to FDA. Pet. 8. This, too, is false. The certification was prepared by Apotex, and Nu-Pharm's president, Richard Benyak, was directed to sign it. Benyak has testified that neither he nor anyone at Nu-Pharm knew anything about the science underlying the product, nor

whether it in fact infringed Abbott's patents, and they commissioned no tests to find out. Instead, Benyak signed the certification simply because "an ANDA wouldn't be filed if it was obviously an infringing product, to my way of thinking." C.A. App. A2167, 2857. For the certification of non-infringement, as with everything else, Nu-Pharm relied completely on Apotex. Yet, despite its own concern that the revised product might be even "more likely to infringe" than the earlier, enjoined product (C.A. App. A2091, 2096), Apotex commissioned no scientific testing to support the assertions of non-infringement in the Paragraph IV certification before presenting it to Nu-Pharm for signature. C.A. App. A2112, 2088.

As required by statute, Nu-Pharm's counsel (the same counsel representing petitioners here and in *Abbott I, II, III, IV, V,* and *VI*) sent notice of the Nu-Pharm ANDA to Abbott. The notice made no mention of Apotex. Under the Hatch-Waxman Act, Abbott had 45 days from receipt of this notice to file a lawsuit to protect its patent rights, and it did so on June 24, 2005. *See Abbott V*, 455 F. Supp. 2d at 835 (referring to *Abbott Labs. v. Nu-Pharm, Inc.*, No. 05 C 3714 (N.D. Ill.) (the Nu-Pharm Litigation)). The suit was assigned to Judge Rebecca Pallmeyer. *Id.* When Nu-Pharm produced the ANDA in discovery, Abbott learned for the first time that Apotex was involved, though its role was described in the ANDA merely as a contract manufacturer. Abbott amended its complaint in the Nu-Pharm Litigation to add claims against petitioners for direct and induced infringement. *See Abbott Labs. v. Apotex, Inc.*, 503 F.3d 1372, 1377 (Fed. Cir. 2007) (*Abbott VI*). Petitioners moved to dismiss, insisting that the Nu-

Pharm ANDA "ha[d] nothing to do with [them]." C.A. App. A3551. That motion remains pending.

C. The Enforcement Proceedings Before Judge Posner And Subsequent Appeal.

Through its own scientific testing, Abbott confirmed that the product described in the Nu-Pharm ANDA is identical to that previously adjudged infringing and enjoined by Judge Posner. Then, in July 2006, Abbott conducted the depositions of Apotex CEO Sherman and Nu-Pharm president Benyak, where Abbott learned for the first time the full nature of Apotex's control of all aspects of the Nu-Pharm ANDA—including the fact that the Nu-Pharm ANDA product does not belong to Nu-Pharm at all, but is instead owned outright by Apotex. Armed with its scientific testing and these critical admissions, Abbott returned to Judge Posner and asked that he enforce the original 2004 injunction order (which, by its terms, barred FDA approval of any ANDA concerning the same infringing product) against the Nu-Pharm ANDA. Pet. App. 26a-27a, 31a-32a. Nu-Pharm elected to have its interests represented by petitioners in the enforcement proceedings (and the lawyers were the same in any event, since the two companies then shared, and continue to this day to share, the same counsel).

After briefing from both sides, Judge Posner held a hearing on August 30, 2006. Pet. App. 32a. On October 6, 2006, Judge Posner granted Abbott's motion and extended the injunction order to cover the Nu-Pharm ANDA. Of note, the court found that "[t]he product for which Nu-Pharm filed the ANDA had been developed by Apotex, is owned by it, and, as Sherman has testified, we [Apotex] will get our profit

out of it, anyway." Pet. App. 30a-31a. Apotex's choice of Nu-Pharm to file the ANDA was, the court concluded, merely "a subterfuge intended to give Apotex a crack at another district judge, who might, in an infringement suit by Abbott, conclude that it was a different, and noninfringing, product from the one I had enjoined." Pet. App. 31a. As to the question of infringement, the court found that "there is no difference at all" between the Nu-Pharm ANDA product and the one previously found infringing and enjoined in 2004 (Pet. App. 37a), and that the fresh infringement evidence presented at the hearing relating to the redesigned "Nu-Pharm" product (including testimony and studies from three experts for petitioners) "overwhelmingly favor[ed] Abbott." Pet. App. 41a.

