UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE OFFICE OF THE UNDERSECRETARY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

OPENSKY INDUSTRIES, LLC, INTEL CORPORATION, Petitioners,

v.

VLSI TECHNOLOGY LLC, Patent Owner.

IPR2021-01064 Patent 7,725,759

BRIEF OF AMICUS CURIAE THE NAPLES ROUNDTABLE IN SUPPORT OF NEITHER PARTY

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On behalf of The Naples Roundtable

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I. INTRODUCTION

The Naples Roundtable, Inc. is a 501(c)(3) non-profit organization whose primary mission is the exploration of ways to improve and strengthen the U.S. patent system. To achieve this goal, the Naples Roundtable supports the advanced study of both national and international intellectual property law and policy. The Naples Roundtable fosters the exchange of ideas and viewpoints among the leading intellectual property experts and scholars. It also organizes conferences and other public events to promote the development and exchange of ideas that improve and strengthen the U.S. patent system. More information about the Naples Roundtable can be found at http://www.thenaplesroundtable.org. The views expressed herein should not be attributed to any individual's employers, law firms, or clients.

This *amicus* brief is filed in support of neither party and takes no position on whether the facts of this case constitute abusive conduct.

The Naples Roundtable submits this *amicus* brief in response to Paper 47, Order Setting Schedule for Director Review (July 7, 2022), which asks two questions:

- 1. What actions the Director, and by delegation the Board, should take when faced with evidence of an abuse of process or conduct that otherwise thwarts, as opposed to advances, the goals of the Office and/or the America Invents Act (AIA); and
- 2. How the Director, and by delegation the Board, should assess conduct to determine if it constitutes an abuse of process, or if it thwarts, as opposed to advances, the goals of the Office and/or the AIA, and what conduct should

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be considered as such.

Paper 47, at 7–8.

The Naples Roundtable files this brief to highlight a particular type of abusive conduct that has not been fully explored and—because of a split within the Board—may go undetected. Abusive petitions, filed for the primary purpose of obtaining a cash settlement, thwart the goals of the Office and the AIA in at least two ways. First, abusive petitions subject patent owners to harassment by petitioners who may have no actual interest in practicing the patented invention. Patent owners, for their part, may be willing to pay off such abusive petitioners with cash simply to make these petitioners "go away" in the short term. These payments—sometimes called "reverse payments" because payment is made by the patent owner to the petitioner—not only fuel more nuisance petitions in the future, but these payments can also raise antitrust concerns if the payments are both "large" and "unexplained." Second, abusive petitions further thwart the goals of the Office and the AIA by denying the Office an opportunity to review a patent that may have been improvidently granted.

In response to question 1 above, the Naples Roundtable submits that, to deter the filing of nuisance petitions by non-practicing petitioners and to make cash settlements less expedient for patent owners, the Board should deny the parties' request to terminate an *inter partes* review based on a purported settlement

agreement where the sole or primary consideration in the agreement is a "reverse payment." Moreover, in certain cases, the Board should refer the matter to the relevant competition authorities in the U.S. Government to investigate potentially anticompetitive behavior.

To implement this solution, the Board should resolve a split in Board decisions that currently hampers the Board's ability to even become aware of abusive settlements: some panels do not require a copy of the settlement agreement to be filed if the proceeding is in its preliminary phase. Therefore, in partial response to question 2, the Naples Roundtable submits that the Director should resolve this split by requiring all settlement agreements to be filed at all stages of an *inter partes* review proceeding—both preliminary and trial phases. In doing so, the Board will improve its ability to detect and deter abusive conduct that otherwise thwarts the goals of the Office and the AIA, while also upholding the Office's role as a depository of patent settlement agreements for competition authorities in the U.S. Government.

II. RELEVANT LEGAL PROVISIONS

35 U.S.C. § 316 provides, in pertinent part:

(a) REGULATIONS.—The Director shall prescribe regulations—

* *

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(4) establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title;

* * *

35 U.S.C. § 317 provides:

(a) In General.—

An inter partes review instituted under this chapter shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner, unless the Office has decided the merits of the proceeding before the request for termination is filed. ...

