Commentary

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How Cuozzo will impact the interplay between post grant proceedings and Hatch–Waxman litigation

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Natasha Mishra
American University, Washington College of Law, Washington, DC, USA; Global Pharma, Pillsbury Winthrop Shaw Pittman LLP, 1650 Tysons Boulevard, McLean, VA 22102, USA

Patrick A Doody
Global Pharma, Pillsbury Winthrop Shaw Pittman LLP, 1650 Tysons Boulevard, McLean, VA 22102, USA

Raj S Davé
Author for correspondence: Global Pharma, Pillsbury Winthrop Shaw Pittman LLP, 1650 Tysons Boulevard, McLean, VA 22102, USA
Tel.: +1 703 770 7782
raj.dave@pillsburylaw.com

Cuozzo Speed Technologies, *LLC v. Lee*

In 2011, Congress enacted the America Invents Act (AIA), creating three new post grant proceedings, including *Inter Partes* review (IPR) [1]. IPR was a new proceeding, intended to replace *Inter Partes* reexamination proceedings, in which third parties could challenge the validity of issued patents before the Patent Trial and Appeal Board (PTAB) at the US Patent and Trademark Office (PTO). The 20 June 2016 decision of the Supreme Court in *Cuozzo* Speed Technologies, *LLC v. Lee*, confirmed the viability of IPRs for generic-drug makers to challenge patents owned by brand name pharmaceutical companies, instead of, or in conjunction with pursuing costly Hatch–Waxman litigation [2]. The *Cuozzo* decision affirmed the constitutionality of IPRs, and profmotes the notion that using IPR to challenge patent validity often proves advantageous over pursuing the alternative: costly and time-consuming district court litigation. The *Cuozzo* Court therefore paved the way for generic pharmaceutical companies to challenge issued patents in a more efficient and cost–effective manner.

Cuozzo addresses the divergence between the claim interpretation standards used by the PTAB (claims construed more broadly), and the standard used by Article III Federal Courts (claims construed more narrowly) [3]. The Court addressed the claim construction divide because the claim construction standard was not specified in the America Invents Act (AIA), but rather was left to the rulemaking authority of the PTO. In a decision authored by Justice Breyer, *Cuozzo* affirmed that the PTAB's use of the 'broadest reasonable interpretation' (BRI) standard for claim construction was appropriately within the PTO's rulemaking authority. The PTO's adoption of the BRI standard for claim interpretation was found reasonable in light of the 'text, nature and purpose' of the statute, 35 U.S.C. §314 [4]. The *Cuozzo* decision therefore set the stage for patent challenges before the PTAB by not only confirming the constitutionality of such challenges, but also by giving its imprimatur to the PTAB's use of the BRI claim construction standard.

Hatch–Waxman Abbreviated New Drug Application litigation: use of IPR in the Abbreviated New Drug Application context up until now

The Drug Price Competition and Patent Term Restoration Act of 1984 (the 'Hatch–Waxman Act') created a procedure regulated by the US FDA for generic drug approval and market entry of the generic drug before and after the brand name drug patents protecting the brand name drug expire [5]. Thus, instead of completing lengthy procedures for new drug approval, which previously could not be conducted until the brand name drug patents expired to avoid the risk of

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being sued for patent infringement, the Hatch–Waxman Act created an expedited pathway for entry of generic drugs into the USA. The changes made in the Hatch–Waxman Act were intended to reverse the decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, and permit generic manufacturers to develop bioequivalent products and request FDA approval without infringing a patent [6]. The Hatch–Waxman Act allows a drug manufacturer to seek regulatory approval of a generic drug by submitting an Abbreviated New Drug Application (ANDA). The application process is abbreviated because preclinical (animal) and clinical (human) data to establish safety and effectiveness (efficacy) are not required. Instead, the ANDA can rely on the safety and effectiveness data submitted in the New Drug Application (NDA) of the reference brand name drug, and approval is based on data establishing bioequivalence between the generic product defined in the ANDA and the reference brand name drug.

