UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS IV LLC
Petitioner
v.
PHARMACYCLICS, INC.
Patent Owner

Case No. IPR2015-01076
Patent No. 8,754,090

PETITIONER'S RESPONSE TO PATENT OWNER'S MOTION FOR SANCTIONS PURSUANT TO 37 C.F.R. § 42.12

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INTRODUCTION

Pharmacyclics' ("PO") motion for sanctions has no merit—it is not supported by the statutes, judicial precedent or public policy. The plain language of the statutes and regulations permit Petitioner Coalition for Affordable Drugs IV LLC ("Petitioner" or "CFAD") to file a petition for *Inter Partes* Review ("IPR") of U.S. Patent No. 8,754,090 ("the '090 patent"). There are no restrictions on who may file a petition based on business form or motivation.

Petitioner's argument is in conflict with Supreme Court precedent finding it in the public's interest for economically motivated actors to challenge patents. *See, e.g.*, *Lear v. Adkins*, 395 U.S. 653, 670 (1969) (holding public interest requires permitting licensees to challenge validity because they "**may often be the only individuals with enough economic incentive to challenge the patentability" and "[i]f they are muzzled, the public may continually be required to pay tribute to would-be monopolists**") (emphasis added). Having an economic motive for petitioning the government simply does not turn the petition into an abuse of process.

This statutory scheme also aligns with the protections afforded by the First Amendment to the U.S. Constitution and the Supreme Court's *Noerr-Pennington* doctrine. The First Amendment and *Noerr-Pennington* protect the rights of citizens to petition the government to redress their grievances. Under that protection,

government petitions are immune from claims, such as abuse of process, unless the challenged action is established to be a "sham." The "sham" exception requires that the challenged action be, among other requirements, objectively baseless. PO has notably failed to even allege, let alone establish, that CFAD's petition is objectively baseless.

Congress and the Supreme Court have recognized a strong public interest in removing poor-quality patents from the public arena. This interest is especially strong for poor-quality pharmaceutical patents that allow companies, such as PO, to charge overinflated drug prices and delay market entry of affordable generic drugs, to the detriment of patients and society as a whole. Thus, regardless of CFAD's motivation for challenging the validity of the '090 patent, the challenge serves an important public interest: it removes an invalid patent from the system and opens the door to competition through a process that is unaffordable to the typical consumer that will benefit most.

ARGUMENT

I. Congress Expressly Authorized Any Person to File a Petition for IPR

A. CFAD Has Standing to Bring This IPR

PO argues that it is improper for CFAD to bring a petition for IPR because CFAD is a hedge fund and is seeking financial gain. To make this argument, PO dodges the unambiguous language of 35 U.S.C. § 311(a), which authorizes any

"person who is not the owner of a patent [to] file with the Office a petition to institute an *inter partes* review of the patent." The Federal Regulations governing IPR mirror this liberal standard. 37 C.F.R. § 42.201 (2015). The liberal standing requirement is consistent with that of the *inter partes* reexamination process it replaced, which permitted "[a]ny third-party requester at any time [to] file a request for *inter partes* reexamination." 35 U.S.C. § 311 (pre-AIA). There are no statutes, regulations or rules limiting IPR standing based on the nature of the petitioner or the motivation behind filing a petition. In contrast, Covered Business Method review ("CBM") standing is limited to a "person or the person's real party in interest or privy [that] has been sued for infringement of the patent or has been charged with infringement under that patent." Leahy-Smith America Invents Act § 8(a)(1)(B), 112 P.L. 29, 125 Stat. 284, 330; 37 CFR § 42.302 (2015).

The different standing requirements of these related sections of the AIA are significant because "Congress generally acts intentionally when it uses particular language in one section of a statute but omits it in another." *Dep't of Homeland Sec. v. Maclean*, 135 S.Ct. 913, 919 (2015). This interpretative canon applies with particular force when the statutes or regulations are part of the same statutory scheme, as is the case with IPR and CBM. *Id*.

Here, the plain language of the statutes and regulations permit CFAD to file its petition for IPR and this should be the end of the inquiry.