(b) Agreements in Writing.—

Any agreement or understanding between the patent owner and a petitioner, including any collateral agreements referred to in such agreement or understanding, made in connection with, or in contemplation of, the termination of an inter partes review under this section shall be in writing and a true copy of such agreement or understanding shall be filed in the Office before the termination of the inter partes review as between the parties. At the request of a party to the proceeding, the agreement or understanding shall be treated as business confidential information, shall be kept separate from the file of the involved patents, and shall be made available only to Federal Government agencies on written request, or to any person on a showing of good cause.

37 C.F.R. § 42.74 provides:

- (a) *Board role*. The parties may agree to settle any issue in a proceeding, but the Board is not a party to the settlement and may independently determine any question of jurisdiction, patentability, or Office practice.
- (b) Agreements in writing. Any agreement or understanding between the parties made in connection with, or in contemplation of, the termination of a proceeding shall be in writing and a true copy shall be filed with the Board before the termination of the trial.
- (c) Request to keep separate. A party to a settlement may request that the settlement be treated as business confidential information and

be kept separate from the files of an involved patent or application. The request must be filed with the settlement. If a timely request is filed, the settlement shall only be available:

- (1) To a Government agency on written request to the Board; or
- (2) To any other person upon written request to the Board to make the settlement agreement available, along with the fee specified in § 42.15(d) and on a showing of good cause.

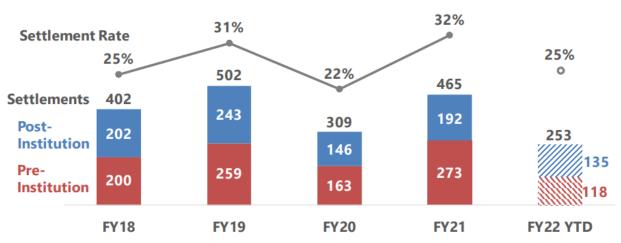
III. TO DETECT AND DETER ABUSIVE NUISANCE-VALUE AND REVERSE-PAYMENT SETTLEMENTS, THE DIRECTOR SHOULD RESOLVE THE SPLIT IN BOARD DECISIONS AND REQUIRE THE SUBMISSION OF SETTLEMENT AGREEMENTS AT ALL STAGES OF PTAB PROCEEDINGS.

As noted above, the filing of nuisance petitions by petitioners, and the payment of "reverse payment" settlements by patent owners, are forms of abusive conduct that thwart the goals of the Office and the AIA. This behavior is mainly abusive on the petitioner side, where the petitioner is primarily interested in obtaining a cash settlement from the patent owner, and the petitioner has no commercial history in the field to which the patent pertains and has no current ability to actually make and sell the patented invention. A rational patent owner may find it expedient to pay this petitioner to end the dispute quickly. A second, albeit less common, abuse is where the patent owner's "reverse payment" to the petitioner is both "large" and "unexplained," thereby triggering anticompetitive concerns under *FTC v. Actavis, Inc.*, 570 U.S. 136, 157 (2013) ("An unexplained large reverse payment ... suggests that the payment's objective is to maintain

supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market....").

The above-described abusive conduct may go undetected by the Office and competition authorities, however, due to a split within the Board regarding whether parties are required to submit copies of their settlement agreement during the pre-institution (preliminary) phase of the *inter partes* review proceeding. This is significant because approximately half of all settlements occur pre-institution, as the Office's most recent data shows:

Settlements (FY18 to FY22 through Q3: Oct. 1, 2017 to Jun. 30, 2022)



Settlement rate is calculated by dividing total settlements by concluded proceedings in each fiscal year (i.e., denied institution, settled, dismissed, requested adverse judgment, and final written decision), excluding joined cases.

uspto

Figure 1. *PTAB Trial Statistics FY 22 Q3 Outcome Roundup IPR*, *PGR*, U.S. Patent & Trademark Office, available at https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2022_q3_roundup.pdf.