Under the Hatch–Waxman scheme, brand name drug manufacturers list in the Orange Book, those patents that cover the NDA drug [7]. ANDA applicants are required to submit a patent certification with respect to each patent listed in the Orange Book for the reference brand product. The ANDA applicant may certify that no patent is listed; a patent has expired; the applicant is not seeking approval until after a listed patent expires; or the patent is invalid, unenforceable or will not be infringed by the manufacture or sale of the drug product for which the ANDA is submitted (the last certification is the so-called 'paragraph IV certification' or 'P-IV') [8]. If an ANDA application certifies that a patent is invalid, unenforceable or not infringed, the applicant must notify the NDA holder via what is commonly referred to as a 'paragraph IV notice letter', of the certification and provide a detailed statement for the basis of its assertion that the relevant patent is invalid, unenforceable or not infringed.

The filing of an ANDA with a paragraph IV certification is defined by the Hatch–Waxman Act as a technical act of infringement, giving the patent holder jurisdiction to sue the ANDA applicant for patent infringement. If the patent holder sues the ANDA applicant for infringement within 45 days of receiving the paragraph IV notice letter, the ANDA will be subject to a 30-month stay, during which time the FDA may not grant final marketing approval to the subject ANDA.

The 30-month FDA stay date is significant because the FDA will not grant the generic drug company final approval for marketing its product for '30-months', without a court decision stating that the patent is not infringed, invalid or unenforceable [9]. The grant of the stay is important to the brand name drug company because it prevents the generic competition from entering the market during the period of stay, even if the generic drug company is willing to enter at risk of infringement. Similarly, the date is important to the generic drug company but this is because it could likely be the first opportunity for the company to launch its generic product into the market [10].

District courts often will seek to implement a litigation schedule that will enable a final court decision close to the end of the 30-month stay, if the parties cannot agree on such a schedule. This goal is not always met, for example, in the case of more complex litigations: numerous patents and/or ANDA filers. Importantly, a court decision in favor of the ANDA filer will terminate the 30-month stay early. On the other hand, if a court decision is not obtained by the end of the 30-month stay, the ANDA filer could be eligible to obtain final FDA approval if the FDA review is complete and would then have the ability to launch its generic product, but only at the risk of infringement. In such cases, an ANDA filer may voluntarily agree to not launch its generic product until after a final court decision, or a patent-holder may seek a preliminary injunction. Although, timing for district court decisions can vary widely, for simplicity in comparing the time for completion of a district court Hatch–Waxman infringement action to IPR proceedings, we can assume that a final district court decision will take approximately 30 months. Note: This is only true for an ANDA filer that is not otherwise barred from receiving final approval due to another patent exclusivity, such as an unexpired paragraph III patent, or a first ANDA filer's 180-day exclusivity.

In contrast, an IPR proceeding must be completed within 1 year from institution, and a petition for IPR cannot be filed more than 1 year after district court litigation is initiated [11]. A decision whether to file a petition for IPR therefore often will need to be made before issues are fully developed in litigation, or even before asserted claims are known [12].

IPR: advantages over district court litigation & why it has become a valuable tool in invalidating patents

IPRs are designed to be faster and cheaper proceedings before the PTAB for determining patent validity. IPR is quasi-judicial in nature, and differs significantly from district court litigation.

Establishing invalidity of patents is often complicated. For parties seeking to invalidate a patent, IPR presents an advantageous forum compared with district court litigation. One advantage is that the standard of review for proving invalidity at the PTAB is

by a preponderance of evidence, whereas the standard at district court is by clear and convincing evidence. Preponderance of the evidence, also known as balance of probabilities, is defined as 'more probable than not'. Clear and convincing evidence is a higher level of burden of persuasion than preponderance of the evidence. The petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence [13].

