



Your Generics & Biosimilars Industry

December 3, 2020

Via Federal eRulemaking Portal (<https://www.regulations.gov>)

The Honorable Andrei Iancu  
Under Secretary of Commerce for Intellectual Property  
Director of the United States Patent and Trademark Office  
Madison Building  
600 Dulany Street  
Alexandria, VA 22313-1450

**Re: Comments from the Association for Accessible Medicines  
Regarding Docket No. PTO-C-2020-0055,  
“Discretion to Institute Trials Before the Patent Trial and Appeal Board”**

Dear Director Iancu:

The Association for Accessible Medicines (“AAM”) is pleased to provide these comments in response to the U.S. Patent and Trademark Office’s (“Office”) Request for Comments, titled “Discretion to Institute Trials Before the Patent Trial and Appeal Board.” Specifically, these comments respond to the Office’s proposed “codification of its current policies and practices, or the modification thereof, through rulemaking” regarding “considerations for instituting trials before the Office under the Leahy-Smith America Invents Act (AIA)” regarding the potential codification of discretionary denials relating to serial petitions, parallel petitions, and proceedings in other tribunals.<sup>1</sup>

*Inter partes* review (“IPR”) provides an important pathway to enable AAM’s members—generic and biosimilar companies—to challenge competition-stifling patents. In particular, IPR was created by Congress to combat “overpatenting and its diminishment of competition,” and to allow parties to “weed out bad patent claims efficiently.”<sup>2</sup> Many generic and biosimilar companies have accordingly used IPR as an outlet to challenge such patents and launch cost-saving versions of various medicines.

AAM strongly urges the Office not to codify its current policies and practices regarding discretionary denials of petitions based on proceedings in other tribunals. The Office’s current policies and practices are inconsistent with the AIA and are particularly prejudicial to generic and biosimilar pharmaceutical companies. Specifically, the Office’s precedential decision in *Apple Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper No. 11 (P.T.A.B. Mar. 20, 2020) allows administrative law judges (“APJ”) to discretionarily deny petitions based on the progress of parallel litigation proceedings, even where such proceedings do not involve the petitioner at all. The *Fintiv* rule lacks any roots in the AIA, and in view of the unique procedural and timing issues inherent to pharmaceutical patent litigation, will significantly impede generic and biosimilar companies from challenging patents in IPR. AAM accordingly urges the Office to abandon the *Fintiv* framework.

AAM also recommends against codification of the Office’s current practices and policies regarding serial and parallel-filed petitions. The Office’s current policies fail to account for critical factors that may compel

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<sup>1</sup> 85 Fed. Reg. at 66502-03, 66506 (Oct. 20, 2020).

<sup>2</sup> H. R. Rep. No. 112-98, pt. 1, p. 40 (2011).

petitioners to either subsequently file—or file in parallel—a petition concerning the same patent. Like *Fintiv*, the Office’s *General Plastic* rule allows APJs to discretionarily deny subsequently-filed petitions filed by different petitioners, even where the petitions concern different prior art or claims. And the Office’s current guidelines regarding parallel petitions fails to safeguard petitioners from discretionary denials where such petitions are necessary in view of the Office’s limits on word count. As they stand, AAM urges the Office against codification.

Finally, codification of any of these practices would implicate the “economically significant” rule. By statute, the Director is obligated to “consider the effect of any . . . regulation on the economy.”<sup>3</sup> Such consideration further requires a cost-benefit analysis showing that “upon a reasoned determination,” the benefits of the proposed rule “justify its costs.”<sup>4</sup> Enacting regulations according to the Office’s current practices would make it substantially more difficult for petitioners to challenge competition-stifling patents in a cost-effective and efficient manner, which would ultimately diminish pharmaceutical competition and result in higher prescription drug prices for patients.

## **I. AAM Has a Strong Interest in an Effective IPR Process**

AAM is the nation’s leading trade association for manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines. AAM’s core mission is to improve the lives of patients by advancing timely access to safe, effective, and affordable generic and biosimilar medicines. Generics represent greater than 90% of all prescriptions dispensed in the United States, but account for only 22% of expenditures on prescription drugs, saving patients and payers nearly \$2 trillion over the past ten years.<sup>5</sup> Our members’ products are used in more than four billion prescriptions every year.<sup>6</sup>

AAM supports a strong and robust patent system to encourage and enable innovation, and applauds the work of the Office in examining and issuing high-quality patents. AAM’s member companies frequently obtain and assert patents themselves. Unfortunately, low-quality patents sometimes issue despite the Office’s best efforts. This is unsurprising because examiners are charged with completing numerous distinct tasks during the examination process—all of which must be completed on average within a mere 19 hours.<sup>7</sup> Not only do these patents discourage and disable innovation, they lead directly to higher health-care costs by closing off market alternatives and foreclosing the savings that generic competition can bring.

Because of two statutory schemes, the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (“BPCIA”), generic and biosimilar pharmaceutical companies generally must address patent issues before launching a product through costly and protracted patent infringement litigation. These statutory schemes were designed to create a robust generic and biosimilar drug marketplace, and, as a whole, have been successful in balancing the need for innovative drug therapies while enabling generic and biosimilar pharmaceutical companies to offer patients affordable medicines.

Despite this statutory scheme, some brand-name pharmaceutical companies have found ways to slow the availability of affordable generics and biosimilar medicines to patients. By abusing the patent system, brand-name pharmaceutical companies can extend patent-supported monopolies for years. In a number of these cases, the later-filed patents claim small, incremental changes that do not represent genuine

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<sup>3</sup> 35 U.S.C. § 316(a).

