

No. 2012-1334, -1335

---

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

---

FRESENIUS USA, INC.  
AND FRESENIUS MEDICAL CARE HOLDINGS, INC.,

*Plaintiffs-Appellants,*

v.

BAXTER INTERNATIONAL, INC.  
AND BAXTER HEALTHCARE CORPORATION,

*Defendants-Cross Appellants.*

---

Appeals From The United States District Court For The Northern District Of  
California In Case No. 03-CV-1431, Judge Phyllis J. Hamilton

---

**BRIEF FOR THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AS  
*AMICUS CURIAE* SUPPORTING REHEARING OF THE PANEL  
DECISION**

Principal Counsel:  
MICHAEL A. GOLLIN  
VENABLE LLP  
575 7th Street, NW  
Washington, DC 20004  
Telephone (202) 344-4000  
Fax (202) 344-8300

Counsel for Biotechnology  
Industry Organization

August, 15, 2013

Of Counsel:  
WILLIAM D. COSTON  
MARTIN L. SAAD  
CHRISTOPHER S. CROOK  
VENABLE LLP  
575 7th Street, NW  
Washington, DC 20004  
Telephone (202) 344-4000  
Fax (202) 344-8300

## CERTIFICATE OF INTEREST

Counsel for *amicus* certifies the following:

1. The full names of every party or *amicus* represented by us are:

Biotechnology Industry Organization

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 us is:

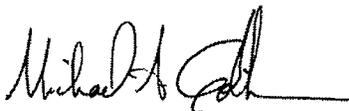
Not applicable.

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 us are:

None.

4. The names of all law firms and the partners or associates who appeared for the party or *amicus* now represented by us in the trial court or agency or are expected to appear in this Court are:

Venable LLP (Michael A. Gollin, William D. Coston, Martin L. Saad, and Christopher S. Crook) is appearing for Biotechnology Industry Organization in this Court.



---

Michael A. Gollin

Dated: August 15, 2013

**TABLE OF CONTENTS**

	<u>Page</u>
IDENTITY AND INTEREST OF <i>AMICUS CURIAE</i> .....	1
ARGUMENT .....	2
I. REHEARING IS NEEDED TO REVISIT THE PANEL’S “FINAL JUDGMENT” REQUIREMENT .....	4
II. REHEARING IS NEEDED TO RESOLVE AMBIGUITY WITHIN FEDERAL CIRCUIT PRECEDENT .....	5
III. REHEARING IS NEEDED TO ADDRESS HOW EQUITABLE FACTORS SHOULD BE CONSIDERED .....	7
CONCLUSION .....	11

**TABLE OF AUTHORITIES**

<u>Cases</u>	<u>Page(s)</u>
<i>Amado v. Microsoft Corp.</i> , Case No. SA-CV-03-242, 2007 U.S. Dist. LEXIS 96487 (C.D. Cal. Mar. 13, 2007) .....	9
<i>In re Baxter</i> , 698 F.3d 1349 (Fed. Cir. 2012) .....	4,6
<i>Central Soya Co. v. George A. Hormel &amp; Co.</i> , 723 F.2d 1573 (Fed. Cir. 1983) .....	8
<i>Flexiteek v. Plasteak et al.</i> , Case No. 08-60996-civ-Cohen/Seltzer, 2012 U.S. Dist. LEXIS 156086 (S.D. Fla. Sept. 10, 2012) .....	8-9
<i>Mendenhall v. Barber-Greene Co.</i> , 26 F.3d 1573 (Fed. Cir. 1994).....	4,5,8,10
<i>In re Swanson</i> , 540 F.3d 1368 (Fed. Cir. 2008) .....	5-6
 <u>Other Authority</u>	
35 U.S.C. § 314(b).....	7
35 U.S.C. § 316(a)(11).....	7
Federal Rule of Appellate Procedure 29(a) .....	2
Federal Rule of Appellate Procedure 29(c)(5).....	2
Federal Rule of Civil Procedure 60(b) .....	8
<i>Inter Partes</i> Reexamination Filing Data, <a href="http://www.uspto.gov/patents/stats/">http://www.uspto.gov/patents/stats/</a> (last visited August 13, 2013) (providing statistics from 11/29/99 through 9/30/12) .....	7

## **IDENTITY AND INTEREST OF *AMICUS CURIAE***

The Biotechnology Industry Organization (“BIO”) is the country’s largest biotechnology trade association, representing over 1,100 companies, academic institutions, and biotechnology centers in all 50 states and in countries around the world. BIO members undertake research and development of biotechnological healthcare, agricultural, environmental, and industrial products. BIO members range from start-up businesses and university spin-offs to Fortune 500 corporations. The vast majority of BIO’s members are small companies that have yet to bring products to market or to attain profitability and, thus, depend on venture capital and other private investment for their growth.

