No. 2010-1548

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MARINE POLYMER TECHNOLOGIES, INC.,

Plaintiff-Appellee,

v.

HEMCON, INC.,

Defendant-Appellant.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT COURT OF NEW HAMPSHIRE IN CASE NO. 06-CV-0100, JUDGE JOSEPH A. DICLERICO, JR.

BRIEF FOR THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* SUPPORTING APPELLEE

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February 10, 2012

CERTIFICATE OF INTEREST

Counsel for *amici* certifies the following:

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

Biotechnology Industry Organization

Pharmaceutical Research and Manufacturers of America

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:

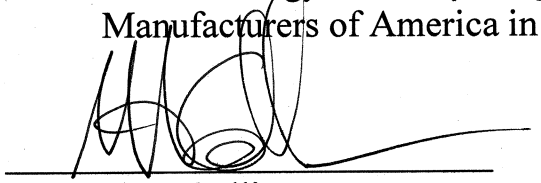
Not applicable.

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, Meaghan H. Kent, and Fabian M. Koenigbauer) is appearing for Biotechnology Industry Organization and Pharmaceutical Research and Manufacturers of America in this Court.



Michael A. Gollin
Dated February 10, 2012

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IDENTITY AND INTEREST OF *AMICI CURIAE*

Biotechnology Industry Organization ("BIO") is the country's largest biotechnology trade association, representing over 1100 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 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 in the range of $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 conduct research, development, and commercialization of new biotechnology products that heal, feed, and fuel the world.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies. In the past decade, PhRMA's

members have invested more than $406 billion to discover and develop new medicines and new uses for existing medicines. *See* PhRMA, PHARMACEUTICAL INDUSTRY PROFILE 2011 at 42 (2011). In 2010 alone, the pharmaceutical industry invested a record $67.4 billion in such research and development. The drug-development process is lengthy, with investment, research, and legal decisions made years in advance of a product launch. In light of the great uncertainties and risks that accompany drug development, PhRMA's members depend on a degree of certainty and predictability in patent law.

To ensure strong patent rights, *amici* must be able to participate in post-grant proceedings, including reexamination, in ways that ensure clarity, enforceability, and validity of their patents. When operating as intended, post-grant proceedings increase patent certainty for all interested parties, so that they may rely on patents with greater confidence for licensing, investment, and product development decisions.

The Federal Circuit's majority panel decision in this case upsets the delicately balanced, congressionally created incentive system for reexamination. It is inconsistent with the relevant statutes and imposes a rule that would create massive implementation challenges in the USPTO. At bottom, the decision conflates the separate and distinct concepts of argument estoppel and claim amendment, thereby creating uncertainty for *amici*, investors, customers, and the

general public, which benefits greatly from innovation in the life sciences industries.

Accordingly, *amici* have a significant interest in the further disposition of this case. *Amici* have no commercial interest in the parties to this action. None of the parties are a member of BIO and PhRMA. Pursuant to Federal Rule of Appellate Procedure Rule 29(c)(5), *amici* further state 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 *amici*, their members, or their counsel made a monetary contribution to its preparation or submission.

ARGUMENT

In its original majority panel decision of September 26, 2011 ("panel decision"), a panel of this Court improperly held that intervening rights apply where there has been no amendment to the language of the claims "if the scope of the claims actually and substantially changed because of ... arguments to the PTO." (pp. 11-12). *Amici* agree with the dissenting view that intervening rights under 35 U.S.C. §§ 307(b) and 252 apply only to amended or new claims and do not apply to claims whose "language was not in any way changed." (Dissent, p. 2). The dissent was correct for both statutory interpretation and policy reasons. Section I of this brief explains why the panel decision is unsupported by the statute, and Section II explains the unintended consequences that will result if the panel decision is followed.

I. THE PANEL'S RULING THAT CLAIMS CAN BE AMENDED BY ARGUMENT RUNS COUNTER TO EXPRESS STATUTORY LANGUAGE

The panel decision is inconsistent with the express statutory language that intervening rights arise only when there is an "amended or new claim ... incorporated into a patent following a reexamination proceeding" but not where the infringer "infringes a valid claim of the reexamined patent which was in the original patent." 35 U.S.C. §§ 307(b), 316(b). Therefore, an express, statutory prerequisite to considering the applicability of intervening rights under Section 252

is the existence of an amended or new claim that is incorporated into a patent following a reexamination proceeding – there is no basis for finding that Congress intended intervening rights under Section 252 to apply except where the patentee amended or added new claims.