<sup>4</sup> See Congressional Research Service, *Counting Regulations: An Overview of Rulemaking, Types of Federal Regulations, and Pages in the Federal Register* at 4 (last updated Sept. 3, 2019), available at <https://fas.org/sgp/crs/misc/R43056.pdf>.

<sup>5</sup> AAM 2019 Generic Drug and Biosimilar Access & Savings in the U.S., <https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf>.

<sup>6</sup> *Id.*

<sup>7</sup> Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data*, Nat’l Bureau of Econ. Research Working Paper 20337, at 7 (July 2014), <http://www.nber.org/papers/w20337.pdf>.

innovation or benefit patients. Yet these low-quality—and often non-innovative—patents effectively delay generic competition. And such non-innovative patents can force generic and biosimilar pharmaceutical companies into years of slow-moving and costly litigation.

*Inter partes* review (“IPR”) provides a means through which generic and biosimilar manufacturers can address and correct these patent abuses. As the Supreme Court recently explained, IPR “protects ‘the public’s paramount interest in seeing that patent monopolies are kept within their legitimate scope.’”<sup>8</sup> According to the Office’s data, between September 16, 2012 and November 30, 2018, nearly 1,000 IPR petitions challenged patents listed in the Orange Book, patents covering biologics, or patents that are otherwise in the field of biologics/pharma.<sup>9</sup> During this timeframe, the institution rates for these categories of patents ranged from 50 to 64%.<sup>10</sup> Thus, contrary to brand companies’ assertions, IPR is indisputably not a “death squad.”

Many generic pharmaceutical companies have used IPR proceedings to successfully launch their products, providing patients with earlier access to more affordable medications. For example, successful IPRs brought by Noven Pharmaceuticals Inc. paved the way for generic competition to the Exelon<sup>®</sup> patch for the treatment of Alzheimer’s and Parkinson’s disease.<sup>11</sup> Similarly, generic pharmaceutical companies successfully defeated the claims of a patent covering the drug Zytiga<sup>®</sup>, allowing for the launch of generic versions of the drug to treat prostate cancer.<sup>12</sup> As a result of this successful IPR, patients saved an average 81% on this life-saving medicine due to the availability of generic Zytiga<sup>®</sup>.<sup>13</sup> Over the course of four IPRs, generic pharmaceutical companies also invalidated all challenged claims of several patents covering OxyContin<sup>®</sup> in response to infringement allegations asserting over a dozen patents.<sup>14</sup> And through a series of IPRs, numerous other drug patents have been invalidated—in whole or in part—through IPR, including patents for Lantus<sup>®</sup>, Herceptin<sup>®</sup>, Rituxan<sup>®</sup>, Avastin<sup>®</sup>, and Neulasta<sup>®</sup>.<sup>15</sup>

For all these reasons, AAM has long been a supporter of IPR and the Office’s efforts to implement IPR proceedings efficiently and effectively. For example, at a Senate Judiciary Committee Hearing for STRONGER, AAM emphasized the importance of IPR, explaining it provides “cost-effective, efficient procedures . . . to ensure that questionable, non-innovative patents may be efficiently invalidated.”<sup>16</sup> AAM explained why IPR is “critically necessary to help get invalid patents—including those blocking more affordable generic and biosimilar medicines—declared invalid as quickly as possible.”<sup>17</sup> At another Senate Judiciary Committee Hearing, AAM highlighted some of the ways IPR has improved the patent system as compared to examination or district court litigation.<sup>18</sup> In particular, IPR “allows a patent owner’s arguments to be tested through cross-examination and the submissions of opposing experts in a way that examination does not allow,” and “allows invalidity issues to go before experts from within the

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<sup>8</sup> *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1374 (2018) (citation omitted).

<sup>9</sup> USPTO, *Orange Book patent/biologic patent study and district court pharma litigation study*, at 14 (July 18, 2019), [https://www.uspto.gov/sites/default/files/documents/Boardside%20Chat%20-%20Orange%20Book%20and%20Biologics%20%282019-07-11%29-IQ\\_807521-Final.pdf](https://www.uspto.gov/sites/default/files/documents/Boardside%20Chat%20-%20Orange%20Book%20and%20Biologics%20%282019-07-11%29-IQ_807521-Final.pdf).

<sup>10</sup> *Id.* at 18.

<sup>11</sup> *Novartis AG V. Noven Pharm. Inc.*, 853 F.3d 1289 (Fed. Cir. 2017) (affirming IPR decisions).

<sup>12</sup> *BTG Int’l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063 (Fed. Cir. 2019) (affirming IPR decisions)

<sup>13</sup> See AAM, Let’s strengthen IPR to accelerate patient access and lower prescription drug prices.

<sup>14</sup> See *Amneal Pharmaceuticals, LLC v. Purdue Pharma, L.P. et al.*, Case Nos. IPR2016-01412, (Feb. 8, 2018), IPR2016-01413, (Jan. 17, 2018), IPR2016-01027, (Nov. 8, 2017), and IPR2016-01028, (Nov. 8, 2017).

<sup>15</sup> See AAM, Statement for the Record, Senate Judiciary Committee Hearing on the “Support Technology and Research for Our Nation’s Growth and Economic Resilience Patents Act of 2019 (‘STRONGER’),” at 2-3 (Sept. 11, 2019).

<sup>16</sup> *Id.* at 2.

<sup>17</sup> *Id.* at 2-3.

<sup>18</sup> See AAM, Statement for the Record, Senate Judiciary Committee Hearing on the “Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition,” at 2-3 (May 7, 2019).

