Paper No. __
Filed: August 20, 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 IPR2015-01103
Patent 6,315,720

PATENT OWNER REPLY IN SUPPORT OF ITS MOTION FOR SANCTIONS PURSUANT TO 35 U.S.C. § 316(a)(6) AND 37 C.F.R. § 42.12

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CFAD's focus on standing and the propriety of short selling is an attempt to divert attention from the real issue: whether the manner in which CFAD uses IPRs should be permitted. The answer is "no." The use of IPRs to execute an investment strategy—shorting stocks and then filing IPRs to drive down stock prices—is improper, and an abuse of the IPR process that turns the AIA on its head. This is true regardless of the merits of any petition. Here, *Noerr-Pennington* does not protect CFAD's actions. And despite CFAD's protests, the regulations expressly allow for "dismissal of ***the petition***"; institution of trial is not necessary.

I. CFAD DOES NOT DENY PATENT OWNER'S FACTS[1]

First, CFAD does not deny that the RPI demanded payment in exchange for not filing IPRs in 2014. Instead, CFAD argues that PO presented no evidence, but ignores that Ex. 2033 explains Spangenberg's negotiation tactics. And at least one court has recognized that the "*or else!* oozes" from statements similar to Spangenberg's 2014 email to Celgene. POM at 2-4 & Ex. 2034. Further, CFAD's counsel admitted during the Board call that authorized this motion that payment was discussed. The discussions may be confidential, but at the Board's request, Celgene can supply evidence of the RPI's substantial demand.

Second, CFAD does not deny its use of IPRs to execute its investment strategy. Instead, it argues that "short selling is common, legal and regulated."

[1] PO responds to CFAD's "material facts" in Appendix A. 37 CFR § 42.24(c).

Opp. at 6. Whether short selling is generally proper is irrelevant. CFAD offers no evidence that taking short positions on publicly-traded companies, and then using government petitions (IPRs) to drive down the companies' stock prices, is proper or contemplated by the AIA. PO presented evidence that the PTO "never thought" that IPRs would be used "to move stock or as an investment vehicle." POM at 9.[2]

Third, CFAD does not deny that it: (1) formed for-profit shell companies whose "primary purpose" is to short stocks; (2) has no competitive interest in the challenged patents; and (3) owes its investors a fiduciary duty that puts its investment strategy above any alleged altruistic mission. POM at 5-7.

II. ARGUMENT

The Petition is improper under the AIA and does not serve the public interest. CFAD's arguments to the contrary lack merit. *First*, CFAD incorrectly argues that the AIA's standing provision is fatal to POM. Opp. at 7. POM is not challenging ***who*** CFAD is, but ***how*** it is using IPR proceedings. While anyone can file a petition, the regulations expressly permit dismissal of a petition that is used for an improper purpose or if it is an abuse of process. 37 CFR § 42.12.

Second, CFAD complains about PO's citations to the 2007 PRA legislative history (Opp. at 7-8), but ignores that all of PO's arguments are supported by the

[2] Contrary to CFAD's incorrect assertion, newspapers are "evidence that is self-authenticating." *See* FRE 902(6); 37 CFR § 42.62.

AIA's 2011 legislative history (POM at 7-8). Congress clearly intended to stop non-practicing entities ("NPE"), like CFAD, from using abusive litigation tactics for personal financial gain. *Id.* Congress did not intend to allow those same NPE to turn around and use abusive IPR tactics for personal financial gain. *Id.*

Third, CFAD's caselaw does not support its position. As CFAD emphasizes, the Supreme Court encouraged "**interested persons**," such as "licensees," to challenge patents. Opp. at 9, 1. CFAD has not presented any evidence that it is an "interested person." It cannot. It does not seek to market a competing generic product, and it has not licensed Celgene's patents. Also, its IPRs (even if successful) will not result in generic competition, at least because, as CFAD admits, it has not challenged all of Celgene's Orange Book patents. Opp. at 4. In any event, FDA, not CFAD, controls access to generics, and FDA has not even tentatively approved any generic version of Thalomid®, Revlimid®, or Pomalyst®. Further, there are several interested parties that can challenge Celgene's patents under the AIA. Their petitions would be proper. CFAD's is not.