Biotechnology products typically require close to a decade of development work and a fully capitalized investment that can approach \$1.2 billion. Biotechnology companies rely heavily on patents to protect such substantial investments of time, resources, and capital. Devaluation of patent assets leads to a reduced incentive for companies to research, develop, and commercialize new biotechnology products that heal, feed, and fuel the world.

To ensure enforceable patent rights, patent owners need clarity regarding the circumstances under which an Article III court decision on patent validity may be nullified by a subsequent invalidity determination of the U.S. Patent and Trademark Office (“PTO”) in a concurrent reexamination or review proceeding.

For the reasons explained below, BIO believes that the rule announced by the panel majority in this case stands in tension with prior decisions of this Court and other circuits. The resulting uncertainty over the standards that govern the impact of a PTO proceeding on conclusively litigated and decided issues in concurrent federal court litigation deserves to be addressed *en banc*.

BIO expresses no views on the outcome of this case or disposition of issues other than those addressed in this brief. BIO has no commercial interest in the parties to this action. Baxter International, Inc. and Baxter Healthcare Corporation are members of BIO. Pursuant to Federal Rule of Appellate Procedure 29(c)(5), BIO states that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than BIO, their members, or their counsel made a monetary contribution to its preparation or submission. Pursuant to Federal Rule of Appellate Procedure 29(a), all parties have consented to the filing of this brief.

### **ARGUMENT**

In a split decision issued on July 2, 2013, a panel of this Court appears to announce a bright-line rule that requires automatic dismissal of a patent infringement claim in a federal court litigation – no matter what stage of the litigation – in the event of a subsequent invalidity determination by the PTO in a

co-pending reexamination proceeding. In effect, the panel majority held that the PTO's invalidity determination divests the court of jurisdiction, thereby nullifying a prior ruling of no-invalidity without any consideration of equitable factors. The present ruling is in tension with prior decisions of this Court and other circuits which have, under similar circumstances, applied the equitable doctrines of issue or claim preclusion, allowing consideration of fairness and judicial economy.

Whether considerations of equity, fairness, and judicial economy may play a role in gauging the impact of a PTO decision on issues conclusively litigated in federal court is worthy of this Court's *en banc* attention. As explained in Judge Newman's dissent, the panel decision appears to be a departure from accepted issue preclusion doctrine already in existence and regularly applied in federal courts, including the Federal Circuit.

BIO is concerned that the panel decision could have a number of unintended consequences, such as incentivizing defendants (or declaratory judgment plaintiffs) to employ dilatory tactics in the federal courts while re-arguing already-decided issues under claim construction more favorable to the patent challenger and lower burden-of-proof standards in the PTO. Courts and parties may be forced to expend considerable time and resources litigating matters that may ultimately become moot. Such uncertainty would not be conducive to innovation or investment.

**I. REHEARING IS NEEDED TO REVISIT THE PANEL'S "FINAL JUDGMENT" REQUIREMENT.**

A keystone of the panel's ruling in *Fresenius II* is the finding that the prior no-invalidity rulings by the district court and this Court did not constitute a "final judgment" on that issue for purposes of *res judicata* or issue preclusion.

The general rule is that a PTO decision will not alter a "final court judgment." Maj. Op. at 26; *In re Baxter*, 698 F.3d 1349, 1351 (Fed. Cir. 2012) (concurrency). The majority in *Fresenius II* held that a judgment is final only when "the litigation [is] entirely concluded so that the cause of action against the infringer was merged into a final judgment, one that ends the litigation on the merits and leaves nothing for the court to do but execute the judgment." Maj. Op. at 28 (citing *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1580 (Fed. Cir. 1994)). The panel majority appears to take the position that, so long as there is any issue still alive in a litigation, a subsequent PTO decision on validity is an intervening legal development to which federal courts must invariably "give effect" in the concurrent litigation. Maj. Op. at 32, 34. Under the panel decision, courts must give effect to the PTO's claim cancellation no matter the circumstances.

