

Paper No. _____
Filed: August 11, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI LLC

PETITIONER

V.

CELGENE CORPORATION

PATENT OWNER

CASE NO.: IPR2015-01092

PATENT NO. 6,045,501

FILED: AUGUST 28, 1998

ISSUED: APRIL 4, 2000

INVENTORS: MARC ELSAYED, BRUCE A. WILLIAMS

TITLE: METHODS FOR DELIVERING A DRUG TO A PATIENT WHILE
PREVENTING THE EXPOSURE OF A FOETUS OR CONTRAINDICATED
INDIVIDUAL TO THE DRUG

**OPPOSITION TO PATENT OWNER'S MOTION FOR SANCTIONS
PURSUANT TO 35 U.S.C. § 316(a)(6) AND 37 C.F.R. § 42.12**

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1020	Orange Book Drug Product Listing Corresponding to U.S. Patent No. 6,315,720, as published by the U.S. Food and Drug Administration on August 4, 2015
1021	Pricing Information for Revlimid® (lenalidomide) capsules from “Information for Vermont Prescribers of Prescription Drugs,” from Medi-Span and Celgene Corporation (July 1, 2015)
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1035	“Evergreening: A Deceptive Device in Patent Rights,” Gaurav Dwivedi <i>et al.</i> , <i>Tech. in Society</i> (2010) 32:324-30
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1048	Fang et al, "Short Selling and Earnings Management: A Controlled Experiment," <i>J. Fin.</i> , (forthcoming, 2015)
1049	Ekkehart Boehmer and Juan (Julie) Wu, "Short Selling and the Price Discovery Process," <i>Rev. Fin. Stud.</i> 26: 287-322 (2013)
1050	Boehmer et al., "Shackling Short Sellers: The 2008 Shorting Ban," <i>Rev. Fin. Stud.</i> 26: 1363-1400 (2013)
1051	Massa et al., "The Invisible Hand of Short Selling: Does Short Selling Discipline Earnings Management?" <i>Rev. Fin. Stud.</i> (forthcoming, 2015)
1052	Massa et al., "Governance through Threat: Does Short Selling Improve Internal Governance?" (INSEAD Working Paper 2013/83/FIN)
1053	He et al., "Short Sellers and Innovation: Evidence from a Quasi-natural Experiment," (Kelley School of Business Research Paper No. 2014-14)
1054	Dechow et al., "Short-Sellers, Fundamental Analysis and Stock Returns," <i>J. Fin. Econ.</i> 61:77-106 (2001)

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1055	Akbas et al., “Peer stock short interest and future returns,” (Working Paper, 2015)
1056	Engelberg et al., “How are Shorts Informed? Short-Selling, News and Information Processing,” <i>J. Fin. Econ.</i> 105: 260-278 (2012)
1057	Diether et al., “Short-Sale Strategies and Return Predictability,” <i>Rev. Fin. Stud.</i> 22: 575-607 (2009)
1058	<i>Hedge funds and independent analysts: How independent are their relationships?: Hearing before the S. Comm. on the Judiciary, 109th Cong. 25 (2006) - June 28, 2006 Testimony by Professor Owen A. Lamont, Yale School of Management</i>

I. INTRODUCTION

Celgene's motion is littered with references to the Petitioner's and Real Parties-in-Interest's (collectively, "CFAD") "admitted profit motive," and makes the curious argument that filing IPR petitions with a profit motive constitutes an "abuse of process." Yet at the heart of nearly *every* patent and nearly *every* IPR, the motivation is profit. Celgene files for and acquires patents to profit from the higher drug prices that patents enable. Generic pharmaceutical companies challenge patents to profit from generic sales. Celgene's argument is in conflict with Supreme Court precedent expressly finding it in the public's interest for economically motivated actors to challenge patents. *See 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**"). Having an economic motive for petitioning the government simply does not turn the petition into an abuse of process.