Based upon these findings, Judge Posner concluded that "[t]he injunction has been violated. Should the violation continue, Apotex—a large, successful, and sophisticated enterprise—will be risking heavy sanctions for its willful disobedience of the injunction. *For the present, however, it will suffice to extend the injunction to embrace the Nu-Pharm ANDA.*" Pet. App. 43a (emphasis added). The court thus revised its original injunction order so as to make clear that "[t]he effective date of any approval by FDA of ANDA Nos. 75-112 [the Apotex ANDA] and 77-615 [the Nu-Pharm ANDA], or any other application concerning defendants' generic divalproex sodium which the Court has found to be infringing, shall be no earlier than January 29, 2008, the date of expiration of Abbott's [patents]." C.A. App. A2.

In the third appeal, the Federal Circuit ruled that petitioners were not in contempt of the 2004

injunction, because that order did not provide "explicit notice" to petitioners that they were prohibited from using another company as a "straw party" to submit a new ANDA for a redesigned, but equally infringing, product. Pet. App. 19a-20a. Even absent an ultimate sanction of contempt, however, the Federal Circuit recognized the trial court's authority to conduct proceedings to examine whether its earlier injunction had been violated, to make factual findings, and to modify the original injunction to address new infringing activity. *Id.* Based upon the detailed factual record, the Federal Circuit ruled that the district court had not abused its discretion in finding the Nu-Pharm ANDA product to be infringing and in modifying the 2004 injunction to bar FDA approval of that ANDA until after the expiry of Abbott's patents. Pet. App. 14a-16a. Petitioners' subsequent request for panel and/or en banc rehearing was denied. Pet. App. 44a-45a.

D. Nu-Pharm Sues The FDA.

On January 14, 2008, just days after filing this petition for a writ of certiorari, petitioners' counsel (this time ostensibly on behalf of Nu-Pharm) instituted an action in the U.S. District Court for the District of Columbia against the FDA and certain senior officials, followed immediately by a motion for a temporary restraining order or preliminary injunction, demanding immediate approval of the Nu-Pharm ANDA prior to the expiry of Abbott's patents. With no notice to Abbott, Nu-Pharm urged the D.C. court to find that it was arbitrary and capricious for FDA to follow Judge Posner's modified 2006 injunction (by this time upheld by the Federal

Circuit), and to order the agency to disregard that injunction and immediately approve the ANDA.

When Abbott learned of this action from FDA, it immediately sought leave to intervene and filed papers opposing the motion for emergency injunctive relief. After a hearing, the D.C. court denied the motion and declined to exercise any further jurisdiction over the case. Nu-Pharm is currently seeking review of that decision before the U.S. Court of Appeals for the D.C. Circuit.

REASONS FOR DENYING THE WRIT

1. The decision of the Federal Circuit was correct, and cannot colorably be alleged to conflict with any decision of any other court of appeals, or of this Court. The crux of petitioners' argument is that a district court in a patent dispute, faced with the contention that a "redesigned" product violates a previously-entered injunctive order, has only two choices: impose the extreme sanction of contempt on the alleged offender, or do nothing at all. Thus, petitioners claim that when the Federal Circuit ruled that petitioners were not technically in contempt of the 2004 injunction order, it was automatically required to vacate the modified injunction order entered by the district court in 2006 and to wash away all of the district court's underlying factual findings. The Federal Circuit correctly rejected this "contempt or nothing" approach.

