

**United States Court of Appeals  
for the Federal Circuit**

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FRESENIUS USA, INC. AND  
FRESENIUS MEDICAL CARE HOLDINGS, INC.,  
*Plaintiffs-Appellants,*

v.

BAXTER INTERNATIONAL, INC. AND  
BAXTER HEALTHCARE CORPORATION,  
*Defendants-Cross Appellants.*

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*Appeal from the United States District Court for the Northern District of  
California in Case No. 03-CV-1431, Judge Phyllis J. Hamilton*

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**BRIEF OF INTELLECTUAL PROPERTY OWNERS  
ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF BAXTER  
INTERNATIONAL INC. AND BAXTER HEALTHCARE  
CORPORATION'S PETITION FOR REHEARING EN BANC**

RICHARD F. PHILLIPS  
President

KEVIN H. RHODES  
Chair, IPO Amicus Brief  
Committee

INTELLECTUAL PROPERTY  
OWNERS ASSOCIATION  
1501 M Street, NW  
Suite 1150  
Washington, DC 20005  
(202) 507-4500

PETER G. PAPPAS

ANN G. FORT

STEPHANIE G. STELLA

SUTHERLAND ASBILL &  
BRENNAN LLP

999 Peachtree Street, NE  
Suite 2300  
Atlanta, Georgia 30309-3996  
(404) 853-8000

*Counsel for Amicus Curiae Intellectual Property Owners Association*

AUGUST 15, 2013

---

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

*Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. v. Baxter International, Inc. and Baxter Healthcare Corporation 2012-1344, -1335*

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Counsel for the *Amicus Curiae* Intellectual Property Owners Association certifies the following:

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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: **NONE**
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of *amicus curiae* represented by me are:  
**NONE**
4. The names of all law firms and the partners or associates that appeared for the *amicus curiae* now represented by me in the trial court or agency or that are expected to appear in this Court are:

Richard F. Phillips  
Kevin H. Rhodes  
Herbert C. Wamsley  
INTELLECTUAL PROPERTY  
OWNERS ASSOCIATION  
1501 M Street, NW  
Suite 1150  
Washington, DC 20005

Peter G. Pappas  
Ann G. Fort  
Stephanie G. Stella  
SUTHERLAND ASBILL &  
BRENNAN LLP  
999 Peachtree Street, NE  
Suite 2300  
Atlanta, Georgia 30309-3996

Date: August 15, 2013

/s/ Herbert C. Wamsley  
Signature of Counsel  
Herbert C. Wamsley  
Counsel for *amicus curiae*  
Intellectual Property Owners  
Association

**TABLE OF CONTENTS**

	<i>Page</i>
INTEREST OF AMICUS CURIAE .....	1
SUMMARY OF ARGUMENT .....	2
ARGUMENT .....	3
I. THE INCREASING NUMBER OF <i>EX PARTE</i> REEXAMINATIONS CREATES A HIGH LIKELIHOOD THAT CONFLICTING REEXAMINATION AND DISTRICT COURT VALIDITY JUDGMENTS WILL CONTINUE TO BE ISSUED. ....	3
II. THIS COURT APPEARS TO HAVE REACHED CONFLICTING CONCLUSIONS REGARDING THE FINALITY OF <i>FRESENIUS I</i> .....	5
III. EVEN IF JUDGMENT IS NOT CONSIDERED “FINAL,” ALLOWING AN ADMINISTRATIVE DECISION TO DISPLACE THE JUDGMENT OF AN ARTICLE III COURT MAY RAISE SERIOUS CONSTITUTIONAL QUESTIONS .....	6
CONCLUSION .....	9
APPENDIX	

**TABLE OF AUTHORITIES**

*Page(s)*

**Cases**

*Fresenius USA, Inc. v. Baxter Int’l, Inc.*,  
No. 03-CV-1431, 2013 WL 3305736 (Fed. Cir. July 2, 2013) .....7, 8

*Gordon v. United States*,  
117 U.S. 697 (1864).....7

*Hooper v. California*,  
155 U.S. 648 (1895).....8

*In re Baxter Int’l, Inc.*,  
698 F.3d 1349 (Fed. Cir. 2012) .....5, 6

*In re Constr. Equip.*,  
665 F.3d 1254 (Fed. Cir. 2011) .....7

*In re Swanson*,  
540 F.3d 1368 (Fed. Cir. 2008) .....7

*NLRB v. Catholic Bishop of Chi.*,  
440 U.S. 490 (1979).....8

*Plaut v. Spendthrift Farm, Inc.*,  
514 U.S. 211 (1995).....7, 8

**Rules**

Fed. R. App. P. 29 .....1

Fed. Cir. R. 29.....1

**Other Authorities**

UNITED STATES PATENT AND TRADEMARK OFFICE EX PARTE REEXAMINATION  
FILING DATA-SEPTEMBER 30, 2012,  
[http://www.uspto.gov/patents/stats/ex\\_parte\\_historical\\_stats\\_roll\\_up\\_](http://www.uspto.gov/patents/stats/ex_parte_historical_stats_roll_up_EOY2012.pdf)  
[EOY2012.pdf](http://www.uspto.gov/patents/stats/ex_parte_historical_stats_roll_up_EOY2012.pdf).....4