B. PO's Citation to Legislative History Is Inapplicable

PO attempts to distort the statute and regulations through selective and misleading reference to inapplicable legislative history. This effort should be disregarded because when "the statutory language is unambiguous, in the absence of a clearly expressed legislative intent to the contrary, that language must ordinarily be regarded as conclusive." *Russello v. United States*, 464 U.S. 16, 20 (1983) (internal quotations omitted). Accordingly, any reference to the legislative history is unwarranted in this case.

Moreover, even considering the legislative history, it does not support PO's argument that Congress created IPR exclusively as an alternative to litigation, or otherwise intended to bar petitions like CFAD's. Contrary to PO's position, the Board has held that "*[i]nter partes* review is not a substitute for district court litigation." *Loral Space & Communications, Inc. v. Viasat, Inc*., IPR2014-00236, IPR2014-00239, IPR2014-00240, Paper 9 at 7 (PTAB July 7, 2014). Although the IPR process can be an alternative to litigation, it is in no way limited to such. Like the *inter partes* reexaminations they replaced, IPRs may be brought absent any threat of litigation.

To the extent there is any relevance to the legislative history, the statute and regulations authorizing sanctions for abuse of process and "improper use of the proceeding" in 35 U.S.C. § 316(a)(6) were not enacted to curb legitimate merit-

based IPR petitions, such as the one filed by CFAD. Instead, according to the alleged legislative history cited by PO, the purpose was to prevent "frivolous" petitions and "repetitive" claims against the same patents and the same parties. (PO Motion, Paper 20 "Mot." at 4) (citing Hr'g, House Jud. Comm., Subcomm. on Intell. Prop. at 53 (Statement of Atty. Pincus) (March 10, 2011). PO makes no allegation that CFAD's petition is either frivolous or repetitive.

II. The *Noerr-Pennington* Doctrine Bars PO's Abuse of Process and Improper Use of the Proceedings Claims

A. The *Noerr-Pennington* Doctrine Protects CFAD's Right to Bring This IPR Petition

CFAD's right to file a petition for IPR is strongly reinforced by the protections it is afforded by the U.S. Constitution and the Supreme Court's *Noerr-Pennington* doctrine. The First Amendment of the United States Constitution prohibits laws "abridging the right of the people . . . to petition the government for redress of grievances," and gives safe harbor to all genuine efforts to influence government decisions. U.S. Const. Amend. I. The "*Noerr-Pennington* doctrine holds that defendants who petition the government for redress of grievances, 'whether by efforts to influence legislative or executive action or by seeking redress in court,' are immune from liability for such activity under the First Amendment." *Nader v. Democratic Nat'l Comm.*, 555 F. Supp. 2d 137, 155, 156

(D.D.C. 2008) (citing *E.R.R. Presidents Conference v. Noerr Motor Freight, Inc*., 365 U.S. 127, 138 (1961)).

Noerr-Pennington's "reach has been extended to include common-law torts such as malicious prosecution and abuse of process." *Nader*, 555 F. Supp. 2d at 156 (dismissing abuse of process claim under *Noerr-Pennington*); *Proportion-Air, Inc. v. Buzmatics,* 57 F.3d 1085, 1995 U.S. App. LEXIS 25871, *4-*6 (Fed. Cir. 1995) (unpublished) (applying *Noerr-Pennington* doctrine to abuse of process claims). The doctrine's immunity applies to federal agency proceedings, including those before the USPTO. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) (extending *Noerr-Pennington* doctrine to "the approach of citizens . . . to administrative agencies" and holding "*Noerr* shields from the Sherman Act a concerted effort to influence public officials regardless of intent or purpose."); *Abbott Labs. v. Brennan*, 952 F.2d 1346, 1355-56 (Fed. Cir. 1991) (reasoning that abuse of process claim not actionable in PTO unless the "entire federal agency action was a 'sham'" and that challenging motives of petition is insufficient to establish sham).

CFAD's right to petition the Board for IPR is protected by the First Amendment and provides CFAD immunity against PO's abuse of process and "improper use" claims.