Additionally, the ability to have a patent challenge decided by highly experienced and technically trained patent judges has been viewed advantageous for those seeking to invalidate a patent on grounds of anticipation or obviousness. Moreover, the PTAB's Broad Claim Interpretation (BRI) standard for claim interpretation potentially enables just that, a broader claim interpretation. Since BRI is broader than that used by district courts, it thereby further aids a patent challenger. In district court, claims are construed based on their "plain meaning--" a much narrower standard. The "plain meaning" claim construction standard, or "Phillips" standard, requires claim terms to be given the meaning that the term would have been accorded by a person of ordinary skill in the art, at time of the invention [14]. District courts are required to presume that the claims of a patent are valid [15]. This is not the case in IPRs because the PTO is simply re-examining its own prior decision to grant a patent [16].

Because of its perceived advantages for those wishing to challenge patents, IPR presents new and unique strategic possibilities for generic drug manufacturers. However, the Hatch–Waxman framework hinges on a complex paradigm in which district court litigation has and will continue to play a central role [17]. Therefore, the decision to pursue IPR on a patent depends largely on how adjudication of an IPR at the PTO will impact the regulatory scheme, in other words, the Hatch–Waxman litigation (commonly referred to as 'ANDA litigation') in district court. Figure 1 below provides a comparison in the timing for district court litigation and IPR at the PTAB for Seroquel®.

In Figure 1, the ANDA was filed with a Paragraph IV certification. As shown above for Seroquel®, the district court's decision was appealed to the Court of Appeals of the Federal Circuit (CAFC) [19]. The petition for IPR was filed by the ANDA filer, and both the final written decision of the PTAB and the decision on appeal of the PTAB decision by the CAFC were quickly reached. This was a specific scenario, but still, before the district court appeal, a final written decision was reached in the IPR process within 18 months, while the discovery process was still ongoing in the district court. The district court decision, which was appealed, took 42 months to reach, and the CAFC did not reach its final decision until 60 months after the complaint was filed. The final CAFC decision in the IPR appeal took only about 30 months from the date the petition was filed.

IPR, therefore, provides a much faster timeline to a decision – this is a significant advantage. The first stage of IPR includes a 6 months screening stage where the PTAB decides if the petition, along with the evidence submitted therewith, shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition by raising a significant issue of patent validity. The first stage ends with an institutional decision of whether to institute a full review of the patent. The second stage is a final decision on patent validity; this takes 12 months from the institution decision date, in other words, 18 months after the petition filing date. IPR's resolution time is remarkably fast in comparison to the completion of an ANDA litigation process.

All of these factors should weigh heavily in favor of filing a petition for IPR, even in the context of patents listed in the Orange Book and embroiled in Hatch–Waxman litigation. But prior to *Cuozzo*, patent challengers were reticent to file petitions for IPR out of concern about the PTO's rulemaking authority with respect to the claim construction standard, as well as the rules governing post grant proceedings in general. This was especially true in the pharmaceutical industry where patent challengers already enjoyed a relatively high success rate in district court litigation.

Cuozzo & its implications for future IPR/ANDA interplay

In *Cuozzo* Speed Technologies, *LLC v. Lee,* the Supreme Court handed the PTO a victory with respect to its rulemaking authority by concluding that the regulation represents a reasonable exercise of the PTO's rulemaking authority, 579 US (2016). The Supreme Court stated that although there was evidence that Congress intended to create a 'litigation-like' proceeding: *"Inter Partes review is less like a judicial proceeding and more like a specialized agency proceeding* [20]." In response to the argument that the PTO's claim construction standard should be the same as the district court's standard, the Court stated, *"neither the statutory language, its purpose, [n]or its history suggest that Congress considered what standard the agency should apply when reviewing a patent claim in inter partes review* [21]*."* The BRI standard 'protects the public' by strictly analyzing patent claims, and has been used by the PTO 'for more than 100 years' [22]. The Court refused to address the existence of any better alternative as a matter of policy, noting that is a question that Congress left to the expertise of the PTO [23].