As the Court of Appeals recognized (Pet. App. 12a-13a & n.3), the problem with petitioners' logic is that it ignores well-established precedent instructing that whether to hold summary contempt proceedings in a patent dispute, and whether to impose a contempt sanction at the culmination of such proceedings, are

two separate inquiries. *See KSM Fastening Sys., Inc. v. H.A. Jones Co.*, 776 F.2d 1522, 1525 (Fed. Cir. 1985) ("(1) when contempt proceedings will be entertained, and (2) when contempt will be found . . . are separate questions . . . "); *see also Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 154 F.3d 1345, 1349-50 (Fed. Cir. 1998) (same). Before ever considering whether to impose a contempt sanction, the trial court first "must address whether a contempt hearing is an appropriate forum for adjudging whether an allegedly redesigned product is infringing." Pet. App. 12a. This threshold determination requires the trial court to weigh the evidence and make a factual finding as to whether there is "'more than a colorable difference' between the accused product and the adjudged infringing product." *Id.* (quoting *KSM*, 776 F.2d at 1532). If such colorable differences are found to exist, then there are "'substantial open issues with respect to infringement,'" and a new lawsuit should be pursued, rather than summary contempt proceedings. Pet. App. 12a (quoting *KSM*, 776 F.2d at 1532); *see also Additive Controls*, 154 F.3d at 1349-50. Where the trial court determines that there are no "colorable differences," however, it can move forward in summary proceedings to adjudge whether the accused, redesigned product is infringing. Pet. App. 12a. If infringement is found by clear and convincing evidence, the trial court may, but certainly is not obligated to, impose a contempt sanction. *See* Pet. App. 16a.

The multi-step process carefully limned by the Federal Circuit in *KSM* and *Additive Controls* necessarily presupposes that there are some cases, like this one, where the facts demonstrate that

contempt *proceedings* are appropriate, even if an ultimate *finding of contempt* is not. In such cases, where new activity infringes the patents supporting a prior injunction, but does not come directly within the scope of that injunction, it is well recognized that the trial court can fashion a remedy of something less than contempt following summary proceedings. Most notably, a court may extend the prior injunction to clarify that it applies to the new infringing activity. *See Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1365 (Fed. Cir. 2006) (holding that, where an accused infringer's purportedly redesigned product was effectively no different from the product previously adjudged infringing, "a court may properly extend the injunction to the new device . . . ." without finding contempt); *Decade Indus. v. Wood Tech., Inc.*, 145 F. Supp. 2d 1075, 1076-77 (D. Minn. 2001) (following *KSM* and finding "redesigned" product to be infringing after summary proceedings, but not imposing contempt sanctions); *cf. Rufo v. Inmates of Suffolk County Jail*, 502 U.S. 367, 380 (1992) ("sound judicial discretion may call for the modification of the terms of an injunctive decree if the circumstances, whether of law or fact, obtaining at the time of issuance have changed, or new ones have since arisen") (internal quotation marks omitted). The Federal Circuit properly declined petitioners' invitation to strip trial judges of this longstanding equitable authority to modify injunctions absent a contempt sanction, a decision not in conflict with any precedent from this or other courts, or with the Hatch-Waxman Act itself.

a. Petitioners rely principally on this Court's 1885 decision in *California Artificial Stone Paving Co. v. Molitor*, 113 U.S. 609. *Molitor* was cited by the

dissent below for the general proposition that the "[p]rocess of contempt is a severe remedy, and should not be resorted to where there is fair ground of doubt as to the wrongfulness of the defendant's conduct." Pet. App. 21a (dissenting opinion) (quoting *Molitor*, 113 U.S. at 618). As the majority correctly rejoined, however, "[i]in patent infringement cases, this inquiry has been restated as whether there is a colorable difference between the accused and adjudged devices." Pet. App. 12a n.3 (citing *KSM*, 776 F.2d at 1536). Moreover, the dissent "d[id] not identify any colorable difference between the adjudged and accused products, and thus seems to agree that there was no 'fair ground of doubt' as to the lower court's determination of infringement." Pet. App. 13a n.3. The decision below thus comports with *Molitor*, and petitioners cannot tenably claim otherwise. (Indeed, they never cited *Molitor* in their briefs or argument before the panel.)