As explained below, the Director should resolve the split in Board decisions by requiring parties to file copies of settlement agreements reached at any phase of the proceeding.

A. Nuisance Petitions and Reverse Payments Thwart the Goals of the Office and the AIA.

Nuisance petitions, filed to obtain a quick payout from a patent owner in exchange for termination of the proceeding, are an unintended consequence of the *inter partes* review system, which is intended to permit review of patents that may have been mistakenly granted. "Inter partes review is an administrative proceeding designed to improve patent quality by giving the [Patent Office] 'a second look at an earlier administrative grant of a patent." *St. Regis Mohawk Tribe v. Mylan Pharms., Inc.*, 896 F.3d 1322, 1335 (Fed. Cir. 2018) (Dyk, J., concurring) (quoting *Cuozzo Speed Techs. LLC v. Lee*, 579 U.S. 261, 279 (2016)).

Rather than actually desire the Office to take a second look, however, some petitioners desire only that the patent owner pay them some money. A rational patent owner, faced with one of these petitions, may decide it is more expedient to pay off the petitioner than to endure the time and expense of an IPR proceeding. Moreover, by paying the petitioner in exchange for terminating the proceeding, the patent owner avoids cancelation of its patent claims—and by paying quickly during the pre-institution stage, the patent owner avoids an institution decision that

raises any question about the claims' patentability. These pre-institution settlements may even seem like a win-win for the petitioner and patent owner.

The loser in these cases is the patent system. To be sure, the law favors settlement of disputes between parties, and thus, there is a public interest in upholding voluntary settlement agreements. *See Bergh v. Dept. of Transp.* 794 F.2d 1575, 1577 (Fed. Cir. 1986). But for settlement agreements of an abusive nature, there is an even stronger public interest in allowing the Office to fulfill its obligation of administrative review under the AIA. Where a patent owner pays off a petitioner who has filed a nuisance petition, the patent is not reconsidered by the Office—there is no administrative "second look"—and the petitioner can then use the payout to fund more of these petitions. Particularly where the parties' objective is to quickly settle during the pre-institution phase—before any institution decision can raise any doubt about the claims' patentability—the goals of the Office and the AIA are thwarted.

B. The Office Has Promulgated Rules Governing the Submission of Settlement Agreements in PTAB Proceedings.

35 U.S.C. § 317(a) states:

An inter partes review instituted under this chapter shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner, unless the Office has decided the merits of the proceeding before the request for termination is filed....

Relatedly, section 317(b) states:

Any agreement or understanding between the patent owner and a petition, including any collateral agreements referred to in such agreement or understanding, made in connection with, or in contemplation of the termination of an inter partes review under this section shall be in writing and a true copy of such agreement or understanding shall be filed in the Office before the termination of the inter parties review as between the parties....

The Office duly exercised its rulemaking authority under 35 U.S.C. § 316(a)(4) ("establishing and governing inter partes review") to promulgate regulations, consistent with 35 U.S.C. § 317, concerning the requirement to file copies of settlement agreements. The regulation, 37 C.F.R. § 42.74(b), states:

Any agreement or understanding between the parties made in connection with, or in contemplation of, the **termination of a proceeding** shall be in writing and a true copy shall be filed with the Board before the termination of the **trial**. (emphasis added).

The regulation's use of the term "proceeding" is broad enough to encompass both "a trial or preliminary proceeding." 37 C.F.R § 42.2 (defining "proceeding"). Moreover, a "preliminary proceeding" is defined as a proceeding that "begins with the filing of a petition for instituting a trial and ends with a written decision as to whether a trial will be instituted." *Id.* (defining "preliminary proceeding").

Accordingly, 37 C.F.R. § 42.74(b) plainly requires parties to file a true copy of any settlement agreement if the parties wish to terminate the proceeding during the *preliminary* phase of the proceeding—which necessarily occurs "before the termination of the trial."