CFAD anticipates that fees and costs to complete an IPR for a single drug is approximately \$1 million dollars. There are a limited number of entities capable of making that financial commitment. And fewer can make such a commitment without the prospect of profiting from their efforts. The fact is CFAD's

motivations do not change the *social value* of its activities. Poor quality patents enable pharmaceutical companies to maintain artificially high drug prices and reap unjust monopoly profits paid for by consumers and taxpayers.

Celgene accuses CFAD of motives that are not entirely “altruistic.” That is a truthful irrelevancy. The U.S. economy is based largely on the notion that individual self-interest, properly directed, benefits society writ large. Celgene’s motive is to profit from consumers and taxpayers from drug sales. Celgene’s patent-conferred monopoly results in Revlimid prices that exceed *\$580 per pill*—creating costs *in excess of \$200,000* per patient year. (*See* Exs. 1021-23, showing prices for three Celgene drugs protected by challenged patents.) Revlimid sales were nearly \$5 billion in 2014. Celgene is not giving Revlimid or its profits away.

CFAD’s IPRs are part of its investment strategy, and it will only succeed by invalidating patents, which would serve the socially valuable purpose of reducing drug prices artificially priced above the socially optimum level. And even if, despite its best efforts, it does not profit—each petition that knocks down a barrier to generic entry benefits the public. It should be axiomatic that people do not undertake socially valuable activity for free—not Celgene, not generics, not shareholders, and not investment funds. Low drug prices will not simply materialize. They must be brought about by agents who will invest significant capital and do the hard work of identifying and challenging weak patents. Generics

sometimes serve this function. But the law does not render it “abuse” for others, including CFAD, to also play this important societal role.

II. STATEMENT OF MATERIAL FACTS

Celgene (Patent Owner or “PO”) listed the challenged ’501 and ’720 patents in the FDA’s Orange Book for not just one—but *three*—of its branded drugs: Thalomid®, Revlimid®, and Pomalyst®. (Exs. 1019, 1020.) PO has asserted both patents to prevent generic entry of Thalomid, and to prevent generic entry of Revlimid. PO asserted both challenged patents (and others) in lawsuits filed against three different generics to delay and prevent FDA approval of their ANDAs until the patents expire. PO asserted the two challenged patents against Barr’s Thalomid ANDA in January 2007 (Ex. 1024), against Natco’s Revlimid ANDA in October 2010 (Ex. 1025), and against Lannett’s Revlimid ANDA in January 2015 (Ex. 1026). PO settled with Barr in May 2010 (Ex. 1027), and was subsequently sued by a union accusing PO of asserting the challenged patents against generics in “sham” litigation (Ex. 1028 at 32, 49-55). Nearly five years have elapsed since PO first asserted the challenged patents against Natco, and no decision on the merits of Natco’s invalidity challenge has issued—and is unlikely to anytime soon because PO moved to stay the litigation on the challenged patents and the stay was granted. (Ex. 1029 at 1-2, Ex. 1030.) Despite PO first asserting

the challenged patents nearly nine years ago—**no court has ever reached a decision on the merits of the validity of either patent.**

In the FDA’s Orange Book, PO currently lists 16 patents for Thalomid (Ex. 1031), 25 patents for Revlimid (Ex. 1032) and 18 patents for Pomalyst (Ex. 1033). None of these Orange Book patents had ever been challenged in any Patent Office proceeding until Petitioner filed challenges in April 2015.

The Federal Trade Commission concluded more than a decade ago that, “in some ways the patent system is out of balance with competition policy” because “poor patent quality” (defined as patents that are “likely invalid” or contain claims that are “likely overly broad”) “may have anticompetitive effects [that] can cause unwarranted market power and can unjustifiably increase costs.” (Ex. 1034 at 5).