The remaining cases proffered by petitioners—which were likewise not cited by petitioners in their briefs or arguments before the Court of Appeals—are even less helpful to their cause. None of them even comes close to addressing the question whether a court may modify an injunction in lieu of finding a party in contempt. *See, e.g.*, *Cooke v. United States*, 267 U.S. 517, 532 (1925) (addressing process due to a lawyer accused of direct contempt of court); *Ex parte Fisk*, 113 U.S. 713, 726 (1885) (lower court lacked jurisdiction to issue the underlying order from which contempt was claimed and was therefore "equally without authority to enforce those orders by process for contempt"); *Hicks v. Feiock*, 485 U.S. 624, 640-41 (1988) (vacating judgment of contempt and remanding to allow the lower court to make

additional factual findings and consider legal arguments as to whether the contempt at issue was civil or criminal); *Fonar Corp. v. Deccaid Servs., Inc.*, 983 F.2d 427, 429 (2d Cir. 1993) (vacating a contempt sanction because the underlying order was unclear and ambiguous; the court left intact the underlying factual findings); *United States v. Spectro Foods Corp.*, 544 F.2d 1175, 1182 (3d Cir. 1976) (vacating contempt sanction where underlying injunctive order was invalid); *Imageware, Inc. v. U.S. W. Commc'ns*, 219 F.3d 793, 797 (8th Cir. 2000) (reversing contempt finding because the underlying protective order was ambiguous); *Proctor v. State Gov't of N.C.*, 830 F.2d 514, 521-22 (4th Cir. 1987) (vacating contempt order and remanding for factfinding where trial court failed to conduct an independent factfinding in the first instance); *Karaha Bodas Co. v. Perusahaan Pertambangan Minyak Dan Gas Bumi Negara*, 335 F.3d 357 (5th Cir. 2003) (contempt cannot lie where underlying injunction is invalid); *Collins v. Barry*, 841 F.2d 1297, 1300 (6th Cir. 1988) (contempt order was inappropriate where underlying law did not apply to plaintiff); *Ferrell v. U.S. Dep't of Hous. & Urban Dev.*, 186 F.3d 805, 813-14 (7th Cir. 1999) (intervening change in underlying law rendered contempt inappropriate); *FTC v. Enforma Natural Prods., Inc.*, 362 F.3d 1204, 1219 (9th Cir. 2004) (vacating one of two injunction orders because the trial court unilaterally altered a stipulated consent decree without giving the parties a chance to object); *FTC v. Kuykendall*, 371 F.3d 745, 759, 762 (10th Cir. 2004) (vacating contempt sanction based upon deficient factual support in the record); *Shepherd v. Am. Broad. Cos.*, 62 F.3d 1469, 1473-74 (D.C. Cir. 1995) (addressing the propriety of default judgment

as a discovery sanction); *United Elec., Radio & Mach. Workers of Am. v. 163 Pleasant St. Corp.*, 960 F.2d 1080, 1099 (1st Cir. 1992) (vacating contempt sanction because the underlying order was invalid for lack of jurisdiction); *Doe v. Bush*, 261 F.3d 1037, 1063-64 (11th Cir. 2001) (reversing contempt sanction where findings upon which sanction was based were legally or factually incorrect, but adding that "under appropriate circumstances and after the proper procedures have been followed, the original injunction in this case might have been modified to address the problems"). None of these decisions conflicts directly, let alone in principle, with the Court of Appeals' decision here.