Patent Office, rather than lay jurors or generalist federal trial judges.”<sup>19</sup> AAM likewise supported the Office’s position and defended the constitutionality—and important role—of IPR in the recent Supreme Court case *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC*.<sup>20</sup>

Accordingly, AAM has a strong interest in defending an IPR framework that permits its members to efficiently invalidate non-innovative patents and chip away at harmful patent monopolies.

## II. Pharmaceutical Patent Litigation Has Unique Procedural and Timing Issues that Impact Co-Pending and Subsequent IPRs

Given the framework of the Hatch-Waxman Act and BPCIA, it is common for multiple generic and biosimilar pharmaceutical companies to face infringement allegations over the same patents. This raises unique procedural and timing issues relevant to discretionary denials of IPR. In particular, these aspects of pharmaceutical patent litigation increase the likelihood that serial and parallel petitions may be warranted, nearly guarantees that proceedings will occur in other tribunals, and makes it imperative that generic and biosimilar pharmaceutical companies are not prejudiced by the actions of their competitors.

Under the Hatch-Waxman Act, an applicant seeking to market a new brand-name drug must prepare a New Drug Application (“NDA”) for consideration by the FDA. Among other things, an NDA must identify any patent that allegedly claims the “drug” or a “method of using [the] drug” for which the NDA was submitted, and for which a claim of patent infringement could reasonably be asserted against an unauthorized user.<sup>21</sup> Upon NDA approval, these patents are subsequently published in “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.”<sup>22</sup>

A pharmaceutical company seeking approval of a generic version of a brand-name drug must submit an Abbreviated New Drug Application (“ANDA”) to the FDA. An ANDA must include a “certification” to each patent listed in the Orange Book in connection with the NDA for the brand-name drug.<sup>23</sup> A “Paragraph IV” certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration.<sup>24</sup> The Hatch-Waxman act requires that an applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications.<sup>25</sup> Upon receiving notice of the Paragraph IV certifications, the patent holder has 45 days to file an infringement suit against the generic manufacturer, which triggers an automatic 30-month stay on the approval of the ANDA.<sup>26</sup> In view of this 30-month stay, district courts typically seek to resolve Hatch-Waxman cases in less than 30 months, most often scheduling trial around the 24-month mark.<sup>27</sup>

In some circumstances, there are time limitations regarding when a generic pharmaceutical company can file an ANDA, and therefore when the ANDA filer can submit a Paragraph IV certification with respect to any Orange Book-listed patents. For example, if an NDA holder receives approval for a new chemical entity (“NCE”), the Hatch-Waxman Act provides that FDA will not accept a generic application for such a

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<sup>19</sup> *Id.* at 3.

<sup>20</sup> 138 S. Ct. 1365 (2018).

<sup>21</sup> See 21 U.S.C. §§ 355(b)(1), (c)(2); 21 C.F.R. §§ 314.53(b)(1), (c)(2).

<sup>22</sup> 21 C.F.R. § 314.53(e).

<sup>23</sup> 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

<sup>24</sup> 21 U.S.C. § 355(j)(2)(A)(vii)(IV); see also 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

<sup>25</sup> 21 U.S.C. § 355(j)(2)(B).

<sup>26</sup> 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. 271(e)(2)(A).

<sup>27</sup> See, e.g., Lex Machina, Hatch-Waxman / ANDA Litigation Report at Fig. 9 (2018).

drug for a period of five years.<sup>28</sup> However, the Act allows generic pharmaceutical companies to file ANDAs with a paragraph IV certification one year before the expiration of the NCE exclusivity, commonly referred to as the NCE-1 date.<sup>29</sup> The NCE framework frequently results in numerous generic pharmaceutical companies filing ANDAs on the same day, though it is also common for additional ANDAs to be filed later.

Absent any regulatory exclusivity, there are no limitations as to when generic pharmaceutical companies can file ANDAs for brand-name drugs. In such circumstances, ANDAs are frequently filed at different times, potentially resulting in numerous generic pharmaceutical companies litigating the same patents, but at different stages of litigation or even in different district courts. This is especially so given recent Federal Circuit rulings on venue.<sup>30</sup>

The BPCIA, too, presents unique procedural and timing issues that impact IPRs. Under the BPCIA, biosimilar pharmaceutical companies may notify the reference biologic product sponsor that it filed an Abbreviated Biologics License Application (“aBLA”) within 20 days of the FDA’s acceptance of the aBLA.<sup>31</sup> Within 60 days of receiving such notice, the biologic product sponsor identifies a list of unexpired patents for which a claim of infringement could reasonably be made.<sup>32</sup> The biosimilar applicant then has 60 days to provide detailed invalidity, unenforceability, and/or non-infringement contentions for each of the identified patents.<sup>33</sup> In response, the biologic product sponsor provides the factual and legal basis for its opinion that such patent will be infringed by the biosimilar applicant.<sup>34</sup> Over many months, the parties engage in negotiations concerning which patents could properly be subject to a patent infringement suit, which culminates with the reference product sponsor filing a complaint for patent infringement in district court.<sup>35</sup> The BPCIA framework can result in the enforcement of a substantial number of patents. In other circumstances, numerous biosimilar sponsors have asserted the same handful of patents against various biosimilar applicants.

In response to infringement allegations in both Hatch-Waxman and BPCIA litigation, generic and biosimilar pharmaceutical companies have frequently sought to challenge patents in IPR.<sup>36</sup> Because of the statutory framework of the Hatch-Waxman Act and BPCIA, such IPR challenges typically occur in tandem with district court litigation, and often while multiple companies have an interest in invalidating the challenged patents.<sup>37</sup> It is therefore crucial that generic and biosimilar companies are able to effectively challenge patents in IPR despite the presence of multiple ANDA or biosimilar filers contemporaneously challenging the same patents in district court or other proceedings before the Office.