It is an unfortunate fact that generic competition is not effective at policing brand evergreening strategies—and a further reason that CFAD’s activities should be encouraged—not sanctioned. (Ex. 1035 at 324). Just three months ago, the FTC stated that the “economic and regulatory context of brand-generic competition creates incentives for [those] companies to collude rather than compete, and the brand’s profits from preserving a monopoly through anti-competitive settlement can be enormous.” (Ex. 1037 at 3.) Such deals “cost consumers and taxpayers billions of dollars, driving up health care costs and depriving patients of needed medications.” *Id.* at 1. The FTC characterizes agreements ending validity

challenges as “‘win-win’ for the companies: brand-name prices stay high, and the brand and generic share the benefits of the brand’s monopoly profits. Consumers lose[]: they miss out on generic prices...as much as 90 percent less than brand prices.” (Ex. 1036 at 3; *see also* Ex. 1038 at 1 (CEPR economic impact study of proposal to exempt pharmaceutical patents from IPRs; finding “it is likely that many dubious claims end up going unchallenged,” and estimating costs arising from improperly granted patents over the next twenty years of \$73–\$220 billion).)

III. RESPONSE TO PATENT OWNER’S “RELEVANT FACTS”

PO’s motion (POM) does not present any *material* facts, it presents only attorney argument and popular press clips. PO’s “relevant facts” section starts by name-calling (POM at 2-3), then cites 16 exhibits to show Mr. Spangenberg and a third-party (IRDP) sent PO’s outside counsel similar draft petitions more than a year before CFAD filed these different Petitions. *Id.* at 3-4.

Nor does PO submit *any* evidence (declarations, emails, or otherwise) establishing that any RPI or IRDP ever demanded payment. Neither email PO submits makes a demand. *See* (Exs. 2033, 2041.) And PO does not cite evidence of any negotiations or even follow-up correspondence. To the contrary, PO admits it “never responded” to Mr. Spangenberg’s email. (POM at 4.) PO does not cite any authority finding abuse of process based on emails attaching draft petitions that do not make a demand and were never filed. It is not abuse of process. *See, e.g.,*

Tedards v. Auty, 232 N.J. Super. 541, 549 (App. Div. 1989) (abuse of process requires “use of process *after* it has been issued”); *Earl v. Winne*, 34 N.J. Super. 606, 615 (Law Div. 1955) (holding no abuse of process if process is not used).¹

The balance of PO’s “relevant facts” primarily quotes various press reports and editorials speculating about or criticizing CFAD for filing Petitions to make a profit. (POM at 5-7, quoting WSJ, Business Insider, Law360, Reuters). None of these articles are evidence—and even if they were they do not establish abuse. The fact is the RPI have not engaged in any misconduct, much less abuse or improper use of these proceedings. In contrast to press gossip, the attached declaration from Dr. Wu (Ex. 1039)—a Finance professor and short selling expert (*id.*, ¶¶ 2-12)—establishes that short selling is common, legal, and regulated (*id.*, ¶¶ 13-19). Markets, shareholders, the investing public, and even shorted companies can and do benefit from short selling. (*Id.*, ¶¶ 20-25.) PO’s suggestions to the contrary (POM at 5-7, 11-14) are baseless. (Ex. 1039, ¶¶ 26-31.) (*See also* Ex. 1058 at 3-4.)

¹ PO accuses an RPI and IRPD of extortion (POM at n.1), but PO admits it did not pay, and the only statute or case PO cites requires “*obtain[ing] property of another* by extortion” for liability. *State v. Roth*, 289 N.J. Super. 152, 158 (1996) (quoting N.J. Stat. § 2C:20-5(g)) (emphasis added). Threats to file lawsuits are not extortion. *U.S. v. Pendergraft*, 297 F.3d 1198, 1205 (11th Cir. 2002).

IV. ARGUMENT

A. The Petitions are proper under the AIA and serve public interests.

PO contends its motion presents a “threshold, gatekeeping” issue (POM at n.3), but then does not address—or even acknowledge—the AIA’s threshold standing provision defining who can petition for IPR. This is fatal to PO’s motion. Statutory interpretation begins with the language of the statute, and “where the statutory language provides a clear answer, it ends there as well.” *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999). 35 U.S.C § 311(a) provides, “[s]ubject to the provisions of the chapter, **a person who is not the owner of a patent may file**...a petition to institute an [IPR] of the patent.” PTO regulations implementing the AIA’s petitioner standing requirement provide, “[**a**] **person who is not the owner of a patent may file** with the Office a petition to institute an inter partes review of the patent unless” the petitioner, RPI, or a privy: **(a)** filed a civil action challenging the patent, **(b)** filed the petition more than one year after being served with an infringement complaint, or **(c)** are estopped from challenging on the grounds in the petition. 37 C.F.R. § 42.101(a)-(c). None of the three enumerated exceptions apply to CFAD, its RPI, or any privy. PO does not allege otherwise.