A. The Panel's Strained Reading of the Statute, Basing Intervening Rights on Estoppel Arising from Argument, Ignores the Categorical Difference between Textual Claim Amendments and Applicant Arguments.

The panel decision fails to recognize the fundamental difference between claim amendments and arguments: amendments change the text of a claim and arguments argue about the meaning of that text. Appellant's position, as adopted in the panel decision, conflates these two concepts, contrary to the statutory scheme, and in conflict with USPTO regulation and long-established practice relied on by the *amici*'s members.

Amici do not need to take a position on whether argument can affect the scope of a claim in different contexts, including through disclaimer or estoppel, because in the situation of intervening rights pursuant to 35 U.S.C. §§ 307(b) and 316(b), the statute is clear. Intervening rights can arise only where there is an "amended or new claim" which is "incorporated into a patent following a reexamination proceeding." 35 U.S.C. §§ 307(b), 316 (b). And under 35 U.S.C. § 252, even a claim that has been amended, but remains substantially identical, is not

subject to intervening rights. As has been decided in the context of reissue, the question of whether a change by amendment is substantial is answered based on the language of the claim, "without reliance on the motives or the correctness of the motives of either the patent examiner or the applicant." *Slimfold Mfg. Co., Inc. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1116 (Fed. Cir. 1987). None of these statutory provisions references patentee argument. The panel decision violates the express limitations of the statute and expands the scope of Section 307 to trigger intervening rights even absent any amendments to the reexamined claims. A rule that conflates argument with amendment confuses the patentee's motives with action, and creates uncertainty where clarity is required.

It is well settled that claims define the metes and bounds of the invention, even though they may be construed in view of the description and prosecution history. *Markman v. Westview Instruments*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). This canon of claim construction means that applicant arguments during prosecution are not part of the claim. Such arguments "can and should be used to understand the language used in the claims," but they "cannot 'enlarge, distinguish or vary' the limitations in the claims.'" *Markman*, 52 F.3d at 980.

The cases[1] cited in the panel decision stand only for the unremarkable proposition that arguments made to the USPTO on reexamination can create the same kinds of estoppel as arguments made during the original prosecution of the application. These cases do not establish a principle that patentee argument during reexamination is equivalent to amendment under the statutory language providing for intervening rights.

B. The Decision Conflicts with the Fundamental Patent Law Principle That Distinguishes Textual Amendments from Arguments

By equating claim amendment with argument, the panel decision effectively redrafts Sections 252, 307 and 316 to trigger intervening rights when a patent owner makes an argument about the scope of a claim. Lawyers understand that "amend" means something categorically different than "argue." Amendments change the text and scope of a legal instrument. Arguments offer an interpretation of what that text means in a particular context, but they do not and cannot change the actual text.

The clear distinction between the text of a legal instrument and its interpretation is a fundamental principle of our legal system. Lawyers argue about

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[1] *See Cole v. Kimberly Clark*, 102 F.3d 524, 532 (Fed. Cir. 1996); *American Piledriving Equip. v. Geoquip* 637 F. 3d 1324, 1326 (Fed. Cir. 2011); *CIAS, Inc. v. Alliance Gambling* 504 F.3d 1356, 1362 (Fed. Cir. 2007); and *C.R. Bard v. United States Surgical Corp.* 388 F.3d 858, 867-869 (Fed. Cir. 2004).

the meaning of language in the United States Constitution, federal and state statutes, treaties, regulations, pleadings in litigation, wills, contracts, deeds -- and patent claims -- and decision makers use established principles of textual interpretation to construe the language as required to resolve a particular matter before them. Different arguments are made in different contexts. Different judges may interpret statutes differently. But until the actual textual language of a legal instrument is changed according to established legal procedures, it simply has not been "amended."

Indeed, the law takes great care in other contexts to ensure that "argument" made subsequent to the establishment of legal instruments is given no or at best minimal weight in construing their scope. For example, wills and deeds cannot be changed by subsequent argument – they must be changed in writing. The continuity of text until amended serves a crucial notice function. To conflate textual amendments with arguments about the text runs counter to core legal principles.