As noted in Judge Newman's dissent, the panel's holding does not appear to sufficiently account for the possibility of issue preclusion. Dissent Op. at 67-76. Issue preclusion, like the related "law of the case" doctrine, stands for the

proposition that courts, absent special circumstances, will generally not revisit a prior ruling on an issue that was fairly litigated and conclusively decided.

*Mendenhall*, 26 F.3d at 1582. Issue preclusion is necessary for an efficient legal system that decides disputes rather than perpetuates them, and provides certainty to litigants. As Judge Newman explains in dissent, a decision by a court does not have to resolve all outstanding issues in a case in order to be “final” for purposes of a particular issue. Dissent Op. at 67-76 (citing cases from each federal appellate circuit).

## **II. REHEARING IS NEEDED TO RESOLVE AMBIGUITY WITHIN FEDERAL CIRCUIT PRECEDENT.**

Even within the Federal Circuit there appears to be uncertainty as to the impact of concurrent PTO decisions and prior rulings in patent litigation. Prior opinions from this Court indicate that an adverse decision in a concurrent reexamination raises questions of issue or claim preclusion, which must be raised as an affirmative defense and require consideration of a number of factors, rather than be given automatic effect. Judge Newman opines in her dissent that the impact of the PTO’s decision on the no-invalidity decision rendered by the district court and affirmed by this Court is governed by “finality and preclusion.” Dissent Op. at 67.

Other Judges in the Federal Circuit have likewise expressed reservations regarding whether a PTO decision may automatically nullify an earlier decision of

a federal court. In *In re Swanson*, this Court cautioned against the reopening of final court decisions based upon administrative action. *See* 540 F.3d 1368, 1379 n.5 (Fed. Cir. 2008). And in *In re Baxter*, a concurring opinion by Judge O'Malley, Chief Judge Rader, and Judge Linn stated:

These conclusions do not mean, however, that, when the PTO does act in the context of a reexamination proceeding its conclusions can alter the binding effect of a prior binding judgment in a judicial proceeding. . . . Well-established principles of *res judicata* will govern the continuing relationship between the parties to any court proceeding and will dictate whether the PTO's reexamination ruling will have any impact on them going forward.

*In re Baxter*, 698 F.3d at 4-5.

BIO submits that “well-established principles of *res judicata*” do not automatically extinguish a patentee's cause of action as under the panel majority's rule. *Res judicata* depends on a careful consideration of the relationship of the parties, their claims for relief against each other, the transaction or occurrence that gave rise to the litigation, and other factors. The panel's bright-line rule operates automatically, without regard to choices made by the parties during years of litigation, and without inquiry as to whether the parties should be bound by such choices.

District courts will increasingly need to address the priority between a final judicial ruling and an administrative decision given the passage of the American Invents Act (“AIA”), which expanded a variety of post-grant opposition

opportunities. Despite safeguards that confine requests for concurrent PTO review to a limited window after initiating civil action, such administrative proceedings still invite conflict with court proceedings. Indeed, of the 1,919 challenges that were filed since November 1999, 66% were in concurrent litigation. *See Inter Partes Reexamination Filing Data*, <http://www.uspto.gov/patents/stats/> (last visited August 13, 2013) (providing statistics from 11/29/99 through 9/30/12).

In addition, the number of filings for post-grant *inter partes* reexamination has gone up each year. While an *inter partes* reexamination used to take three to four years, the PTO has committed to trying to resolve future *inter partes* reviews in 18 months. *See* 35 U.S.C. § 314(b) (Director must decide whether to institute IPR within 3 months of petition filing); 35 U.S.C. § 316(a)(11) (Final determination of IPR required to issue no later than one year after Director notices institution of review unless Director extends the period by not more than six months for good cause). Couple the increase in reexaminations with the PTO's goal of completing a given reexamination within a year-and-a-half, the impact of determinations from the PTO on concurrent litigation will surface more frequently in the near future. As a result, courts and litigants need certainty on this issue.

### **III. REHEARING IS NEEDED TO ADDRESS HOW EQUITABLE FACTORS SHOULD BE CONSIDERED.**

The Court should rehear the panel decision to evaluate how judges may take equitable considerations into account in determining the impact of PTO

determinations on prior Article III rulings on the same issue. Indeed, one of the cases primarily relied upon by the panel majority involved the application of non-mutual collateral estoppel, and as such, properly considered equitable factors. *See Mendenhall*, 26 F.3d at 1583 (considering whether the subsequent decision was an “exceptional circumstance,” the marketplace analysis and effect on defendants if precluded from practicing the patent, and the stage of the litigation). *See also Central Soya Co. v. George A. Hormel & Co.*, 723 F.2d 1573, 1580 (Fed. Cir. 1983).