Having ignored the statutory text, PO’s *lead argument* purports to cite legislative history revealing that the AIA intended to forbid for-profit petitions from petitioners who short sell the PO’s stock. (POM at 7-9.) PO’s citations utterly

fails to support its view of the AIA's IPRs. PO's first cite (POM at 7) is not from the AIA, it is from the Patent Reform Act of 2007 (PRA), and it refers not to IPRs but the PRA's litigation venue restrictions. And PO's "very clear litigation abuses" cite (*id.*) was made in support of ending *qui tam* false marking lawsuits. PO's "litigation reforms to rein in abusive lawsuits" cite (POM at 8) is from the PRA, not the AIA, and refers to PRA's venue and damages provisions. PO's "talking about the patent trolls" cite (*id.*)—in the portion replaced with ellipses—refers to entities that "vacuum up" patents, not IPR petitioners. *Cf.* (Exs. 1031-33 (listing dozens of patents, including patents issued to Celgene and those it vacuumed up).) PO's final two cites fare no better. The "alternative to litigation" cite (POM at 8) is from the PRA, not the AIA—and that cite, as well as the "decrease litigations costs" cite (*id.*) supports CFAD. If successful, the Petitions *would* reduce litigation costs for the two generics seeking to sell generic Revlimid—as well as future Thalomid, Revlimid, and Pomalyst ANDA filers.

Congress created the IPR process to vanquish low quality patents and improve quality. Congress resisted efforts to create IPR limits at odds with the essential reform: "enabling the experts at the PTO to correct errors in the examinations system[.]" (Ex. 1040 at 29; *see also id.* at 52-54 (concerns about IPR abuse were limited to abuses of the process *after* review begins; and citing Fed. R. Civ. P. 11 and the threshold standard for instituting review as tools that prevent

harassment of patentees); Ex. 1041 at 52 (Mr. Kappos preferring more IPRs rather than less because invalid patents are “more costly to our economy(”).)

A long line of Supreme Court cases establish that federal patent policy errs on the side of more patent validity challengers. After citing its prior case holding that public policy requires permitting even a seller of a patent issued to itself to challenge the patent’s validity, the Supreme Court explained why expanding validity challenges serves the public interest:

In thus emphasizing the necessity of...**keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid**, the Court was stating an often expressed policy that [i]t is the public interest which is dominant in the patent system, and that **the right to challenge is not only a private right to the individual, but it is founded on public policy...for the interest of the public fostered by freedom from invalid patents[.]**

Edward Katzinger Co. v. Chicago Metallic Mfg., 329 U.S. 394, 400-01 (1947)

(emphasis added; internal citations omitted). *See also Lear*, 395 U.S. at 670;

SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1131, 1354 (Fed. Cir. 2005)

(“Both this court and the Supreme Court have recognized that there is a significant public policy interest in removing invalid patents from the public arena”).

B. Neither the Petition nor RPI abused or improperly used process.

The Board instructed the parties to address the elements of abuse of process.

(Paper No. 5 at 2.) PO presents a collection of quotes, including two from

Neumann v. Vidal, 710 F.2d 856 (D.C. Cir. 1983). (POM at 10-11.²) *Neumann* has been abrogated, criticized, and distinguished. (Ex. 1042.) By way of example:

Houlahan repeatedly cites *Neumann*...[which] is arguably inconsistent with the stricter standard formulated by the D.C. Court of Appeals in *Bown v. Hamilton*, 601 A.2d 1074, 1080 n.14 (D.C. 1992), and *Morowitz*. Several courts in this jurisdiction properly have declined to adopt the expansive formulation outlined in *Neumann*[]. *See Nader v. Democratic Nat'l Comm.*, 555 F. Supp. 2d 137, 160-61 (D.D.C. 2008), *aff'd on other grounds*, *Nader v. Democratic Nat'l Comm.*, 567 F.3d 692, 386 U.S. App. D.C. 164 (D.C. Cir. 2009) (noting that *Neumann*...ha[s] been “superceded by more recent decisions embracing the more restrictive standards of *Bown*...and *Morowitz*”)[.] *Houlahan v. WorldWide*, 677 F. Supp. 2d 195, 199, n.3 (D.D.C. 2010).