Likewise, patent prosecution law has long relied on the distinction between claim amendments and argument. In pre-grant prosecution and post-grant proceedings, amending a claim always requires adding or deleting text, and formally showing the changes in the official file. *See* 37 C.F.R. § 1.121 (pre-grant amendment); § 1.530(d) (amendment in re-examination); and § 1.173(b) (2)

(reissue). Claim amendments are, and should be, treated differently from arguments.

II. PUBLIC POLICY MILITATES AGAINST BASING INTERVENING RIGHTS ON ARGUMENTS RATHER THAN AMENDMENTS, WHICH WILL CAUSE UNCERTAINTY, DELAY, AND MERITLESS PROCEEDINGS

A. Expanding Intervening Rights According to The Panel's Ruling Would Discourage Constructive Reexamination, Reissue and Other Post-Grant Proceedings, and Burden the System without Increasing Patent Quality

Reissue, reexamination, and other *inter partes* and post-grant review are desirable proceedings intended to reduce ambiguities, make for clearer and stronger patents, and allow for greater reliance on patents by interested parties.[2]

The biotechnology and pharmaceutical industries have long recognized these benefits. For these industries, significant investments in product research and development create unusually strong reliance interests that require predictable and practically workable principles governing interpretation of claim scope and

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[2] Congress recently enacted new post-grant and *inter partes* review proceedings, established a new supplemental examination proceeding, and enacted a suite of other provisions also aimed at providing clearer, more transparent and robust procedures for reviewing and enhancing patent quality, such as enhanced third party rights to submit information during initial examination, and subsequently, and; enhanced reexamination authority by the Director; (*see e.g.*, 35 U.S.C. §§ 122, 257, 311 et seq., 321 et seq.). Enactment of these new provisions underscores Congress' interest in workable proceedings that result in clearer patents that are more unambiguously valid and enforceable. *See, e.g.* 157 Cong. Rec. E1182 (daily ed. June 23, 2011)(remarks of Hon. L. Smith on H.R. 1249).

enforceability. New biologic drugs, for example, require on average close to a decade of development work and a fully-capitalized investment exceeding $1.2 billion. DiMasi and Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, Manag. Decis. Econ. 28: 469, 475 (2007). It is not uncommon for such products to be protected by only a handful of patents, which accordingly count among biotechnology and pharmaceutical companies' most important business assets. Knowing that such patents may eventually be attacked by any means possible, these companies must be able to participate in post-grant proceedings in ways that allow them to confirm the absence of any defects without devaluing their patent assets.

As a result of the panel decision, patentees would be less likely to participate constructively in such proceedings for fear that any argument could be construed as an "amendment" to the claims, triggering intervening rights. The panel decision will discourage disclaimers, lead to hardened positions in *inter partes* proceedings, and result in drawn-out proceedings and increased appeals. These effects will be felt with relatively greater impact by patentees who are facing actual or possible infringement of their patents, or who seek to negotiate licenses or cross-licenses with competitors in the marketplace.

Voluntary post-grant proceedings would be particularly discouraged, since patentees could only know with hindsight – after the claim has been conclusively

construed by this Court - whether their prosecution argument caused a variance in claim scope. Rather than strengthen their patents, patentees would be opening their patents up to significant devaluation even absent any amendment. Few patentees would be willing to take this risk. By driving such counterproductive outcomes, the panel's ruling in no way contributes to patent quality and instead frustrates the reliance on patents that is so critical to biomedical innovation.

The panel's game-changing departure from established patent doctrine raises real concerns about the decision's effect on incentives for innovation. Undoubtedly, it increases uncertainty and imbalances the settled rights protected by existing patents. *Amici* trust that this Court will proceed with caution when faced with such a change from the status quo. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 32 n.6 (1997) ("To change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous patents ... which would be affected by our decision.").

B. The Panel Decision Inverts the Incentives For Administrative Patent Review Proceedings And Promotes Abuse Of The Process.

The purpose of post-grant proceedings is to review and interpret claims, with the incentive of resolving ambiguity, clarifying patents, improving reliability of patents, and generally improving patent quality. *In re Portola*, 110 F.3d 786, 789 (Fed. Cir. 1997). The goal for the typical accused defendant is to limit or

invalidate claims. *Id.* The panel decision creates a completely different incentive system: accused infringers are encouraged to initiate post-grant proceedings, under the pretext of seeking patent quality review, in an attempt to earn intervening rights by forcing a patentee to make statements or arguments, even absent any corrections to the patent.