### III. Discretionary Denials of Petitions are on the Rise

Over the past two years, the Office has used precedential decisions to expand the Office’s exercise of discretionary denials. In 2019, the Office designated several decisions precedential regarding procedural

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<sup>28</sup> 21 U.S.C. § 355(j)(5)(F)(ii).

<sup>29</sup> See *id.*

<sup>30</sup> See *Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc.*, 978 F.3d 1374 (Fed. Cir. 2020).

<sup>31</sup> 42 U.S.C. § 262(l)(2).

<sup>32</sup> See 42 U.S.C. § 262(l)(3)(A).

<sup>33</sup> 42 U.S.C. § 262(l)(3)(B).

<sup>34</sup> 42 U.S.C. § 262(l)(3)(C).

<sup>35</sup> 42 U.S.C. § 262(l)(4)-(5).

<sup>36</sup> See, e.g., *supra* Part I.

<sup>37</sup> See, e.g., Petition at 6-7, *Mylan Pharm. Inc. v. Merck Sharp & Dohme Corp.*, IPR2020-00040 (P.T.A.B. Oct. 30, 2019) (challenging a patent asserted against over a dozen ANDA filers under the Hatch-Waxman Act); Petition at 73, *Kashiv Biosciences v. Amgen Inc.*, IPR2019-00797 (P.T.A.B. Mar. 7, 2019) (challenging a patent asserted against three unrelated biosimilar filers under the BPCIA).

bases to deny institution, including *General Plastic* and *Valve* concerning subsequently-filed petitions and *NHK* concerning co-pending district court litigation and previously-considered prior art.<sup>38</sup> This past year, the Office designated as precedential *Fintiv*, which set forth a six-factor test for discretionarily denying petitions based primarily on parallel litigations.<sup>39</sup>

These and other precedential decisions have resulted in an uptick in discretionary denials based solely on procedural grounds rather than the merits. One study observed that between 2016 and 2019, the percent of the Office’s procedural denials nearly doubled.<sup>40</sup> A recent analysis likewise observed that even by the first half of 2020—shortly after *Fintiv* was designated precedential—the Board had already discretionarily denied more petitions on procedural grounds than it did in all of 2019, potentially accounting for 30% of all denials this year.<sup>41</sup>



As *Fintiv* is applied to more cases, it is expected that absent a change to the Office’s policies, the Office will continue to discretionarily deny a greater percentage of petitions in the coming years.

#### IV. The Director’s Discretion to Deny IPRs is Limited

As the Office recognizes in its request for comments, there is “no mandate to institute review.”<sup>42</sup> But the Director’s “discretion” is not as sweeping as the Office’s current policies and practices suggest.

In particular, the Director’s discretion does not extend to pure procedural bases unrelated to proceedings before the Office. While the AIA expressly allows the Director to deny a petition based on the similarity of arguments previously “presented to the Office,” it does not contemplate that the Director may also deny a

<sup>38</sup> *General Plastic Co. v. Kaisha*, IPR2016-01357, Paper No. 10 (P.T.A.B. Sept. 6 2017); *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00062, Paper No. 11 (P.T.A.B. Apr. 2, 2019); *NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper No. 8 (P.T.A.B. Sept. 12, 2018); see also *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper No. 8 (P.T.A.B. Dec. 15, 2017).

<sup>39</sup> *Apple Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper No. 11 (P.T.A.B. Mar. 20, 2020).

<sup>40</sup> Unified Patents, PTAB Procedural Denials and the Rise of § 314 (May 13, 2020), available at <https://www.unifiedpatents.com/insights/2020/5/13/ptab-procedural-denial-and-the-rise-of-314>.

<sup>41</sup> Unified Patents, PTAB Discretionary Denials: In the First Half of 2020, Denials Already Exceed All of 2019 (July 27, 2020), available at <https://www.unifiedpatents.com/insights/2020/7/27/ptab-discretionary-denials-in-the-first-half-of-2020-denials-already-exceed-all-of-2019>.

<sup>42</sup> 85 Fed. Reg. at 66503 (Oct. 20, 2020) (quoting *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016)).

petition based on the similarity of arguments previously presented in a district court case, or any other tribunal.<sup>43</sup> Under the negative-implication canon, Congress excluded from the Director's consideration whether the same or substantially the same prior art or arguments were presented in district court litigation.<sup>44</sup>

Nor does the AIA contemplate that the Director has discretion to deny a petition based on the progress of a parallel litigation proceeding or based on the parties involved in such litigation. The AIA prohibits the Director from instituting review if the petition is filed "more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent."<sup>45</sup> This provision highlights four important points. First, when discussing parallel litigation proceedings—as compared to proceedings before the Office—Congress did not authorize the Director to exercise discretion at all, and instead set forth a bright line rule.<sup>46</sup> Second, § 315(b) expressly contemplates that parallel litigation proceedings can occur during the pendency of an IPR. Third, Congress identified 1 year after the date of the complaint as the only stage of a parallel litigation proceeding relevant to the decision to institute. And fourth, Congress identified only "the petitioner, real party in interest, or privy of the petitioner" as relevant defendants in district court litigation.

Taken together and in view of the statutory scheme as a whole, nothing in the AIA suggests that the Director has discretion to deny a petition based on factors such as the progress of a district court case or investment in such a case by the parties, particularly where the district court case does not involve the petitioner, real party in interest, or privy of the petitioner at all. Rather, exercising such discretion would be at odds with the AIA, and could result in institution denials without the Director considering the merits of a petition at all.