Abuse of process occurs “when ‘process has been used to accomplish some end which is without the regular purview of the process, or which compels the party against whom it is used to do some collateral thing which he could not

² PO’s *Heck v. Humphrey* quote is dicta, but “a **perversion** of lawfully initiated process to **illegitimate** ends” is consistent with CFAD’s decisions analyzing abuse of process. Merely filing a petition is not and cannot be a perversion of the process (unless fraudulent or a “sham”), and short selling is not illegal. (*See* Ex. 1039, ¶¶ 13-19.) PO’s FCC cites found that—unlike the Petitions here—the petitions at issue “do not serve the public interest.” 5 FCC Rcd. 3911, 3912 (1999).

legally and regularly be required to do.” *Houlahan*, F. Supp. 2d at 199 (quoting *Morowitz v. Marvel*, 423 A.2d 196, 198 (D.C. 1980)). Abuse of process has two elements: “(1) the existence of an ulterior motive; and (2) an *act* in the use of process other than such as would be proper in the regular prosecution of the charge.” *Id.* (quoting *Hall v. Hollywood Credit Clothing Co.*, 147 A.2d 866, 868 (D.C. 1959) (emphasis in original)). Contrary to PO’s argument, “the fact that a person acted spitefully, maliciously, or with an ulterior motive in *instituting* a legal proceeding is insufficient to establish abuse of process[.]” *Scott v. District of Columbia*, 101 F.3d 748, 756 (D.C. Cir. 1996) (citing *Restatement (Second) of Torts* § 682 cmt. b (1977) (emphasis added)). *Morowitz* held:

The critical concern in abuse of process cases is whether process was used to accomplish an end unintended by law, and **whether the suit was instituted to achieve a result not regularly or legally obtainable. The mere issuance of the process is not actionable, no matter what ulterior motive may have prompted it; the gist of the action lies in the improper use after issuance.** Thus, in addition to ulterior motive, one must allege and prove that there has been a **perversion of the judicial process...**

423 A.2d at 198 (emphasis added). Thus, PO cannot establish abuse of process.

First, the only process that has been used is filing Petitions, so regardless of ulterior motives, there has not been any abuse of process “after issuance.” *Second*, neither Petitioner nor RPI have performed any act—within or outside the

proceeding—that is not “legally obtainable.” Apart from PO’s misinformed suggestions that short selling is “nefarious,” it has not identified any illegal acts or perversion of this process.³ In fact, PO does not present any evidence establishing CFAD’s Petitions caused it any harm at all. PO has thus “failed to make a colorable showing that [RPI] committed a willful *act* in the use of the process other than such as would be proper in regular prosecution of the charge.” *Houlahan*, F. Supp. 2d at 201 (original emphasis).

Moreover, before even addressing whether PO has a claim for sanctions based on abuse of process, PO must first establish the sham exception to the *Noerr-Pennington* doctrine, which “holds that [individuals] 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*, 555 F. Supp. 2d at 155 (internal cite omitted).

³ PO contends the PTO has not defined a standard of proof, and urges the “reasonable likelihood” standard. (POM at 10, n.3.) PO is wrong on both counts. The PTO defined the standard of proof in 37 C.F.R. § 42.1(d), providing: “[t]he default evidentiary standard is a preponderance of the evidence.” The Board should apply that default standard to PO’s motion and deny it for lacking *any* evidence.

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.