Reexamination proceedings almost always result in arguments by the patentee to either distinguish the claims from the prior art, or to point to support for the claims in the specification. A patentee subject to reexamination must usually make arguments of this sort, since the USPTO often adopts the requester's proposed rejections in its first Office Action on the merits in reexamination. *See* Mark D. Janis, *Rethinking Reexamination: Toward a Viable Administrative Revocation System for U.S. Patent Law*, 11 Harv. J.L. & Tech. 1, 48 (1997); M.P.E.P. § 2246. Even if amendment is not needed, a patentee must necessarily make some statements on the record to seek confirmation of the claims. 37 C.F.R. § 1.530(c); M.P.E.P. § 2260. Many such arguments could, with hindsight, be recast as having changed the scope of the claims.

According to the panel decision, by initiating reexamination and forcing the patentee to respond and make such arguments or statements, the challenger may well be able to establish intervening rights even absent amendment, and even if later found to infringe the claim as construed during the reexamination. In fact, as

in this case, a literal infringer – *both before and after* reexamination – will be released from liability.

The possibility for accused infringers to get a "free pass" that cuts off all past damages will provide a powerful new incentive to flood the USPTO with administrative challenges. A defendant in infringement litigation would be incentivized to initiate a post-grant proceeding on any claim of the patent that shares a common term with the claims that are asserted in the litigation. Even if the claim under reexamination is not asserted in the litigation, the patentee's arguments in construing a common claim term could trigger intervening rights for unambiguously valid claims that are asserted in the litigation, even if they could not have been subject to administrative review because *e.g.*, for these claims there was neither a "substantial new question of patentability," 35 U.S.C. § 303, nor a "reasonable likelihood" of the challenger's prevailing, 35 U.S.C. § 313. In such ways, the panel decision would encourage the filing of administrative patent review requests that are not even seriously intended to invalidate any claim.

Congress intended that the "broad purpose of [the reexamination statutes] must be balanced against the potential for abuse, whereby unwarranted reexaminations can harass the patentee and waste the patent life." *In re Recreative Techs. Corp.*, 83 F.3d 1394, 1397 (Fed. Cir. 1996). The USPTO should not be

burdened in this way, particularly given its backlog[3] and the prospect of additional filings that will not likely be meritorious.

Reexamination proceedings are already vulnerable to abuse and gamesmanship from third-party requesters. The new rule would invite even more challenges on issues of claim scope because the USPTO gives claims in examination their broadest reasonable interpretation, while courts typically apply a narrower interpretation. *See Becton Dickinson and Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 799 n.6 (Fed. Cir. 1990) ("when faced with a construction that would invalidate a patent claim there are admonitions to construe words in claims narrowly, if possible, so as to sustain their validity"). For example, infringers may now be incentivized to present absurd positions of claim scope to entice a patent owner to respond with statements that the claims do not cover such inoperable embodiments. Such gaming should not be permitted to create intervening rights.

C. The Policy Concern Underlying the Panel Decision is Unlikely to Materialize.

1. The Statute Does Not Express a Preference for Amendment over Argument.

The panel decision expressed concern that allowing intervening rights only where patent claims are amended during reexamination would create an incentive

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[3] According to the BPAI website, there is a backlog of over 25,000 pending *ex parte* appeals. *BPAI Statistics - Receipts and Dispositions by Technology Center*, available here: http://www.uspto.gov/ip/boards/bpai/stats/receipts/index.jsp

for patentees "to abuse the reexamination process by changing claims through argument rather than changing the language of the claims to preserve otherwise invalid claims, and at the same time, avoid creating intervening rights." (p. 11). This indicates that the court views patent owners who argue against an attack on their patents with a degree of skepticism that favors amendment. However, the statute expresses no such preference. Instead, it empowers an applicant or patentee on notice of rejection or objection to "persist" in the original claim, even without amendment, 35 U.S.C. § 132, and states that intervening rights arise only for "amended and new claims." 35 U.S.C. §§ 307(b) and 316(b). It does not state that patentees who "persist" by making arguments regarding the scope of non-amended claims in any way trigger intervening rights.