b. Similarly, neither the Hatch-Waxman Act, nor the policies underlying it, conflicts in any way with the Federal Circuit's decision. Indeed, the authority to summarily modify an injunction is *especially* necessary in Hatch-Waxman Act litigation where, by statute, only injunctive relief is typically available. *See* 35 U.S.C. § 271(e)(4). The district court put it aptly: if petitioners' contrary position were correct, "[i]njunctions in pharmaceutical patent cases would be worthless and the Federal Circuit's characterization of contempt proceedings as a shield protecting the patentee against an infringer's flagrant disregard for court orders would be a sour joke." Pet. App. 42a. The facts of *this* case make that conclusion all the more apt, for petitioners used a "stalking horse" to submit a "new" ANDA covering the same product previously enjoined. As the Court of Appeals recognized,

> [s]ince neither infringement nor the inapplicability of the injunction to the accused conduct was

> doubtful, summary determination before the district court was appropriate. A different rule would require a defendant to participate in full litigation, even though he could be absolved summarily of contempt liability when, as here, there is no doubt about the issue at hand. Such a rule would serve neither defendant's due process interests nor judicial economy.

Pet. App. 13a n.3. The Act (like patent law generally) may promote good-faith efforts to design around patents, but that is *not* what happened here. To the contrary, the district court found that Apotex CEO Sherman's "failure to conduct any scientific testing and his cavalier disregard for judicial findings that the patent was valid and infringed by his original product, as well as his use of Nu-Pharm as a stalking horse, were the antithesis of good faith." Pet. App. 41a-42a. Nothing in the Act is designed to reward such "contumacy." *See* Pet. App. 35a.

2. Casting aside petitioners' "contempt or nothing" approach, all that remains is a challenge to the Federal Circuit's treatment of the underlying fact-finding by the district court. In particular, the Federal Circuit held that the district court did not abuse its discretion in holding summary contempt proceedings (based upon its finding that there was "no difference at all" between the product described in the Nu-Pharm ANDA and the product previously enjoined), and did not clearly err in finding, by clear and convincing evidence, that the "redesigned" Nu-Pharm ANDA product infringed Abbott's patents. Pet. App. 14a-15a. The Federal Circuit's decisions in this regard are inextricably linked to the detailed factual record developed before the trial court—

including extensive briefing, scientific documents, deposition testimony, expert reports, and live testimony of numerous scientific experts for both sides. Such hopelessly factbound determinations are inappropriate fodder for this Court. *See, e.g., United States v. Johnston*, 268 U.S. 220, 227 (1925) ("We do not grant a certiorari to review evidence and discuss specific facts.").

3. Finally, the unique posture of this case makes it an exceedingly poor vehicle for certiorari. For one, it is the rare case where, as here, an enjoined defendant employs a "stalking horse" in bad faith in order to avoid the terms of an injunction, and so this case would be an exceptionally poor vehicle for addressing the question presented.

More critically, however, is the fact that there is so little at stake here. The patents-in-suit already have expired, so Abbott can no longer sue any entity for patent infringement. The only thing that animates the case at this point is the fact that, having completed important studies showing the efficacy of Depakote® in children, Abbott has been awarded by FDA a period of *regulatory* exclusivity extending six months from the expiry of its patents, during which time no application for a generic divalproex sodium product can be approved by FDA. *See* 21 U.S.C. § 355a(c)(1)(B). That pediatric exclusivity period will expire on July 29, 2008 (barely more than three months from the filing of this brief), and that expiration will open the door for generic approvals from all proper applicants, and render this case unquestionably moot. Thus, even were the Court otherwise inclined to examine the "contempt or nothing" standard advocated by petitioners, which it

need not do, it surely should not undertake this task in a matter where so little is at stake at this point.

* * * *

In light of the factbound nature of this case, the absence of any conflict within or among the circuit courts, the correctness of the decision below, and the fact that so little is at stake at this point, the petition presents no colorable basis for review.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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