Noerr-Pennington immunity from liability for government petitioning is lost only when a petition is *both* "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits;" *and* subjectively "brought with specific intent to further wrongful conduct 'through the use of the governmental process—as opposed to the outcome of that process.'" *Id.* (citing *Profl Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 60-61 (1993)). "Objectively baseless" means no reasonable litigant could realistically expect success on the merits. *PRE*, 508 U.S. at 60-61. When a petition is not objectively baseless there is no "sham" petition and intent is irrelevant. *Id.* "Subjectively baseless" means the petition is brought with specific intent for wrongful conduct "through use [of] the governmental process—as opposed to the outcome of that process." *Id.* "The sham exception does not extend to genuine attempts to secure governmental action even though the [petitioner] harbors a wrongful motive." *Nader*, 555 F. Supp. 2d at 157.

The Federal Circuit applied these principles to reject an abuse of process claim arising from interference-related petitioning activity. *See Abbott Labs. v. Brennan*, 952 F.2d 1346, 1355-56 (Fed. Cir. 1991) (holding abuse of process claim based on interference petitioning not actionable unless the "entire federal agency

action was a ‘sham’” and that “challenging motives” of petition is insufficient to establish sham); *see also Baker Driveaway Co. v. Bankhead Enterprises, Inc.*, 478 F. Supp. 857, 859 (E.D. Mich. 1979) (filing PTO protest implicates the freedom to petition the government and “will not be curtailed without some extraordinary showing of abuse”). PO has not put forth any material facts establishing—or even alleging—that these Petitions are objectively or subjectively baseless—and that should end abuse of process and “improper use of the proceedings” inquiry.

C. The Board cannot dismiss petitions prior to institution as a sanction.

35 U.S.C. § 316 delegated authority to the PTO to prescribe regulations for the conduct of IPRs. Specifically, § 316(a)(6) empowers the PTO to “prescrib[e] sanctions for abuse of discovery, abuse of process, or any other improper use of *the proceeding*, such as to harass or to cause unnecessary delay or an unnecessary increase in the cost of *the proceeding*.” The Federal Circuit held that the AIA differentiates between a petition for a proceeding, and the act of instituting a proceeding. *Intellectual Ventures II LLC v. JP Morgan Chase & Co.*, 781 F.3d 1372, 1376 (Fed. Cir. 2015). While *IV* analyzed the AIA’s CBMR provision, the opinion applied the AIA’s PGR provisions that cover IPRs—and the court’s reasoning establishes the same result for IPRs. *Id.* For instance, Chapter 31 of Title 35 covers IPRs and refers to “the petition requesting the proceeding,” and *IV* held the same language suggests a petition is a request for an IPR proceeding rather

than the proceeding itself. “Because the language of the statutory scheme consistently defines ‘proceeding’ as beginning when the PTAB institutes review, we adopt that interpretation.” *Id.* at 1377.

IV establishes that when Congress delegated rule-making authority to the PTO to prescribe sanctions for improper use of *the proceeding*, that authority referred to post-institution conduct. Because there has been no institution decision, the Board lacks authority to dismiss the Petitions pursuant to § 316(a)(6) or 37 C.F.R §§ 42.12(a)(6)-(7). *See also Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1335-36 (Fed. Cir. 2008) (PTO is authorized to establish “procedural” rules, but cannot establish a “substantive” rule that “‘effects a change in existing law or policy’ which ‘affect[s] individual rights or obligations.’”). Even if the PTO would receive deference “with respect to procedural rules of conduct before the PTO itself” (*IV* at 1378) to permit *pre-institution* sanctions, a *dismissal* sanction before institution would not receive deference. A dismissal sanction would amount to an impermissible substantive rule that changes existing law governing an individual’s standing to file an IPR petition (“a person not the owner of a patent”). The motion may be denied for this reason alone.

V. CONCLUSION

For all of the foregoing reasons, PO’s motion should be denied.

Respectfully submitted,

August 11, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on August 11, 2015, a copy of this Opposition to Patent Owner's Motion for Sanctions Pursuant to 35 U.S.C. § 316(a)(6) and 37 C.F.R. § 42.12, including all exhibits, was served by filing these documents through the Patent Review Processing System, as well as emailing copies to nickcerrito@quinnemanuel.com and aminsogna@jonesday.com.

Date: August 11, 2015

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