#### **V. Proceedings in Other Tribunals Should Not Limit the Availability of IPRs (Responsive to Questions 5 and 6)**

As discussed above, nothing in the AIA suggests that the Director has discretion to deny a petition based on the progress of a parallel litigation or investment in a case by the parties, particularly where the litigation is unrelated to the petitioner. Yet this is precisely what the Director has instructed APJs to do in *Apple Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper No. 11 (P.T.A.B. Mar. 20, 2020) (precedential). The Office's application of the *Fintiv* rule violates the AIA and severely undermines the ability of generic and biosimilar companies to challenge patents in IPR.

##### **a. The *Fintiv* Rule is Inconsistent With the AIA**

*Fintiv* sets forth a six-factor test for APJs to consider discretionarily denying institution, five of which depend on the progress of a parallel litigation proceeding or the parties involved in such litigation:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;

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<sup>43</sup> See 35 U.S.C. § 325(d).

<sup>44</sup> See, e.g., *Lindh v. Murphy*, 521 U.S. 320, 330 (1997) (explaining that Congress can express its intent regarding the reach of a statute through "negative implication" by deliberately omitting language from a provision).

<sup>45</sup> 35 U.S.C. § 315(b) (stating that an IPR "may not be instituted" after the 1-year statutory bar).

<sup>46</sup> Compare 35 U.S.C. § 325(d).

5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board's exercise of discretion, including the merits.

*Fintiv*, IPR2020-0019 at 5-6.

Simply put, *Fintiv* has no roots in the AIA. Rather, the *Fintiv* factors are inconsistent with the statutory scheme devised by Congress. For example, Factors 1-3 instruct APJs to consider the progress and stage of a parallel litigation proceeding, despite the AIA's bright-line rule—which never once mentions “discretion”—that petitions may be filed within 1 year of the filing of a complaint.<sup>47</sup> Factor 4 instructs APJs to consider the overlap between issues raised in the petition and in the parallel proceeding, despite the AIA's clear message that such discretion exists *only* with regard to proceedings “presented to the Office.”<sup>48</sup> And Factor 5 instructs APJs to consider whether the petitioner and the defendant in the parallel proceeding are the same party, despite the AIA's clear instruction that a parallel proceeding is only relevant if it concerns “the petitioner, real party in interest, or privy of the petitioner.”<sup>49</sup> Each of these Factors inappropriately direct APJs to consider aspects of parallel litigation that should have no bearing on the decision to institute.

The *Fintiv* rule is also inconsistent with the spirit of the AIA. Congress intended IPRs as a lower-cost, more efficient alternative to challenging the validity of patents in the district courts. Thus, IPRs must remain freely available to challenge patents that are subject to district court infringement proceedings.

#### **b. The Office has Overused *Fintiv* to Discretionarily Deny Petitions**

APJs are repeatedly denying petitions under the guise of the *Fintiv* rule which, as applied, can operate as a statutory bar simply because of the anticipated timing of the district court trial date.<sup>50</sup> Particularly because institution denials cannot be appealed, the *Fintiv* rule risks severely undermining petitioners' ability to challenge bad patents.<sup>51</sup> The result of APJs exercising their “discretion” in this setting is that there will be a large number of non-substantive denials, which is contrary to Congress' intent in making IPRs available to challenge invalid patents.

For example, in *Cisco Sys., Inc. v. Ramot at Tel Aviv University Ltd.*, the Board discretionarily denied a petition under *Fintiv* because trial was scheduled to begin in six months, even though the district court had not yet ruled on claim construction and the APJs acknowledged that the district court case was in a “similar state” as the IPR.<sup>52</sup> In *Intel Corp. v. VLSI Tech. LLC*, the Board discretionarily denied a petition under the *Fintiv* rule, holding that the proximity to the parties' trial date weighed of favor of denial, despite

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<sup>47</sup> 35 U.S.C. § 315(b).

<sup>48</sup> 35 U.S.C. § 325(d).

<sup>49</sup> 35 U.S.C. § 315(b).

<sup>50</sup> See, e.g., Complaint ¶¶ 52-60, *Apple Inc. v. Iancu*, 5:20-cv-6128 (N.D. Cal. Aug. 31, 2012) (cataloguing examples where petitions have been discretionarily denied under *Fintiv*).

<sup>51</sup> See 35 U.S.C. § 314(d).

<sup>52</sup> IPR2020-00123, Paper No. 14, at 7-9 (P.T.A.B. May 15, 2020).

the fact that trial had been **suspended** due to COVID-19.<sup>53</sup> Such discretionary denials will only balloon if the Office codifies the *Fintiv* rule.<sup>54</sup>

**c. Allowing the Director to Discretionarily Deny Petitions on the Bases of Proceedings in Other Tribunals is Unfairly Prejudicial to Generic and Biosimilar Pharmaceutical Companies**

Left unaltered, the *Fintiv* rule will be repeatedly used to deny IPRs in the context of pharmaceutical patent litigation given the unique statutory scheme in which patent challenges arise. In fact, the posture of pharmaceutical patent litigation suggests that, more often than not, APJs may discretionarily deny petitions for IPR. Brand-name pharmaceutical companies have recognized as much, including in an article penned by counsel at Eli Lilly that recognizes the *Fintiv* rule “gives NDA holders the hook they have long sought to stave off PTAB petitions by ANDA applicants trying to supplant litigation.”<sup>55</sup> This is abundantly clear upon analyzing the *Fintiv* factors in light of the statutory scheme in which pharmaceutical patent litigation arises:

- ***Fintiv Factor 1:*** District courts do not routinely stay Hatch-Waxman litigation pending IPR—and particularly not pending a mere petition for IPR—given the 30-month stay and the statute’s mandate to expedite Hatch-Waxman cases.<sup>56</sup> It is therefore unlikely that this factor will weigh in favor of a petitioner.
- ***Fintiv Factor 2:*** Given the statutory 30-month stay of FDA approval on ANDA products, there is likely always to be close proximity between a district court trial date and the anticipated final written decision date. Trials in Hatch-Waxman cases typically occur at approximately month 24, and rarely occur after the 30-month mark.<sup>57</sup> If a generic applicant waits until month 6 to file an IPR (a reasonable decision, given that it might take even longer than that to get clarity on asserted claims), the final written decision will be at or near the trial time.<sup>58</sup> It is therefore likely that this factor will weigh against a generic applicant petitioner. Absent a stay—which, as noted above, is also unlikely to occur—the only practical way for a petitioner to avoid a contemporaneous trial date is to file an IPR prior to, or shortly after, being sued in the district court. But such a solution is plainly at odds with the AIA, which expressly allows an IPR to be filed up to 1 year after suit is instituted.<sup>59</sup>
- ***Fintiv Factors 3-5:*** These factors will almost always favor denial in a Hatch-Waxman case, making factors 1 and 2 (which are likely to cut against a generic petitioner as explained above) dispositive. These cases typically include early disclosure of invalidity contentions (*Fintiv 3*).<sup>60</sup> The issues are typically overlapping such that the patent challenger is arguing invalidity in both courts (*Fintiv 4*). And, under *Fintiv 5*, the petitioner is also typically the defendant in the related

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<sup>53</sup> IPR2020-00106, Paper No. 17, at 7-8 (P.T.A.B. May 5, 2020).

<sup>54</sup> See generally *supra* Part III.

<sup>55</sup> K. Helm et al., “PTAB Mylan Decision Could Be Boon To Drug Innovators,” Law360 (Nov. 12, 2020), available at <https://www.law360.com/appellate/articles/1327929/ptab-mylan-decision-could-be-boon-to-drug-innovators>.

<sup>56</sup> See, e.g., *Allergan, Inc. v. Deva Holding A.S.*, No. 2:16-cv-01447 (E.D. Tex. July 28, 2017) (denying stay pending IPR and noting that “because this is an ANDA lawsuit, a stay could postpone district court proceedings until after the expiration of the 30-month regulatory stay” and that “in light of the nature and purpose of the 30-month stay, postponing the district court action could require costly preliminary injunction proceedings, wasting both the Court’s and the parties’ resources”).

<sup>57</sup> See, e.g., Lex Machina, Hatch-Waxman / ANDA Litigation Report at Fig. 9 (2018) (showing that trial for Hatch-Waxman cases occurred at a median of 731 days and 795 days after the complaint in the Districts of Delaware and New Jersey, respectively).

<sup>58</sup> See 35 U.S.C. 316(a)(11).

<sup>59</sup> See 35 U.S.C. § 315(b).

<sup>60</sup> See, e.g., Del. Default Standard ¶ 4.

district court action consistent with the Hatch-Waxman scheme, because patent holders have only 45 days to file suit to trigger the 30-month stay.<sup>61</sup>

Thus, the *Fintiv* rule will likely result in a discretionary denial of *any* petition filed as a result of a co-pending pharmaceutical patent litigation.

The Board's institution denial in *Mylan Labs. Ltd. v. Janssen Pharmaceutica NV*, IPR2020-00440, Paper 17 (Sept. 16, 2020), highlights the unfairness of the *Fintiv* rule as applied to generic manufacturers. On August 9, 2019, Janssen filed a complaint alleging that Mylan's proposed ANDA for a generic paliperidone product infringed claims of U.S. Patent No. 9,439,906 ("the '906 patent").<sup>62</sup> Six months later—and well before the AIA's statutory deadline for filing a petition for IPR—Mylan filed a petition for IPR challenging the validity of each claim of the '906 patent.<sup>63</sup> As Mylan aptly explained in its petition, Mylan's prior art grounds had never been considered by the Office, because "[t]he Examiner raised no prior art rejections during prosecution" and Mylan's petition was "the first IPR directed to the '906 patent."<sup>64</sup> In other words, in *Mylan*, "the same or substantially the same prior art or arguments" were never previously before the Office, and there was not "another proceeding or matter involving the patent . . . before the Office."<sup>65</sup> The only basis for the Director to deny Mylan's petition was accordingly based on whether Mylan presented a "reasonable likelihood" that it would prevail with respect to at least one of the challenged claims.<sup>66</sup>

The Board, however, discretionarily denied Mylan's petition based solely on parallel litigation proceedings, and, of particular concern, gave significant weight to another district court case that **did not involve Mylan at all**.<sup>67</sup> Long before Janssen sued Mylan for infringement of the '906 patent, Janssen filed a complaint alleging infringement of the '906 patent against one of Mylan's competitors in *Janssen Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.*, 2-18-cv-00734 (D.N.J.). The Board reasoned that trial in the *Teva* litigation was nearing and that "the validity of claims 1–21 of the '906 patent is the only issue to be resolved at trial, and all claims are challenged as being obvious for reasons overlapping those of the instant Petition."<sup>68</sup> The Board also observed that Mylan's 30-month stay was set to expire in approximately 16 months, and that as is typical, trial was tentatively scheduled about 6 months before the stay expired.<sup>69</sup>

In denying institution, the Board's decision makes clear that the *Fintiv* rule deeply prejudices petitioners engaged in Hatch-Waxman litigation. The Board reasoned that under *Fintiv* Factor 1, a stay was "unlikely" given the "the 30-month limit provided for by 21 U.S.C. § 355(j)(5)(B)(iii)."<sup>70</sup> Under *Fintiv* factor 2, the Board found that the upcoming trial in the *Teva* litigation and likelihood that Mylan's trial would occur before the deadline for the final written decision weighed "strongly in favor of denying institution."<sup>71</sup> The Board found that *Fintiv* factor 3 weighed in favor of denial for similar reasons, citing again the upcoming *Teva* trial and unlikelihood that the *Mylan* case would be stayed.<sup>72</sup> Finally, the Board found

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<sup>61</sup> 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. 271(e)(2)(A).