C. There Is a Split in Board Opinions Interpreting This Rule.

There is currently a split in Board opinions interpreting Rule 42.74(b). This split is illustrated by the *Samsung* and *Biofrontera* cases described below. Because of this split, parties lack clear guidance as to whether a pre-institution settlement agreement must be filed with the Board and, in the case of the nuisance petitions and reverse payments described above, this split allows abusive settlements to go unchecked within the Office.

1. Samsung Elecs. Co. v. Telefonaktiebolaget LM Ericsson, IPR2021-00446, Paper 7 (PTAB Aug. 3, 2021)

In *Samsung*, the parties reached a settlement during the preliminary phase of the *inter partes* review proceeding, and the petitioner requested dismissal prior to a decision on institution. A fractured panel of the Board construed § 42.74(b) as requiring the filing of settlement agreements only after a trial has been instituted, asserting that "to read the language requiring parties to file settlement agreements to apply to all 'proceedings' would read out the language 'before termination of the trial' from the Rule." *Samsung*, at 4. Additionally, the panel majority found the term "termination" at odds with the pre-institution phase, noting that the Board's regulations permit *dismissal* of a petition, rather than "termination." *Samsung*, at 4–5. Because no statute or regulation addresses settlement agreements in

conjunction with "dismissals" of a petition, the panel majority in *Samsung* declined to require settlement agreements to be filed prior to institution. *Id.* at 5.

APJ Quinn dissented. APJ Quinn noted that the majority's interpretation disregarded anticompetitive concerns, rewrote an unambiguous rule, and was inconsistent with "a substantial majority of the Board's settlement-driven terminations pre-institution." *Id.* at 7. APJ Quinn explained that § 42.74(b) had consistently been interpreted to require pre-institution settlement agreements to be filed and to construe the rule otherwise would "create inconsistency in [the Board's] decision-making and have the potential to confuse stakeholders and the public-at-large." *Samsung*, at 11.

2. Biofrontera Incorporated v. Dusa Pharmaceuticals, Inc., IPR 2022-00056, Paper 7 (PTAB Dec. 28, 2021)

On the same material facts as *Samsung*, the Board in *Biofrontera* came to the opposite conclusion.

The petitioner in *Biofrontera* moved to dismiss the petition based on a settlement agreement during the preliminary phase of the proceeding. The petitioner cited the majority opinion in *Samsung* (discussed above) to argue that it was not required to file a copy of the settlement agreement. The Board in *Biofrontera* disagreed. The Board acknowledged the majority opinion in *Samsung*

but determined that APJ Quinn's dissenting opinion had the better interpretation of § 42.74(b).

The unanimous panel in *Biofrontera* agreed with APJ Quinn that "proceeding" is defined as "a trial or preliminary proceeding" and that a "preliminary proceeding" is defined as one that "begins with the filing of a petition for instituting a trial and ends with a written decision as to whether a trial will be instituted." *Biofrontera*, at 3 (quoting dissent by APJ Quinn in *Samsung Elecs. Co. v. Telefonaktiebolaget LM Ericsson*, IPR2021-00446, Paper 7 (PTAB Aug. 3, 2021)). Given these definitions, the *Biofrontera* panel unanimously held that parties are required to file any settlement agreement made in connection with, or in contemplation of, the termination of a proceeding, which includes the preinstitution phase. Because the petitioner had not filed its settlement agreement, the Board denied the petitioner's motion to dismiss. *Biofrontera*, at 3.

D. The Director Should Resolve the Intra-Board Split to Help Detect and Deter Abusive Conduct that Thwarts the Goals of the Office and the AIA.

Because of the split in Board decisions interpreting § 42.74(b), it is incumbent on the Director to clarify this issue and eliminate the "inconsistency" and "confus[ion]" APJ Quinn warned about in the *Samsung* case. Indeed, the *Biofrontera* panel noted that "the Board currently has no precedential decision or written directive from the Director resolving different interpretations regarding the

applicability of Rule 42.74(b) to motions to dismiss petitions based on preinstitution settlement agreements." *Biofrontera*, at 2–3. Therefore, to allow the Board to detect and deter abusive conduct that thwarts the goals of the Office and the AIA, the Director should resolve the split and require copies of all settlement agreements to be filed regardless of the stage of the proceeding.