B. PO Has Failed to Establish That CFAD's Petition Falls Within the Narrow Sham Exception to the *Noerr-Pennington* Doctrine

Noerr-Pennington immunity from liability for seeking government redress is lost only when the challenged action is *both* (1) "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" *and* (2) "brought with specific intent to further wrongful conduct 'through the use of the governmental process – as opposed to the outcome of that process." *Nader*, 555 F. Supp. 2d at 156 (citing *Prof'l Real Estate Investors, Inc. ("PRE") v. Columbia Pictures Indus*., 508 U.S. 49, 60-61 (1993)). PO has proved neither.

1. PO has failed to allege, let alone establish, that CFAD's petition is objectively baseless

PO's only criticism of the merits of CFAD's petition is relegated to a footnote and asserts that the petition "raise[s] the patent owner's own alleged prior art references . . . all of which the Examiner considered during prosecution." (Mot. at 6 fn. 3.) This criticism is not only incorrect, but amounts to no more than PO believing that the '090 patent will survive IPR. This is insufficient to establish objective baselessness. The "Supreme Court has forbidden [courts] to equate loss on the merits with objective unreasonableness." *FilmTec Corp. v. Hydranautics*, 67 F.3d 931, 938 (Fed. Cir. 1995). Instead, objective baselessness requires "pursuit of claims so baseless that no reasonable litigant could realistically expect to secure favorable relief." *Id*.

PO's argument is further flawed because there is nothing wrong with asserting invalidity based on prior art cited during prosecution. The Board in several instances has instituted an IPR based on prior art considered during prosecution. *See, e.g.*, *Macauto U.S.A. v. BOS GmbH & KG*, IPR2012-00004, Paper 18 (PTAB Jan. 24, 2013); *Illumina, Inc. v. Trs. of Columbia Univ. in the City of N.Y.*, IPR2012-00006, Paper 28 (PTAB Mar. 12, 2013); and *LKQ Corp. v. Clearlamp, LLC*, IPR2013-00020, Paper 18 (PTAB Mar. 29, 2013). Thus, PO has offered absolutely *nothing* to establish the "objectively baseless" prong of the sham exception.

2. PO has failed to establish CFAD's petition is brought with the specific intent to further wrongful conduct through the use of the process rather than the outcome of the process

The subjective prong of the sham exception should not even be considered where, as is the case here, PO has failed to establish the first prong. *PRE*, 508 U.S. at 60. Indeed, the "sham exception does not extend to genuine attempts to secure government action, even though the defendant harbors wrong intent." *Nader*, 555 F. Supp. 2d at 157.

Regardless, PO fails to meet the subjective prong. PO's attack on CFAD's intent boils down to its assertion that CFAD filed its petition for financial gain. (Mot. at 3.) That attack has no merit. "[E]very litigant has a personal stake in an action and, thus, a selfish motive of some sort. . . . Were the court to adopt the . . .

principle that any motive other than the altruistic impulse to see that the law is observed renders a litigant liable, then . . . the ability of individuals to petition the government for a redress of grievances would be endangered . . . .” *Nader*, 555 F. Supp. 2d at 158. The PO’s allegations are completely consistent with CFAD desiring to win on the merits of its petition, and do not even make a *prima facie* case that the petition is a sham.

PO suggests that CFAD’s alleged *method* of financial gain, through “short selling” of PO’s stock in connection with its challenge to the validity of the ‘090 patent, is somehow improper. Contrary to PO’s unsupported argument, short selling is legal, not improper, not manipulative and important to an efficient stock market. (Ex. 1026 [Wu Declaration].) According to the Securities and Exchange Commission, “market participants who believe a stock is overvalued may engage in short sales in an attempt to profit from a perceived divergence of prices from true economic values. Such short sellers add to stock pricing efficiency because their transactions inform the market of their evaluation of future stock price performance.” Securities Exchange Commission, Public Comments for New Regulation SHO, Rel. No. 3235-AJ00 (proposed Oct. 28, 2003). PO’s assertion that short selling is improper is unsupported by any evidence and contrary to the opinion of the federal securities regulator and academic authorities.