<sup>62</sup> *Janssen Pharm., Inc. v. Mylan Labs. Ltd.*, No. 2:19-cv-16484 (D.N.J.).

<sup>63</sup> Petition, *Mylan*, IPR2020-00440.

<sup>64</sup> *Id.* at 65-66.

<sup>65</sup> 35 U.S.C. §§ 315(d), 325(d).

<sup>66</sup> 35 U.S.C. § 314(a).

<sup>67</sup> *Mylan*, IPR2020-00440, Paper 17.

<sup>68</sup> *Id.* at 9-10.

<sup>69</sup> *Id.* at 11.

<sup>70</sup> *Id.* at 14.

<sup>71</sup> *Id.* at 15.

<sup>72</sup> *Id.* at 15-19.

that both the *Mylan* and *Teva* cases concerned substantially the same issues, which weighed in favor of denying institution for both *Fintiv* factors 4 and 5.<sup>73</sup>

Ironically—and perhaps most troubling of all—the only *Fintiv* factor that the Board found neutral was Factor 6, which considers the merits.<sup>74</sup> The Board declined to “provide a complete analysis of the merits,” but explained that one of the disputed issues was “a close call.”<sup>75</sup>

Congress expressed no intention that pharmaceutical patents subject to Hatch-Waxman litigation should be categorically excluded from eligibility for IPR, yet *Mylan* illustrates that this is what the *Fintiv* rule accomplishes. Instead, bills precluding ANDA filers from filing IPRs have been introduced before Congress, but never enacted.<sup>76</sup> The *Fintiv* rule is unworkable in the context of Hatch-Waxman litigation and should be revoked, and certainly should not be codified.

## **VI. Subsequent IPRs Should Remain Available for Viable Challenges (Responsive to Questions 1 and 2)**

Like the *Fintiv* factors, the *General Plastic* factors fail to account for relevant considerations that could make a subsequent IPR critical.<sup>77</sup> Specifically, *General Plastic* sets forth seven factors for APJs to consider when determining whether to discretionarily deny subsequently-filed petitions:

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
3. whether at the time of filing of the second petition the petitioner already received the patent owner’s preliminary response to the first petition or received the Board’s decision on whether to institute review in the first petition;
4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;
6. the finite resources of the Board; and
7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

*Id.* at 9-10.

There are numerous circumstances in which a subsequently-filed petition may be warranted. For example, the subsequent petitioner may be unrelated to the original petitioner and wish to frame its arguments differently than the original petitioner.<sup>78</sup> As discussed above, the Hatch-Waxman

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<sup>73</sup> *Id.* at 19-23.

<sup>74</sup> *Id.* at 23-25.

<sup>75</sup> *Id.* at 24-25.

<sup>76</sup> See, e.g., S. 344, Hatch-Waxman Integrity Act of 2019 § 2(b)(3)(I) (stating that “neither the applicant nor any party in privity with, related to, or cooperating with the applicant has filed, or will file, a petition to institute inter partes review”).

<sup>77</sup> See *General Plastic Co. v. Kaisha*, IPR2016-01357, Paper No. 10 (P.T.A.B. Sept. 6 2017) (precedential).

<sup>78</sup> See, e.g., *Pfizer Inc. v. Biogen, Inc.*, IPR2018-00186, Paper 15 at 17-20 (P.T.A.B. June 14, 2018) (instituting review of a subsequent petition, despite some overlap with a prior petition).

Act and BPCIA in particular make it likely that multiple generic and biosimilar pharmaceutical companies will be interested in invalidating the same patents, and therefore makes it likely that more than one petitioner may intend to file an IPR to challenge the same patent claims. In other cases, another petition for IPR may address additional claims or claims left unresolved by the prior petition. A subsequent petitioner may also raise new prior art grounds that were not identified in the originally-filed petition. Or the same petitioner may need to file a serial petition in order to address claims that were altered during the course of litigation.

Yet, the *General Plastic* rule fails to account for many of these important factors that may make subsequently-filed petitions necessary.<sup>79</sup> For example, *General Plastic* does not emphasize that petitions directed to new claims and/or prior art should be fully considered on the merits—which still gives APJs the option to deny a petition if there is not a “reasonable likelihood” that the petitioner would prevail.<sup>80</sup> *General Plastic* also fails to account for patent holder conduct that may compel a subsequently-filed petition, such as asserting additional claims or belatedly departing from original infringement theories.

Worse, the Office has expanded the *General Plastic* rule to expressly hold that a subsequent petition filed by a different petitioner may also be discretionarily denied.<sup>81</sup> In *Valve*—now precedential—APJs discretionarily denied a subsequently-filed petition, crediting that both the original and subsequent petitioners were once co-defendants concerning the challenged patent.<sup>82</sup> As a result, as with the *Fintiv* rule discussed above, *General Plastic* severely risks penalizing generic and biosimilar companies attempting to challenge patents in IPR based on the actions of their competitors. Such a rule is unworkable and should be abandoned.