The Intellectual Property Owners Association (IPO) submits this brief as an *amicus curiae* pursuant to Fed. R. App. P. 29 and Rule 29 of this Court. IPO takes no position on the underlying merits of the parties' appeal. IPO supports the petition for rehearing en banc filed by Baxter International, Inc. and Baxter Healthcare Corporation (Baxter) to seek clarity on the issues of finality of a judgment and the effect of an administrative agency decision on such judgment.

### **INTEREST OF AMICUS CURIAE**

*Amicus curiae* Intellectual Property Owners Association is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights.<sup>1</sup> IPO's membership includes more than 200 companies and over 12,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO regularly represents the interests of its members before Congress and the USPTO and has filed *amicus curiae* briefs in this Court and other courts on significant issues of

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<sup>1</sup> No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae* or its counsel made a monetary contribution to its preparation or submission.

intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.<sup>2</sup>

### **SUMMARY OF ARGUMENT**

In *Fresenius II*, this Court's panel majority held that the cancellation of patent claims during USPTO reexamination is binding on concurrent non-final infringement litigation. Such circumstances are likely to arise again because a substantial number of patents are involved in parallel proceedings, including infringement suits in federal district court and post-grant administrative review proceedings before the USPTO. There is thus a high likelihood that reexamination decisions will continue to be issued that conflict with district court validity judgments, even after this Court issues a mandate affirming that portion of the district court's judgment. Furthermore, allowing an administrative decision by an executive branch agency to displace the judgment of an Article III court may raise serious constitutional questions regarding the separation of powers between the two branches. IPO supports Baxter's petition because of the universal benefit of the further clarity that would result from this Court's en banc rehearing, particularly in view of this Court's ostensibly conflicting views in *Fresenius I* and *Fresenius II* regarding "administrative nullification" of a district court's validity holding.

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<sup>2</sup> IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

## ARGUMENT

### **I. THE INCREASING NUMBER OF *EX PARTE* REEXAMINATIONS CREATES A HIGH LIKELIHOOD THAT CONFLICTING REEXAMINATION AND DISTRICT COURT VALIDITY JUDGMENTS WILL CONTINUE TO BE ISSUED.**

A substantial number of patents are involved in parallel proceedings including district court infringement suits and post-grant administrative review proceedings before the USPTO. The America Invents Act (AIA) addressed the major ways in which *inter partes* reexamination proceedings threatened to conflict with parallel district court litigation. The AIA eliminated *inter partes* reexamination proceedings and replaced them with *inter partes* review proceedings (IPR), which are designed to be more difficult to commence, based on a new higher “reasonable likelihood of prevailing on at least one claim” standard for instituting the review. The AIA also imposed strict limitations on IPR and parallel litigation, e.g., once a party has been served with an infringement complaint, that party only has one year to challenge the patent in an IPR proceeding, and a party who has brought a free-standing declaratory judgment action challenging a patent cannot subsequently challenge the patent in an IPR proceeding. Furthermore, if a party files a request for an IPR and subsequently files a declaratory judgment action, that action is automatically stayed, although the stay may be lifted under certain circumstances (most of which are within the control of the patent owner).

And IPR’s estoppel provisions apply not only to later civil actions, but also to later USPTO and ITC proceedings.<sup>3</sup>

These restrictions, however, do not apply to *ex parte* reexamination (EPR) proceedings—like those initiated here by Fresenius—the procedures for which remain substantially intact and unchanged following the passage of the AIA. A request for EPR may be filed at any time after a patent has issued; thus, a party unsuccessful in invalidating a patent in a district court, and even after appeal to this Court, still may be able to do so in a USPTO proceeding—just as Fresenius did here—thereby potentially eliminating any certainty or finality resulting from federal court patent litigation.

The annual number of EPR filings has risen more than 320% (from 187 to 788) since the 1981 launch of EPR.<sup>4</sup> Of the nearly 13,000 EPR requests filed, 92% were granted, and approximately one-third of the subject patents were also in litigation. All claims were canceled in only 11% of cases. The majority of EPRs—68% of cases—resulted in the claims being amended. Thus, even if a

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<sup>3</sup> The scope of estoppel appears to have been narrowed, however, from any grounds that a petitioner “raised or could have raised” during an *inter partes* reexamination to those that petitioner “raised or *reasonably* could have raised” during an IPR.