1. The issue is too important to continue to allow different panels to enforce (or not) the rule requiring the submission of settlement agreements.

Under the PTAB's standard operating procedure, "The Director has an interest in creating binding norms for fair and efficient Board proceedings, and for establishing consistency across decision makers under the Leahy-Smith America Invents Act." *Standard Operating Procedure 2 (Rev. 10)*. Here, not only is the interpretation of § 42.74(b) concerning pre-institution settlement agreements the subject of conflicting Board decisions, but it is also a matter of great importance to the Office and to the integrity of the patent system.

The Office plays a vital role as the depository of patent settlements in contested Office proceedings. Once a settlement agreement has been filed with the Office, it becomes available for inspection by "Federal Government agencies on written request, or to any person on a showing of good cause." 35 U.S.C. § 317(b).

As APJ Quinn herself noted in *Samsung*, failing to require parties to submit copies of their settlement agreements "disregards anticompetitive concerns that

have been part of the history of contested cases at the USPTO for over 50 years." *Samsung*, Dissenting Op. at 7–9 (noting the "USPTO's role as the depository of the settlement agreements so that the Federal Trade Commission and the Department of Justice would have easier access to documents germane to investigations regarding violations of antitrust laws").

2. The *Biofrontera* panel decision and APJ Quinn's dissent in *Samsung* correctly interpret § 42.74(b) and further address abusive conduct that thwarts the goals of the PTAB and the AIA.

In resolving the split in Board opinions, the Director should side with the *Biofrontera* panel for two reasons: as a matter of interpretation and as a matter of policy. Both the text of § 42.74(b) and the purpose behind the rule weigh in favor of requiring copies of settlement agreements to be filed regardless of the stage of the proceeding.

As a matter of interpretation, § 42.74(b) applies to both pre- and post-institution settlements. The use of "proceeding" and "trial" within the same sentence of § 42.74(b) strongly suggests that these terms have different meanings. The *Biofrontera* panel and APJ Quinn in *Samsung* interpreted this rule in this way. Moreover, these terms are explicitly defined in § 42.2 and, therefore, must be given their defined meanings. Finally, these two terms are being used in two different capacities, again supporting that they have two different meanings. The term

"proceeding" in § 42.74(b) is attached to the idea of termination—that is, ending the proceeding by removing it from the Board's jurisdiction. The term "trial," by contrast, is used as a deadline—the last possible date by which the settlement agreement must be filed before the conclusion of the trial phase. Thus, if a "proceeding" is sought to be terminated during the preliminary phase (and thus before trial), it necessarily meets the deadline ("before the termination of the trial"). A deadline is simply the <u>last</u> moment an action can occur (here, the act of "filing" a copy of the settlement agreement).

As a policy matter, copies of settlement agreements should be required to be filed regardless of the phase of the proceeding. The purpose of the requirement is to ensure that potentially anticompetitive behavior does not evade detection by the Office and the competition authorities. *See Samsung*, Dissenting Op. at 8 (noting the "USPTO's role as the depository of the settlement agreements so that the Federal Trade Commission and the Department of Justice would have easier access to documents germane to investigations regarding violations of antitrust laws"). This purpose is true not just for post-institution settlements but applies equally to pre-institution settlements as well. In fact, since the Board in the preliminary phase has not yet decided the threshold question of whether the petition establishes a reasonable likelihood of unpatentability, any settlement during the preliminary phase allows the patent owner to entirely avoid the Office expressing any doubt

over the claims' patentability. Settling the proceeding during the pre-institution phase also eliminates the possibility that third parties can "join" the initial petitioner's challenge under 35 U.S.C. § 315(c). The parties are thus motivated to settle during the preliminary phase, which is when approximately <u>half</u> of all settlements occur.