AAM accordingly recommends that the Office abandon the *General Plastic* framework and modify its current policies and practices to require APJs to consider the merits of petitions subsequently-filed by different petitioners and/or based on new claims or prior art. AAM does not recommend that the Office formally promulgate a rule setting forth the *General Plastic* framework.

## **VII. Parallel Petitions Should Be Allowed When Warranted (Responsive to Questions 3 and 4)**

As with subsequently-filed petitions, the Office should allow parallel petitions when warranted. And there are many circumstances where such petitions are warranted.

The Trial Practice Guide identifies a preference for one, perhaps two—and rarely more than two—petitions on a single patent.<sup>83</sup> Most petitioners hue closely to this guidance and multiple parallel petitions are not an overarching problem. In fact, the Trial Practice Guide acknowledges that “a substantial majority of patents have been challenged with a single petition.”<sup>84</sup> A recent survey found that the vast majority of challenged patents face only a single petition.<sup>85</sup> Plus, the non-trivial filing fees for each petition likely further discourages abuse.

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<sup>79</sup> See *General Plastic*, IPR2016-01357, at 9-10.

<sup>80</sup> 35 U.S.C. § 314(a).

<sup>81</sup> See *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00062, Paper No. 11, at 9 (P.T.A.B. Apr. 2, 2019) (precedential) (“[O]ur application of the *General Plastic* factors is not limited solely to instances when multiple petitions are filed by the same Petitioner”).

<sup>82</sup> *Id.* at 9-10.

<sup>83</sup> Consol. Trial Practice Guide at 59 (Nov. 2019).

<sup>84</sup> *Id.*

<sup>85</sup> M. Grewal et al., *Ranking Parallel Petitions Before the PTAB: A Survey*, 19 Chi. Kent J. Intell. Prop. 523-535, 525 (2020) (identifying only “39 occurrences of ranked parallel petitions that challenge the same claims of the same patents, as well as 2 occurrences of ranked parallel petitions that challenge different claims of the same patent”).

There are, however, numerous circumstances that justify the filing of more than one petition. For example, a petitioner is bound by word limits, which can be quickly exhausted depending on the number of claims at issue and the number of grounds.<sup>86</sup> As for the number of challenged claims, it is common in Hatch-Waxman and BPCIA litigation that generic and biosimilar companies will need to “clear the decks” and challenge every patent claim, potentially implicating dozens of claims. This may be exacerbated by the patent owner declining to narrow the number of asserted claims or based on a patent owner’s shifting infringement theories. Accordingly, a petitioner will need to address all claims, and must do so persuasively in order to carry its burden to show a reasonable likelihood of succeeding on the merits. As for the number of grounds, there may be circumstances that necessitate multiple alternative grounds, especially where there are disputes regarding prior art status, or where an additional reference or ground is necessary to address a limitation found in a dependent claim. In such cases, alternative grounds relying on other art are prudent. Both of these scenarios can strain a petitioners’ ability to address all grounds in a single petition, particularly given the Office’s rules against buttressing the *prima facie* case in reply.<sup>87</sup>

A petitioner may also need to file a second petition in order to address all relevant invalidating prior art. Under the AIA, a petitioner is estopped from asserting in district court that a “claim is invalid on any ground that the petitioner raised or reasonably could have raised” during the IPR.<sup>88</sup> Given the severe consequences of estoppel, a challenger will want to present all the grounds known to the petitioner, which may need to span across more than one petition. Ironically, petitioners may also have to dedicate a portion of its petition to explain why their petitions should not be discretionarily denied, further necessitating the need for multiple petitions.

The Office’s current practice of permitting parallel petitions in certain circumstances is appropriate, but the Office should further clarify that in many cases, discretionary denials are generally unwarranted. For example, the Trial and Practice Guide properly recognizes that “there may be circumstances in which more than one petition may be necessary, including, for example, when the patent owner has asserted a large number of claims in litigation or when there is a dispute about priority date requiring arguments under multiple prior art references.”<sup>89</sup> The Office should amend its current practices and policies to affirmatively allow petitioners to file more than one petition under circumstances such are these. Otherwise, under the Office’s current practices and policies, APJs could discretionarily deny a petition despite the presence of factors that the Office acknowledges make the filing of more than one petition “necessary.”<sup>90</sup>

AAM accordingly recommends that the Office continue to apply a case-specific analysis to determine whether to institute a parallel petition, but recommends that the Office amend its policies to expressly allow petitioners to file more than one petition where warranted, including when either the number of challenged claims or presence of priority disputes necessitate more than one petition. At this time, AAM does not recommend that the Office formally promulgate a rule on this subject.

## VIII. Conclusion

AAM thanks the Office for its tireless efforts in ensuring the high quality of the United States patent system. IPRs are an important safeguard put in place by Congress to help the Office maintain its high standards. As explained above, the Office should abandon its current practices and policies allowing for the discretionary denial of petitions based on proceedings in other tribunals, which makes it immensely more difficult for generic and biosimilar companies to challenge competition-stifling patents in IPR. For

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<sup>86</sup> See 37 C.F.R. § 42.24.

<sup>87</sup> 37 C.F.R. § 42.23(b).

<sup>88</sup> 35 U.S.C. § 315(e)(2).

<sup>89</sup> Consol. Trial Practice Guide at 59 (Nov. 2019).

<sup>90</sup> *Id.*

similar reasons, the Office should modify its current practices and policies regarding discretionary denials of serial and parallel petitions, which fail to account for factors that necessitate such petitions and likewise risk thwarting petitioners from challenging patents. AAM urges the Office not to adopt the proposal to codify any of its current practices and policies regarding discretionary denials.

Sincerely,

/s/

Jeffrey K. Francer,  
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