C. PO's Abuse of Process and Improper Use Claims Are Legally Deficient in Other Respects

PO argues that the Board should follow the Restatement (second) of Torts § 682 for abuse of process claims in IPR proceedings. Regardless of the elements, *Noerr-Pennington* protects the *filing* of the IPR petition. Abuse of process claims are directed to something else: abuse of the proceedings *after* they have begun.

In advocating for the Restatement approach, PO selectively quotes Comment a. to argue that under the Restatement standard, "the Board need not consider the Petition on its merits to reach the conclusion of misconduct." (Mot. at 8.) Comment a. read in context says nothing of the sort. Comment a. supports CFAD's position because it provides that abuse of process is "*not* the wrongful *procurement* of legal process . . . *it is the misuse of the process* . . ." and that only "*subsequent* misuse of process, though properly obtained, constitutes the misconduct for which the liability is imposed." Restatement (second) of Torts § 682 cmt. a (1977) (emphasis added). Initiating legal process is not abuse of process.[1] Any other reading would fly in the face of the *Noerr-Pennington* doctrine.

[1] PO's "improper use of the proceedings" claim also depends solely on actions during the proceedings, not the mere filing of the petition. 37 C.F.R. § 42.12(7) (improper use of proceedings includes "actions that harass or cause unnecessary delay or an unnecessary increase in the cost of the proceeding").

Also, PO ignores that the use of "primarily" in the Restatement rule with respect to motivation means that "there is no action for abuse of process when the process is used for the purpose for which it is intended, but there is an incidental motive or an ulterior purpose of benefit to the defendant." *Id.* at cmt. b. This essentially incorporates the *Noerr-Pennington* doctrine into abuse of process by requiring the challenged claim to be objectively baseless before liability may attach. PO has not even attempted to establish that CFAD's petition is objectively baseless or that it is for a purpose other than to invalidate the '090 patent.

Significantly, none of PO's cases find an abuse of process. *See, e.g.*, *In re Applications of High Plains Wireless, L.P.*, 15 F.C.C. Rcd. 4620, 4623 (2000) (dismissing abuse of process claim because petition was used for proper purpose); *Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, No. 4-98-CV-90083, 1999 WL 33268173, at *5 (S.D. Iowa Sept. 30, 1999) (dismissing abuse of process claim); *Dassault Systemes, S.A. v. Childress*, No. 09-10534, 2014 U.S. Dist. LEXIS 167548, *29-*30 (E.D. Mich. Dec. 3, 2014) (stating that the misconduct "is not the wrongful procurement of legal process or the wrongful initiation of criminal or civil proceedings, it is the misuse of process").[2]

[2] PO's evidentiary burden of proof for an abuse of process claim should be "preponderance of the evidence" because it is the burden utilized in abuse of process cases (*see, e.g., World Enters. v. Aquila, Inc.,* 2013 U.S. Dist. LEXIS

III. Dismissal of This Proceeding as a Sanction Would Be Arbitrary, Capricious and Would Violate Due Process

Were the Board to grant PO's request as a sanction, that decision would be arbitrary, capricious and would violate due process. Under "[t]raditional concepts of due process incorporated into administrative law" an agency is precluded "from penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule." *Satellite Broadcasting Co. v. FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987) (reversing FCC's dismissal of SBC's applications because the FCC regulation at issue was unclear). An agency "through its regulatory power cannot, in effect, punish a member of the regulated class for reasonably interpreting Commission rules." *Id*. at 4. If the agency "wishes to use [its] interpretation [of a rule] to cut off a party's right, it must give full notice of its interpretation." *Id*. "Dismissal of an application . . . is a sufficiently grave sanction to trigger this duty to provide clear notice." *Id*. at 3.

Like in *Satellite Broadcasting*, CFAD's interpretation of the statutory requirements for filing a petition for IPR is reasonable. If the Board were to grant PO's motion, it would have failed to give fair notice and its actions would be arbitrary, capricious and would violate due process.