The statutory language makes practical sense given that claims may need to be construed in many different contexts, by different parties. The contexts, the parties, the rules of construction, and the purpose of construing claims are different during prosecution, litigation, reexamination, and appeal. In litigation, claims are construed based on the contentions of the parties for the purpose of determining whether the claim is infringed, or whether it is shown to be invalid by clear and convincing evidence. During prosecution, on the other hand, claims are construed for the affirmative purpose of granting (or confirming) exclusionary rights. In each case, the parties and the decision maker construe the claims and may argue about

their meaning. The arguments about the claims may differ in each situation; the claims themselves do not.

2. Patentee Estoppel and Intervening Rights Are Different Doctrines that Serve Different Purposes.

Patentees may of course be bound by their arguments in subsequent litigation. But the panel decision improperly engrafts principles of estoppel and claim construction on to the different jurisprudence of intervening rights, even though these two areas of jurisprudence serve different policy purposes.

Estoppel by argument is "forward-looking": it prevents the patentee, as an equitable matter, from afterwards alleging infringement for something the patentee surrendered at the time of prosecution argument. Based on the patentee's prosecution arguments, the litigated claims can be construed to exclude subject matter from their scope, thereby precluding a finding of infringement. That, if anything, is the normal and proper effect of argument estoppel.

Intervening rights, in contrast, are "backward-looking": they eliminate liability for activities prior to certain, defined events such as amendments of claims or abandonment and reinstatement of a patent. They go further than argument estoppel because they excuse conduct found to infringe even after the claims have been construed and any estoppel applied. Because intervening rights are an extraordinary remedy that excuses even the willful infringement of a valid claim, it

is absolutely critical that patentees and the public have clear notice of the triggering events.

Amendments, substitute claims, statutory disclaimers, and abandonment are definite, fixed events that put the patentee and the public on clear notice. In contrast, prosecution arguments and statements that at best subjectively change claim scope are so unclear that they fail to provide meaningful notice to the patentee and to others who seek to evaluate the scope of the claims.

3. The Panel's Policy Concern is Properly Addressed by Established Estoppel Doctrines.

Given the well-established applicability of estoppel doctrines during claim construction and other stages of litigation, it is neither appropriate nor necessary to invoke intervening rights to address the panel's concern that patentees might seek to change their claims through argument instead of amendment. Accused infringers remain free to build a defense around any estoppel the patentee may have created. Defendants are free to argue that they do not infringe patent rights that the patentee has clearly and unambiguously disavowed. Or they are free to argue that the patentee, having represented its claim in one way, cannot now say that the claim does not read on certain prior art. Like any affirmative defense, the burden of establishing an estoppel is properly on the accused infringer, and if carried should result in a judgment of noninfringement or invalidity.

The panel decision would now create a new tool that particularly, even uniquely, favors defendants whose noninfringement and invalidity defenses fail and who cannot mount an estoppel defense because they infringe the asserted claim even as construed under the patentee's "narrowing" prosecution argument. Faced with long-accrued damages and an inescapable finding of infringement of valid, original claims, such defendants should not be able to trigger intervening rights.

CONCLUSION

For the reasons above, *amici* respectfully ask the Court to reject the panel decision's ruling as it pertains to intervening rights.

DATED: February 10, 2012

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CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of February 2012, two copies of the foregoing BRIEF FOR THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* SUPPORTING REVERSAL will be served by first class mail and electronic mail to each of the following:

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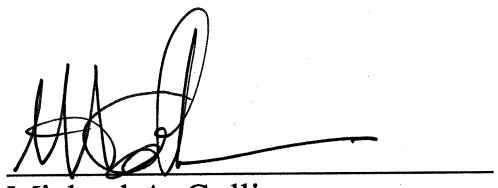

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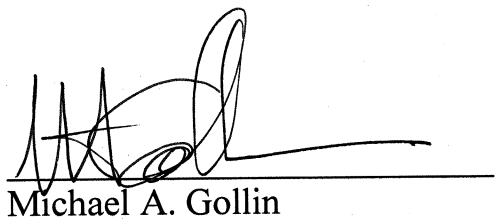
CERTIFICATE OF COMPLIANCE

Counsel for *Amici Curiae* Biotechnology Industry Organization and Pharmaceutical Research and Manufacturers of America 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 3912 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.



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