IV. TO DETER ABUSIVE CONDUCT AND ADVANCE THE GOALS OF THE OFFICE AND THE AIA, THE DIRECTOR SHOULD DENY TERMINATION BASED ON REVERSE-PAYMENT AND NUISANCE-VALUE SETTLEMENTS AND REFER THE MATTER TO COMPETITION AUTHORITIES.

Requiring parties to submit copies of their settlement agreements at all phases of the proceeding will better allow the Office to determine whether the settlement between the petitioner and patent owner is a potential shake-down or involves other potentially anticompetitive behavior. This course of action alone—requiring the parties to file copies of their settlement agreements at any phase—may be sufficient to deter the filing of nuisance petitions in the first place. Indeed, if a petitioner knows that the Office will be scrutinizing any agreement the petitioner reaches with a patent owner, the petitioner may be deterred from filing a nuisance petition in the first place. Likewise, a patent owner will be less likely to pay-off such a petitioner simply to make the petitioner go away if the patent owner knows that a copy of its reverse-payment settlement agreement will be available

for inspection by "Federal Government agencies on written request, or to any person on a showing of good cause." 35 U.S.C. § 317(b).

To provide even greater deterrence, and to further address abusive conduct, the Office should deny the parties' request to terminate the proceeding if the Board suspects that the settlement agreement involves abusive conduct by the petitioner, the patent owner, or both. Additionally, if the settlement agreement contains an "unexplained large reverse payment" by the patent owner to the petitioner, the Office could take the additional step of referring the matter to the Federal Trade Commission (FTC) and the Department of Justice-Antitrust Division (DOJ), who could then request access to the settlement agreement. *FTC v. Actavis, Inc.*, 570 U.S. 136, 157 (2013). Referring such settlement agreements to FTC-DOJ is a proven course of action that has demonstrated positive results in the pharmaceutical industry.

A. Scrutinizing Settlement Agreements Provides an Opportunity to Identify Conduct that Thwarts the Office and the AIA.

Parties will be less likely to engage in abusive settlement behavior if they know the Office will scrutinize the terms of their settlement agreements for signs of abusive conduct. One telltale sign of abusive conduct is where the sole or primary consideration in a settlement agreement is a "reverse payment" paid by a patent owner to a petitioner in exchange for the petitioner's promise not to

challenge the patent or other patents owned by the same owner. This conduct is especially problematic if (1) the petitioner has no prior history or current commercial ability to actually practice the patented invention or (2) the payment to the petitioner is "large" and "unexplained." *Actavis*, 570 U.S. at 156–57 (contrasting anticompetitive payment with "traditional settlement considerations" such as "fair value for services" rendered by the payee).

B. When Faced with an Abusive Settlement, the Board Should Deny the Parties' Request to Terminate the Proceeding and May Also Forward the Matter to the FTC and DOJ.

Addressing the Director's question 1 as to what actions the Director or Board should take when faced with evidence of misconduct (here, in an abusive settlement agreement), the simplest response is to deny the parties' request to terminate the proceeding. If the circumstances warrant, the Director or Board may also forward the matter to the FTC and DOJ for further investigation into the potentially anticompetitive behavior.

Particularly where a petitioner files a nuisance petition—and, relatedly, where the patent owner pays to make this petition go away—terminating the proceeding is precisely what the parties want. After all, the purpose of a nuisance petition is to extract cash that the patent owner would otherwise pay its lawyers to go through a full proceeding before the Board. Likewise, the point of a reverse payment is to end the proceeding so as to avoid the risk of cancelation of the patent

claims. Thus, to deter both nuisance petitions and reverse payments, the solution is to deny the parties' request to terminate the proceeding. Allowing the institution decision to be made on the merits advances the goals of the Office and the AIA by permitting a second look at patent claims that may have been improvidently granted.

In egregious cases, such as where a petitioner has demonstrated a history of filing nuisance petitions with no history or ability to practice the patented invention, or where a patent owner has made a "large" and "unexplained" reverse payment, these circumstances warrant the Director to refer the matter to the FTC or the DOJ, who may then request a copy of the settlement agreement under 35 U.S.C. § 317(b). *See Samsung*, Dissenting Op. at 7–9 (noting "USPTO's role as the depository of the settlement agreements so that the Federal Trade Commission and the Department of Justice would have easier access to documents germane to investigations regarding violations of antitrust laws").