122830, *22 (D. Utah 2013)) and it is the default burden in IPR proceedings. 37 C.F.R. § 42.1(d).

IV. The Public Has a Strong Interest in Invalidating Poor-Quality Patents

A. The Supreme Court and Congress Have Recognized the Strong Public Interest in Invalidating Poor-Quality Patents

PO ignores the useful public purpose served by CFAD's petition. Both the Federal Circuit and "the Supreme Court have recognized that there is a significant public policy interest in removing invalid patents from the public arena." *SmithKline Beecham Corp. v. Apotex Corp*., 403 F.3d 1331, 1354 (Fed. Cir. 2005). This is because there is a "strong federal policy favoring the full and free use of ideas in the public domain," *Lear,* 395 U.S. at 674 and "[i]t is as important to the public that competition should not be repressed by worthless patents." *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224, 234 (1892). Likewise, Congress implemented administrative challenges to patents, such as IPR, to "ensure that poor-quality patents can be weeded out through administrative review rather than costly litigation." 157 Cong. Rec. S5402, S5409 (Sept. 8, 2011) (Statement of Sen. Schumer).

B. The Public Has Expressed a Strong Interest in Having Poor-Quality Pharmaceutical Patents Invalidated through the IPR Process

CFAD's interest in challenging PO's poor-quality patent aligns with that of the public. Organizations such as AARP and health insurers have expressed disagreement and concern to Congress about proposed legislation that would shield or "carve-out brand name drug manufacturers from the inter partes review (IPR)

process." (Ex. 1027 at 1.) Their concern focuses on the "widely-used practice known as 'evergreening' where manufacturers make minor modifications to existing products in order to extend the patent protection for years." (*Id*.) Those organizations are keenly aware, "[e]vergreening results in substantial additional spending on prescription drugs that do not measurably improve quality of care." (*Id*.)

The Center for Economic Policy Research ("CEPR") studied this issue and concluded that "the IPR process appears to be an effective mechanism for quickly removing dubious patent claims before they impose major costs on the economy" and that exempting pharmaceutical patents from the IPR process could cost the public as much as an additional $220 billion over the next 20 years. (Ex. 1028 at 1.) Thus, the ability of anyone to challenge the validity of pharmaceutical patents through IPR is "a critical consumer protection against abusive patent extensions that limit patient access to more affordable treatment options, delay market entry of less expensive generic therapies, and drive up drug costs." (Ex. 1027 at 1.)

PO's '090 patent is a prime example of abusive evergreening for its drug Imbruvica. The '090 patent covers a known and obvious method of using an already-patented drug. PO has at least 11 patents directed to Imbruvica and the '090 patent is part of a second wave of patents that expire in 2031—five years after the original patents. (Ex. 1029.) Removing the '090 patent from the public arena is

a step towards opening competition and speeding the entry of a less expensive generic product. With Imbruvica, bringing down the cost is critical. It is priced at about $130,000 per patient per year—making it one of the most expensive cancer therapies on the market. (Ex. 1030.) If any party is guilty of an abuse of process for a financial gain, it is the PO for misusing the patent system to inappropriately extend patent coverage for a product to obtain unconscionable profits.

Few, if any, consumers have the financial wherewithal to challenge poor-quality pharmaceutical patents. *Lear*, 395 U.S. at 670. Thus, regardless of CFAD's business form or motivation for challenging the validity of the '090 patent, the challenge serves an important public interest: it removes an invalid patent from the system and opens the door to competition through a process that is unaffordable to those who will benefit most.

CONCLUSION

CFAD respectfully requests that the Board deny PO's motion for sanctions.

Respectfully submitted,

Date: August 13, 2015

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CERTIFICATION OF SERVICE

The undersigned hereby certifies that PETITIONER'S RESPONSE TO PATENT OWNER'S MOTION FOR SANCTIONS PURSUANT TO 37 C.F.R. § 42.12, PETITIONER'S UPDATED APPENDIX OF EXHIBITS and EXHIBITS 1026 - 1046 for the above-captioned matter were served in their entirety on August 13, 2015, upon the following parties via electronic mail:

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