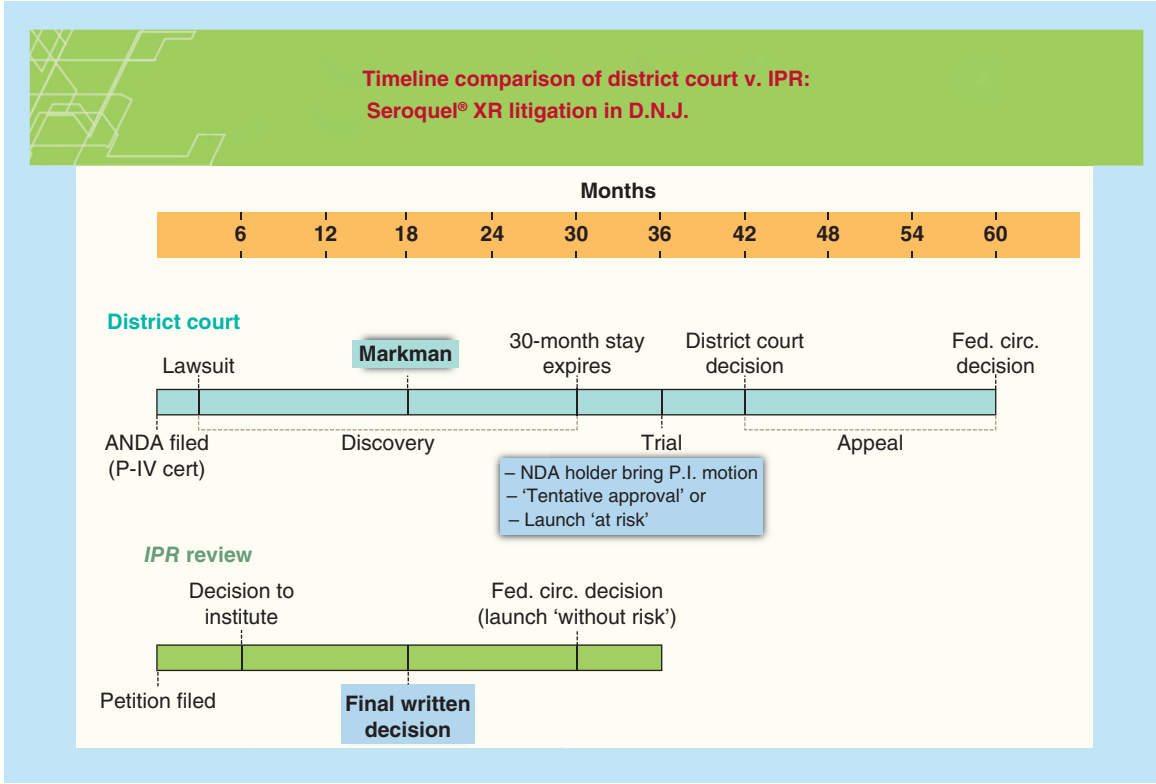

Figure 1. The timeline for filing an Abbreviated New Drug Application through district court, and the timeline for IPR in the Seroquel® XR Abbreviated New Drug Application litigation [18].
ANDA: Abbreviated New Drug Application; Fed. circ.: Federal Circuit; D.N.J.: District of New Jersey: IPR: *Inter Partes* review; NDA: New Drug Application; P.I.: Preliminary injunction; P-IV cert: Paragraph IV certification.

The Court also rejected the argument that the district court standard was more appropriate, stating that IPR is similar to a judicial proceeding. Instead, the Court listed factors that suggest 'the proceeding offers a second look at an earlier administrative grant of a patent' [24].