CFAD is abusing and improperly using the IPR process. CFAD does not challenge that its actions are an abuse of process under *Neumann*. Rather, it argues that "*Neumann* has been abrogated, criticized, and distinguished." Opp. at 10. This is false. *Neumann* remains good law. State and/or federal district courts cannot "abrogate" a circuit court decision, and later decisions from the same court

do not reverse earlier ones unless they do so explicitly; that has not occurred. Regardless, CFAD's actions are an abuse of process even under its cited caselaw, which focuses on improper motive (which is admitted) and some other act that is not a "regular" part of the proceedings. Here, CFAD is admittedly using IPRs to affect stock prices to cash in on "short" positions. This is "***some*** end which is without the ***regular*** purview of [IPRs]," and an "***act*** in the use of process other than such as would be proper in the ***regular*** prosecution of [IPRs]." Opp. at 10-12. Even if CFAD's short positions are not illegal, its use of IPRs to execute its investment strategy is not within the regular purview of IPRs.[3]

***Noerr-Pennington* ("*NP*") does not shield CFAD from sanctions.** *NP* is not a defense to "common litigant sanctions imposed by courts themselves." *BE&K Const. v. NLRB*, 536 U.S. 516, 537 (2002). This logically extends to the Board's discretion to issue sanctions here. *NP* also requires a "grievance," which CFAD does not have; it cannot be injured by the '720 patent. Even assuming that *NP* applies—it does not—CFAD mischaracterizes the standard for proving that its petitions are a "sham." Opp. at 12-14 (alleging that PO must prove objective and subjective baselessness). Instead, when the petitioner "is accused of bringing a

[3] CFAD also argues that dismissal is improper because filing the Petition does not constitute process being issued, but ignores that even threats to file petitions can support abuse of process. *See* 5 FCC Rcd. 3911, 3912 (1990).

whole series of legal proceedings"—as is the case here—"the test is . . . [w]ere the legal filings made, not out of a genuine interest in redressing grievances, but as a part of a pattern or practice of successive filings undertaken essentially for purposes of harassment?" *Primetime 24 v. Nat'l Broad Co.*, 219 F.3d 92, 101 (2d Cir. 2000). Here, the answer is "yes." CFAD's "series of legal proceedings" is "harassment" that is, among other things, frightening off investors. This is an abuse of process under *Neumann*. POM at 11-13. Further, *Abbott* and *Baker* do not support CFAD's position. Opp. at 13-14. Both rejected tort abuse-of-process claims because, as *Abbott* noted, "PTO procedures themselves provide a remedy." 952 F.2d at 1357; *Baker*, 478 F. Supp. at 860 (PTO should "decide [issues] without interference from this court"). Here, the PTO's remedy is sanctions.

The Board can dismiss the Petition prior to institution. CFAD is wrong to suggest that the statute's use of the word "proceeding" requires the Board to wait until after institution. *See, e.g.*, CBM2014-00142, Paper 10 (dismissing petition under § 42.12(b)(8) before institution for failing to comply with "[c]onduct of the ***proceeding***"). In any event, abuse of process and improper use of the proceeding are separate sanctionable actions under 37 CFR § 42.12(a), and no "proceeding" is required for "abuse of process."

III. CONCLUSION

For these reasons and those in POM, the Petition should be dismissed.

Date: August 20, 2015

Respectfully submitted,

By: /F. Dominic Cerrito (Reg. No. 38,100)/

F. Dominic Cerrito (Reg. No. 38,100)
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
Tel: (212) 849-7000
Fax: (212) 849-7100
nickcerrito@quinnemanuel.com

Anthony M. Insogna (Reg. No. 35,203)
JONES DAY
12265 El Camino Real
Suite 200
San Diego, CA 92130
Tel: (858) 314-1200
Fax: (858) 314-1150
aminsogna@jonesday.com

Attorneys for Celgene Corporation

APPENDIX A

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. 1034, 1035.)

PO admits that it submitted the '501 and '720 patents to the FDA for listing in the "Orange Book" in connection with the New Drug Applications for Thalomid®, Revlimid®, and Pomalyst® and, except as so admitted, denies CFAD's allegations.

PO has asserted both patents to prevent generic entry of Thalomid, and to prevent generic entry of Revlimid.

PO admits that it asserted the '501 and '720 patents against filers of Abbreviated New Drug Applications ("ANDA") that infringed those patents by filing certifications with the FDA pursuant to 21 USC § 355(j)(2)(A)(vii)(IV) against those patents and, except as so admitted, denies CFAD's allegations.

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 admits that it asserted patents against ANDA filers that infringed those patents by filing certifications with the FDA pursuant to 21 USC § 355(j)(2)(A)(vii)(IV) against those patents and, except as so admitted, denies CFAD's allegations.

PO asserted the two challenged patents against Barr's Thalomid ANDA in January 2007 (Ex. 1039), against Natco's Revlimid ANDA in October 2010 (Ex. 1040), and against Lannett's Revlimid ANDA in January 2015 (Ex. 1041).