C. Declining to Terminate the Proceeding in the Face of Misconduct and Requiring that Settlement Agreements Be Submitted at Any Stage, Has Been Demonstrated to Be Effective in Other Areas.

The PTAB is not the only forum that has dealt with misconduct that threatens the purpose of the system in which the forum exists. In fact, other forums have been impacted by settlement agreements that threaten to impede their underlying statutory or regulatory scheme. One example is the pharmaceutical

industry and the Hatch-Waxman scheme. There, settlement agreements are handled in a way that provides a positive view of how the above proposed solution could also work for the PTAB.

While not all settlements are problematic and, in fact, settlements are often a preferable resolution to disputes between private parties, there are some settlement agreements that thwart the purpose of the system in which the dispute arose. Known as "pay-for-delay," the misconduct at issue in Hatch-Waxman cases was the settling of cases where a generic pharmaceutical company sought to enter the market and was given a payout by the brand name drug manufacturer to cease those efforts. As the Supreme Court in *FTC v. Actavis* explained:

Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement.

570 U.S. at 140-141.

The problem is that one of the primary goals of the Hatch-Waxman regulatory scheme is to facilitate entry of generic drug manufacturers into the market. Settlement thwarts that entry because the generic drug manufacturer is paid to <u>not</u> enter the market. *Id.* Moreover, much like settlements in the IPR context, settlements in the Hatch-Waxman context also prevent patents from being

reviewed post-issuance for possible invalid claims. These two concerns harm competition because the relevant generic drugs do not enter the market until after a date the patent could be found invalid. FEDERAL TRADE COMMISSION,

AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT ii

(Aug. 2011).

Not all settlement agreements between brand-name drug makers and generic drug manufacturers are anticompetitive, just like not all settlement agreements between petitioners and patent owners thwart the goals of the Office and the AIA. However, the only way to ensure this is to require all settlement agreements be filed with the relevant body.

After the Supreme Court in *FTC v. Actavis* held that reverse-payment settlement agreements would be scrutinized under the antitrust rule-of-reason test, the FTC found that fewer drug manufacturers entered into fewer reverse payment settlements. *See* FEDERAL TRADE COMMISSION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, & MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2014: A REPORT BY THE BUREAU OF COMPETITION (Jan. 2016).

One can similarly expect the number of abusive IPR petitions and reversepayment settlements to drop, if the Director clarifies that: (1) all settlement agreements must be filed with the Board regardless of the phase of the proceeding and (2) abusive settlements will not result in termination but may instead be referred to competition authorities.

V. CONCLUSION

Abusive behavior in AIA trial proceedings is potentially going undetected by the Board because of a split within the Board regarding the requirement to file settlement agreements during the preliminary phase of the proceeding. This abusive behavior mainly involves a petitioner, who has no commercial history or actual ability to practice the patented invention, filing a petition for the primary purpose of obtaining a cash settlement. In rarer cases, the patent owner's "reverse payment" to the petitioner may trigger anticompetitive concerns where the payment is both large and unexplained. Both of these forms of abusive conduct could be detected, however, if the Board uniformly required parties to file a copy of their settlement agreement at all stages of the AIA trial proceeding.

In response to the second question, the Director should require copies of all settlement agreements to be filed regardless of the stage of the proceeding. This will allow the Director (and by delegation the Board) to scrutinize the conduct of the parties in relation to any settlement and to uphold the Office's role as a depository of patent settlement agreements.

In response to the first question, when faced with evidence of abusive conduct in a settlement agreement, the Director (and by delegation the Board)

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should deny the parties' request to terminate such proceeding and, where warranted, refer the matter to the FTC and DOJ, who may then request a copy of the settlement agreement.

Respectfully submitted,

Date: August 4, 2022 /Kristen Osenga/

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On behalf of The Naples Roundtable, Inc.