There are many factors that parties should consider before availing themselves an IPR proceeding. It is not necessary for a generic drug company to file a paragraph IV certification, or even have an ANDA on file at all, to file an IPR challenge. For example, Kyle Bass' Coalition for Affordable Drugs has filed several IPRs [25]. If a generic drug company does not file a petition for IPR first, but instead waits to be sued, the first consideration is that IPR is relevant only to validity challenges and not to noninfringement defenses. The generic drug company therefore must weigh the strengths and weaknesses of its validity and noninfringement positions before deciding the appropriate course of action. If a company that is being sued in district court decides to file a petition for IPR, an initial issue to address is whether the district court litigation would be stayed during the IPR process 35 U.S.C. §315(a)(2) [26]. District courts have been granting stays pending post grant proceedings more frequently today, than during the prior reexamination (*ex parte* and *inter partes*) era [27]. In the ANDA context, however, stays are not as common, presumably due to some of the reasons unique to Hatch–Waxman litigation [28]. As a practical matter, Hatch–Waxman litigation often involves multiple ANDA filers, so if only one, or a subset of the litigants files a petition for IPR, it would not make sense to stay some or all of the litigations.

Companies should also weigh the success rates before the PTAB and district courts, as well as the type of patent being challenged (e.g., active pharmaceutical ingredient [API] patents, formulation patents and method of use patents) in deciding whether to pursue a patent challenge through IPR before the PTAB. One study indicates that, for ANDA litigation, the patent owner prevails in cases involving API patents at a far higher rate than in cases involving methods of use and formulation patents; in cases involving API patents, the patent owner prevails about 60% of the time; for cases involving methods of use patents, the patent owner prevails about 24% of the time; and for cases involving formulation patents, the patent owner almost never prevails, with the generics prevailing for about 65% of the time, 31% are resolved

through settlements [29]. Interestingly, the success rate at the PTO for generic companies, is fairly similar, although there have only been roughly 220–240 petitions for IPR filed for Orange Book listed patents, compared with the 5502 petitions filed to date [30]. Recent statistics on IPR show that before the PTAB, about 40% of bio/pharma patent (not limited to Orange Book listed patents) claims are found unpatentable, 10% of the claims are canceled and 27% of the claims are found not unpatentable [31]. Given the relatively reasonable success rate before the PTAB, we would expect to see more patent challenges by generic pharmaceutical companies before the PTAB (particularly on API patents which are most difficult to invalidate in district court and for which the success rate in IPR is about 60%, while simultaneously the generic pharmaceutical companies could take a noninfringement position on the formulation patents) due to the reduced cost, increased speed and the recent seal of approval of these proceedings from the Supreme Court in *Cuozzo*.

It, therefore, is not surprising that a dual strategy for patent challenges in the pharmaceutical industry has recently emerged, as soon as Hatch–Waxman litigation begins in the district court, the same patents are simultaneously attacked at the PTAB. The existence of the dual strategy is based on the idea that the innovator company faces attack in two fronts: the PTAB and the district court. Indeed, the PTAB's own data (Figure 2) show that, as a percentage of all post grant petitions, the percentage of petitions in the pharmaceutical industry has steadily increased from about 6% in fiscal year (FY) 2014, to about 9% in FY 2015, to about 14% in FY 2016, as of 31 August 2016 [32].

Future perspective

Overall, IPR remains a powerful tool for challenging patents, and in the future, parties most likely will continue to explore the rapidly developing dual strategy when attacking the validity of a bio/pharma patent. Patent challengers may choose to make use of the PTAB's expertise, broader claim construction standard and lower standard of proof to present the most technical prior art arguments. Challengers can then focus on efforts during any concurrent litigation on