PO admits that it asserted the '501 and '720 patents against Barr in January 2007, against Natco in October 2010, against Lannett in January 2015, and, except as so admitted, denies CFAD's allegations. In particular, no patents were asserted against any "ANDA" and, to PO's knowledge, Lannett has never filed a Revlimid ANDA.

PO settled with Barr in May 2010 (Ex. 1042), and was subsequently sued by a union accusing PO of asserting the challenged patents against generics in "sham" litigation (Ex. 1043 at 32, 49-55).

PO denies that it settled with Barr. Barr voluntarily and unilaterally withdrew its ANDA (*see Celgene Corp. v. Barr Labs., Inc.*, No. 07-286 at D.I. 157 (D.N.J. May 13, 2010)), after which the case against Barr was dismissed and Barr's counterclaims were dismissed with prejudice (*see Celgene Corp. v.*

***Barr Labs., Inc.*, No. 07-286 at D.I. 160 (D.N.J. May 26, 2010)). PO admits that the International Union of Bricklayers and Allied Craft Workers Local 1 Health Fund filed suit against PO and, except as so admitted, denies CFAD's allegations.**

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. 1044 at 1-2, Ex. 1045.)

PO admits that it first sued Natco in October 2010 and that no decision on the merits of Natco's invalidity challenge has issued. PO admits that it filed a meritorious motion to bifurcate and stay the litigation on the '501 and '720 patents due to facts and circumstances that are subject to a Discovery Confidentiality Order in Civil Action No. 10-5197 (D.I. 36) (D.N.J.), and Judge Arleo granted that motion. PO otherwise lacks knowledge or information sufficient to form a belief about the truth of the remainder of CFAD's allegations.

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.

PO admits that no court has ever reached a decision on the merits of the validity of the '501 and '720 patents, and, except as so admitted, denies CFAD's allegations.

In the FDA's Orange Book, PO currently lists 16 patents for Thalomid (Ex. 1046), 25 patents for Revlimid (Ex. 1047) and 18 patents for Pomalyst (Ex. 1048).

PO admits that it submitted the currently listed patents to the FDA for listing in the "Orange Book" in connection with the New Drug Applications for Thalomid®, Revlimid®, and Pomalyst® and, except as so admitted, denies CFAD's allegations.

None of these Orange Book patents had ever been challenged in any Patent Office proceeding until Petitioner filed challenges in April 2015.

It is unclear what CFAD is implying. To the extent CFAD is referring to IPRs, PO admits that no IPRs had been filed against any of the Orange Book patents for Thalomid®, Revlimid®, or Pomalyst® before April 2015. Celgene's U.S. Patent No. 6,315,517, however, has been through reexamination.

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. 1049 at 5).

PO admits that the quoted language appears in Ex. 1049. PO otherwise lacks knowledge or information sufficient to form a belief about the truth of the remainder of CFAD's allegations at least because it is an opinion, and not a fact.

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. 1050 at 324).

PO denies CFAD's allegations.

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. 1052 at 3.)

PO admits that the quoted language appears in Ex. 1052, and, except as so admitted, denies CFAD's allegations.

Such deals "cost consumers and taxpayers billions of dollars, driving up health care costs and depriving patients of needed medications." Id. at 1.

PO admits that the quoted language appears in Ex. 1052, and, except as so admitted, denies CFAD's allegations.

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. 1052 at 3; see also Ex. 1053 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).)

PO admits that the quoted language appears in Ex. 1052 and Ex. 1053, and, except as so admitted, denies CFAD's allegations.

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CERTIFICATE OF SERVICE

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Pursuant to 37 C.F.R. § 42.6(e), the undersigned hereby certify that PATENT OWNER REPLY IN SUPPORT OF ITS MOTION FOR SANCTIONS PURSUANT TO 35 U.S.C. § 316(a)(6) AND 37 C.F.R. § 42.12 was served on August 20, 2015 by filing this document through the Patent Review Processing System, as well as e-mailing a copy to sarah.spires@skiermontpuckett.com, parvathi.kota@skiermontpuckett.com, and paul.skiermont@skiermontpuckett.com.

Date: August 20, 2015

Respectfully submitted,

By: /F. Dominic Cerrito (Reg. No. 38,100)/

F. Dominic Cerrito (Reg. No. 38,100)
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
Tel: (212) 849-7000
Fax: (212) 849-7100
nickcerrito@quinnemanuel.com

Anthony M. Insogna (Reg. No. 35,203)
JONES DAY
12265 El Camino Real
Suite 200
San Diego, CA 92130
Tel: (858) 314-1200
Fax: (858) 314-1150
aminsogna@jonesday.com

Attorneys for Celgene Corporation