<sup>4</sup> The 788 *ex parte* reexamination filings in 2012 is the total through September 30, 2012 (the latest date for which data is currently available). UNITED STATES PATENT AND TRADEMARK OFFICE EX PARTE REEXAMINATION FILING DATA-SEPTEMBER 30, 2012, [http://www.uspto.gov/patents/stats/ex\\_parte\\_historical\\_stats\\_roll\\_up\\_EOY2012.pdf](http://www.uspto.gov/patents/stats/ex_parte_historical_stats_roll_up_EOY2012.pdf).



defendant fails to invalidate the claims in litigation, it may still avoid infringement by forcing the patentee to amend its claims in reexamination.

The 80% rate of claim cancellation or amendment, lack of time restrictions on filing, and lower “substantial new question of patentability” standard for initiating the review, all will continue to make EPR an attractive litigation defense strategy. There is thus a high likelihood that EPR decisions will continue to be issued that conflict with district court validity judgments, even after mandate issues affirming the district court judgment. The continuing importance of this issue underscores the need for this Court to rehear *Fresenius II* en banc in order to erase the uncertainty remaining following its split panel decision.

**II. THIS COURT APPEARS TO HAVE REACHED CONFLICTING CONCLUSIONS REGARDING THE FINALITY OF *FRESENIUS I***

In *Fresenius II*, this Court’s panel majority determined that the Court’s *Fresenius I* remand decision was “not sufficiently final” so as to preclude application of the USPTO’s intervening invalidity determination. But it is unclear whether a different panel would have reached the same conclusion. *See In re Baxter Int’l, Inc.*, 698 F.3d 1349, 1350 (Fed. Cir. 2012).

As noted by Baxter in its petition, Judge O’Malley, joined by Chief Judge Rader and Judge Linn, declined to vote for en banc review of the USPTO’s EPR invalidity ruling in *In re Baxter* because of an understanding that the panel opinion

did not “endorse ‘[the USPTO’s] administrative nullification [by a contrary reexamination invalidity decision] of a final judicial decision [of the district court]’”—i.e., *Fresenius I*. Baxter’s Combined Petition for Panel Rehearing and Rehearing En Banc in *Fresenius II*, at 2 n.2 (citing *In re Baxter*, 698 F.3d at 1350 (O’Malley, J., concurring)). In her dissent, Judge Newman disagreed with Judge O’Malley’s view of the panel opinion but agreed with the premise that an agency review cannot alter the binding effect of a prior judicial decision. *See In re Baxter*, 698 F.3d at 1351. Although it thus appears that “at least four members of this Court agree” that a decision on reexamination cannot nullify a prior adverse decision of this Court, *Baxter Pet.* at 2, only a rehearing en banc will settle the question.

**III. EVEN IF JUDGMENT IS NOT CONSIDERED “FINAL,”  
ALLOWING AN ADMINISTRATIVE DECISION TO  
DISPLACE THE JUDGMENT OF AN ARTICLE III COURT  
MAY RAISE SERIOUS CONSTITUTIONAL QUESTIONS**

Whether or not the district court’s validity judgment is considered “final,” allowing an administrative decision by an executive branch agency to displace the judgment of an Article III court may raise serious constitutional questions regarding the separation of powers between the two branches. In her *Fresenius II* dissent, Judge Newman disagreed with the panel majority, arguing that its decision violates constitutional principles establishing the relative authority of an Article III court versus an administrative agency, because “judgments of Article III courts are

‘final and conclusive upon the rights of the parties.’” *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, --- F.3d --- , 2013 WL 3305736, at \*15–16 (Fed. Cir. July 2, 2013) (Newman, J., dissenting) (citing *Gordon v. United States*, 117 U.S. 697, 702 (1864); *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 226 (1995)). That opinion continues a split within the Federal Circuit regarding the concept of finality of judgments, and underscores the potential constitutional question regarding separation of powers. *Cf. In re Constr. Equip.*, 665 F.3d 1254 (Fed. Cir. 2011) (upholding the USPTO’s invalidation based on reexamination of a patent that had been litigated and held not invalid eleven years earlier where the reexamination was initiated by a party to the prior litigation); *In re Swanson*, 540 F.3d 1368, 1379 n.5 (Fed. Cir. 2008) (upholding the USPTO’s invalidation of claims of a patent that had been held not invalid by the Federal Circuit in prior litigation, although the court acknowledged that “an attempt to reopen a final federal court judgment of infringement on the basis of a reexamination finding of invalidity might raise constitutional problems”).