The panel decision here, by adopting a rule requiring automatic dismissal, does not allow for consideration of the equities, fairness, or judicial efficiency; the PTO decision is given supremacy as a matter of law. If the timing of a PTO claim cancellation relative to a court’s entry of “final” judgment can automatically void prior court rulings in a potentially lengthy litigation, factors such as delay, inadvertence, whether or when a party requested a stay of the litigation, or fraud would become irrelevant.

The questions raised by the instant case have interesting parallels to the disposition of motions for relief from final judgment under Fed. R. Civ. P. 60(b). In *Flexiteek v. Plasteak*, for example, the court granted relief from an order to execute a final judgment after considering the patentee’s nondisclosure of prior art in response to an interrogatory, the promptness of filing a reexamination request

after defendant became aware of the prior art, the defendant's timeliness of seeking relief from final judgment, the scope of claim amendments during reexamination, and the fairness of executing a portion of an award that depended on an amended claim. *Flexiteek v. Plasteak et al.*, Case No. 08-60996-civ-Cohen/Seltzer, 2012 U.S. Dist. LEXIS 156086 (S.D. Fla. Sept. 10, 2012). In *Amado v. Microsoft*, on the other hand, the court denied a Rule 60(b) motion because the defendant had been "aware of the prior art upon which its reexamination petition was based well before trial, [but] failed to file the reexamination petition until after the unfavorable judgment was entered." *Amado v. Microsoft Corp.*, 517 F.3d 1353, 1363 (Fed. Cir. 2008).

To be sure, the application of a flexible standard will not interfere with the PTO's reexamination of the patent at issue, and will not change the impact of the PTO's reexamination decision going forward against non-parties to the concurrent litigation. At most, the application of a flexible standard will affect parties that had ample opportunity to litigate their position on patent validity.

Whether conduct by the parties and other equitable considerations can be taken into account will have significant incentive effects on litigants. If equity is inapplicable, accused infringers would be encouraged to simultaneously pursue invalidity in a district court and before the PTO. For example, given the high stakes in many patent litigations, particularly those affecting the biotechnology

industry, there would be no downside for the defendant to request a parallel patent reexamination, even late in a litigation. Defendants would be incentivized to wait as long as possible to file a reexamination request in order to get a “second bite at the apple” at the PTO in the event of an unfavorable court ruling. *Mendenhall*, 26 F.3d. at 1584 (dissent, Mayer, J.). Indeed, there would be good reason for accused infringers to game the available post-grant proceedings, for example by filing multiple reexaminations, one after the other. Cases that would ordinarily be ripe for settlement would be dragged out needlessly, with the unscrupulous incentive that a successful challenge at the PTO would trump any prior federal court ruling so long as a “final” judgment on each and every issue had not been entered.

Such gamesmanship is a long way from the intent of Congress in enacting post-grant procedures. Dissent Op. at 52-54. Indeed, Congress intended post-grant proceedings to lighten the load for the federal courts. Instead, under the panel decision, they would result in an inescapable war on two fronts for patentees. To at least allow the consideration of equitable principles should encourage more efficient outcomes and bring the application of Congress’s legislation closer to the legislature’s original intent.

**CONCLUSION**

For the reasons above, BIO respectfully ask the Court to rehear its previous decision in *Fresenius II*.

DATED: August 15, 2013

Respectfully submitted,



---

Michael A. Gollin  
Principal Counsel:  
MICHAEL A. GOLLIN  
VENABLE LLP  
575 7th Street, NW  
Washington, DC 20004  
Telephone (202) 344-4000

Of Counsel:  
WILLIAM D. COSTON  
MARTIN L. SAAD  
CHRISTOPHER S. CROOK  
VENABLE LLP  
575 7th Street, NW  
Washington, DC 20004  
Telephone (202) 344-4000



## CERTIFICATE OF COMPLIANCE

Counsel for *Amicus Curiae* Biotechnology Industry Organization hereby certify that:

1. The brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(d) and 32(a)(7)(B)(i) because exclusive of the exempted portions it contains 2,380 words as counted by the word processing program used to prepare the brief; and
2. The brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a) (5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a) (6) because it has been prepared using Microsoft Office Word 2010 in a proportionally spaced typeface: Times New Roman, font size 14.



---

Michael A. Gollin

Dated: August 15, 2013