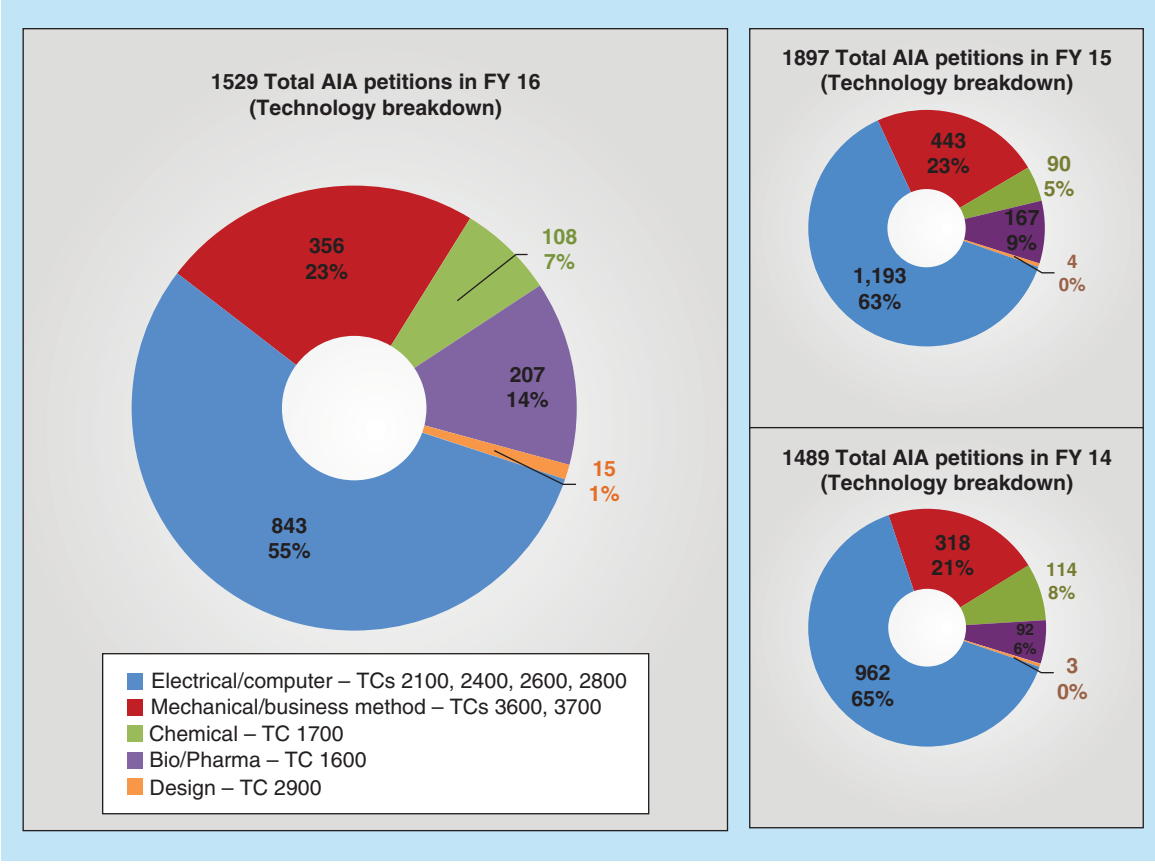

Figure 2. Patent Trial and Appeal Board Statistics [33].
The government's FY is not the same as a calender year.
AIA: America Invents Act; TC: Technology center; FY: Fiscal Year.

other grounds of invalidity, such as arguments regarding patentable subject matter under 35 U.S.C. § 101, written description or enablement under 35 U.S.C.§ 112, or prior art under 35 U.S.C. §§ 102 and 103 that is unavailable for use in IPR [34]. Under 35 U.S.C. §311(b), IPR is limited to consideration of patents and printed publications. Accordingly, nonprinted material, such as public use, sales or offers for sale cannot be used as prior art in IPR.

After *Cuozzo*, with the PTAB's continued use of the BRI claim interpretation standard, and the district courts' continued use of the Phillips standard, the patent challenger will not be precluded from arguing differing claim interpretations in district court litigation and the PTAB, as differing standards are clearly permissible and contemplated under the law. Accordingly, the lower standard of proof and broader claim construction standards before the PTAB should inure to the benefit of the patent challenger, making IPR an attractive avenue for generic companies seeking to challenge the validity of bio/pharma patents.

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The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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