Judge Newman further opined:

The court’s ruling that PTO reexamination overrides the prior adjudication of patent validity is contrary to the legislative purposes of reexamination, offensive to principles of litigation finality and repose, and violative of the Constitution. The judicial decision of patent validity is not available for review, revision, or annulment by the PTO. When the issue of patent validity has been litigated and finally decided in the courts, this binds not only other courts, the parties, and the public; it binds the other branches of government.

*Fresenius USA*, 2013 WL 3305736, at \*32 (Newman, J., dissenting).

The *Fresenius II* dissent also challenged the panel majority’s claim that “Congress expected reexamination to take place concurring with litigation, and that cancellation of claims during reexamination would be binding in concurring infringement litigation.” *Id.* at \*8. Under the dissent’s view, the majority has “authorize[d a] PTO reexamination to override a prior judicial adjudication of patent validity,” thereby “creat[ing] a constitutional violation that should have been avoided. *See NLRB v. Catholic Bishop of Chi.*, 440 U.S. 490, 500–01 (1979) (courts are required to choose any reasonable construction of a statute that would eliminate the need to confront a contested constitutional issue); *Hooper v. California*, 155 U.S. 648, 657 (1895) (courts must resort to “every reasonable construction . . . in order to save a statute from unconstitutionality”).” *Fresenius USA*, 2013 WL 3305736, at \*20 (Newman, J., dissenting).

The panel majority agrees that, under *Plaut*, “allowing a PTO determination to control the outcome of pending litigation is unconstitutional, because it offends the separation of powers,” *id.* at \*13, but disagrees that its decision violates any constitutional principles based on its determination that Baxter lacked final judgment in *Fresenius I*. The majority’s decision in this case relied on a ruling by an agency of the executive branch when overturning this Court’s affirmance of validity, liability, accounting, and injunction, and denial of rehearing and rehearing en banc, and the Supreme Court’s denial of certiorari. That an agency decision has

had—and will most likely continue to have—such weighty influence on decisions of this Court demands the further discussion of an en banc rehearing.

Where a case presents such an important constitutional issue, touching on the proper role of each of our branches of government, an en banc decision would offer an opportunity for continued thorough analysis of the question for the good of all parties who come before this Court.

### **CONCLUSION**

For all of the foregoing reasons, IPO respectfully requests that this Court grant Baxter’s petition and rehear this matter en banc.

Respectfully submitted,

/s/ Peter G. Pappas

Richard F. Phillips  
*President*  
Kevin H. Rhodes  
*Chair, IPO Amicus Brief Committee*  
INTELLECTUAL PROPERTY  
OWNERS ASSOCIATION  
1501 M Street, NW  
Suite 1150  
Washington, DC 20005  
(202) 507-4500

Peter G. Pappas  
Ann G. Fort  
Stephanie G. Stella  
SUTHERLAND ASBILL &  
BRENNAN LLP  
999 Peachtree Street, NE  
Suite 2300  
Atlanta, Georgia 30309-3996  
(404) 853-8000

# APPENDIX

## APPENDIX<sup>1</sup>

### Members of the Board of Directors Intellectual Property Owners Association

---

Tina M. Chappell Intel Corp.	Jack E. Haken Koninklijke Philips N.V.
Mark Costello Xerox Corp.	Jennifer M. Hall Mars Inc.
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**United States Court of Appeals  
for the Federal Circuit**

*FRESENIUS USA v. BAXTER INTERNATIONAL*, 2012-1334, -1335

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I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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On **August 15, 2013**, Counsel for Amici Curiae has authorized me to electronically file the foregoing **Brief for *Amicus Curiae*** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to any of the following counsel registered as CM/ECF users:

Michael E. Florey  
FISH & RICHARDSON, P.C.  
60 South Sixth Street  
Dain Rauscher Plaza  
Minneapolis, MN 55402  
(612) 335-5070  
florey@fr.com

Juanita R. Brooks  
FISH & RICHARDSON, P.C.  
12390 El Camino Real  
San Diego, CA 92130  
(858) 678-5070  
brooks@fr.com

*Attorneys for Plaintiffs-Appellants*

Michael J. Abernathy  
Devon C. Beane  
Sanjay K. Murthy  
K & L GATES LLP  
70 West Madison Street  
Chicago, IL 60602-4207  
(312) 372-1121  
michael.abernathy@klgates.com  
devon.beane@klgates.com  
sanjay.murthy@klgates.com

Christina N. Goodrich  
K & L GATES LLP  
10100 Santa Monica Blvd., 7<sup>th</sup> Floor  
Los Angeles, CA 90067  
(310) 552-5547  
christina.goodrich@klgates.com

David A. Simons  
K & L GATES LLP  
1 Lincoln Street  
State Street Financial Center  
Boston, MA 02111  
david.simons@klgates.com

*Attorneys for Defendants-Cross-  
Appellants*

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/s/ Peter G. Pappas  
Peter G. Pappas  
*Counsel for Amicus Curiae*