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## Do Not Pass Go, Do Not Stop for Summary Judgment: The U.S. District Court for the District of Delaware's Seemingly Disjunctive Yet Efficient Procedures in Hatch-Waxman Litigation

Katherine Rhoades

k-rhoades2016@nlaw.northwestern.edu

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# **Do Not Pass Go, Do Not Stop for Summary Judgment: The U.S. District Court for the District of Delaware’s Seemingly Disjunctive Yet Efficient Procedures in Hatch-Waxman Litigation**

**By Katherine Rhoades\***

## ABSTRACT

*With the multi-billion dollar generic pharmaceutical industry growing annually, litigation under the Hatch-Waxman Act—the legislation that expedited the Food & Drug Administration’s (“FDA”) approval process for generic drugs—can have substantial economic implications on American consumers. Under the Hatch-Waxman Act, a generic drug company can challenge a brand-name pharmaceutical company’s pioneer drug patent(s) in an Abbreviated New Drug Application (“ANDA”) by filing a Paragraph IV certification with the FDA, and the patentee can—and usually does—sue for infringement. The court may find the pioneer drug patent(s) invalid or not infringed by the generic drug, which results in savings to American consumers when the affordable generic drug is eventually brought to market. The United States District Court for the District of Delaware’s four Article III judges hear the majority of cases arising under the Hatch-Waxman Act. However, unlike other patent-heavy dockets, the District of Delaware does not have uniform local patent rules and very rarely entertains motions for summary judgment in Hatch-Waxman litigation. This article evaluated the District of Delaware’s procedures in handling Hatch-Waxman cases and presents an empirical study of the district’s summary judgment practice in these cases. The empirical study shows that the District of Delaware’s practice is efficient and predictable and not contrary to the purpose behind the Hatch-Waxman Act: to bring more low-cost generic drugs to consumers. Because the district has a bench experienced in patent litigation, the District of Delaware does not need to adopt local patent rules and should continue its current practice of rarely hearing summary judgment motions in ANDA cases.*

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\* J.D. candidate, Northwestern University Pritzker School of Law, 2016; B.S. Chemistry, Illinois Wesleyan University, 2012. The author wishes to thank Laura A. Lydigsen, a Shareholder at the firm of Brinks, Gilson & Lione and Northwestern Pritzker Law Professor David L. Schwartz for each of their helpful insights, comments, feedback, and guidance throughout the writing process and the staff and executive board of the *Northwestern Journal of Technology & Intellectual Property* for their amazing support and patience.

## TABLE OF CONTENTS

INTRODUCTION .....	83
I. BACKGROUND OF THE HATCH-WAXMAN ACT .....	84
A. ANDA Approval Process.....	85
B. Purpose and Policy of the Hatch-Waxman Act .....	86
C. Paragraph IV Certifications .....	87
II. LOCAL RULES AND SUMMARY JUDGMENT PRACTICE IN THE DISTRICT OF DELAWARE .....	88
A. The Local Rules: Delaware vs. New Jersey.....	89
B. The District of Delaware’s Local Rules.....	89
1. Delaware’s ANDA Procedures and Its Judges’ Idiosyncrasies .....	90
III. EMPIRICAL STUDY: SUMMARY JUDGMENT PRACTICE IN DELAWARE VS. NEW JERSEY .....	92
A. Data Collection for the Empirical Study.....	92
B. The Results of the Study .....	93
C. Summary Judgment Is Rare in the District of Delaware .....	95
D. Delaware’s Practice: Disjunctive or Consistent and Predictable? .....	97
IV. NO NEED FOR DELAWARE TO CHANGE ITS PROCEDURES IN ANDA CASES .....	98
A. The Purpose and Benefit of Local Patent Rules .....	98
1. Local Patent Rules Are Not Necessary in Delaware .....	100
2. The Benefits of Early Disclosure in ANDA Cases .....	102
B. Is Summary Judgment Proper in ANDA Litigation?.....	103
1. Summary Judgment Motions Are Not Necessary in ANDA Cases.....	103
2. Delaware’s Practice Is Consistent with the Purpose of the Hatch-Waxman Act . .....	106
CONCLUSION.....	106

## INTRODUCTION

¶1 The United States pharmaceutical industry is a multi-billion dollar industry that continues to grow. Generic drug companies make up a large part of the pharmaceutical market, accounting for roughly seventy-one percent of the prescription drugs purchased annually.<sup>1</sup> Many Americans rely on these low-cost alternatives to brand-name drugs, but this booming industry did not always exist. The prior lengthy and expensive Food & Drug Administration (“FDA”) approval regime for pharmaceutical drugs left little incentive for generic drug manufacturers to seek FDA approval. This resulted in few low-cost alternatives for Americans unhappy with costly brand-name drug prices.

¶2 Congress sought to increase the availability of low-cost generic drugs to consumers. In September 1984, Congress created a streamlined approval process for generic drugs by passing the Drug Price Competition and Patent Term Restoration Act of 1984, which launched a new era in the generic drug industry.<sup>2</sup> This landmark legislation, commonly known as the Hatch-Waxman Act, allows a generic drug manufacturer (“generic”) to file an Abbreviated New Drug Application (“ANDA”) with the FDA, which significantly expedited the process to get the FDA approval necessary for bringing many generic drugs to the market. Congress sought to strike a balance between generics and innovators with this new legislation. Along with the expedited approval process for generics, the Hatch-Waxman Act also provided additional incentives to innovators such as a patent term extension and restrictions on the generic drugs eligible for the ANDA process.<sup>3</sup> For example, the Hatch-Waxman Act does not allow generics to place generic equivalents of patented drugs on the market, and owners of valid pharmaceutical patents can seek recourse in federal court under the Hatch-Waxman Act.<sup>4</sup>

¶3 The United States District Court for the District of Delaware and the United States District Court for the District of New Jersey are overwhelmingly the favored jurisdictions of brand-name pharmaceutical companies seeking to enjoin generics from placing their allegedly infringing generic drugs on the market under the Hatch-Waxman Act.<sup>5</sup> This is due in part to the high number of drug companies headquartered or incorporated in Delaware or New Jersey. The local rules and local practice governing ANDA cases in these two districts vary significantly. Hatch-Waxman litigation in the District of Delaware can be described as “courtroom-specific”; that is, the local rules and procedures vary noticeably among its four Article III judges.<sup>6</sup> In comparison, the District of New Jersey

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<sup>1</sup> Somnath Pal, *Shifts in the Generic-Drug Market: Trends and Causes*, U.S. PHARMACIST (June 21, 2013), <http://www.uspharmacist.com/content/s/253/c/41309/> [<https://perma.cc/QZY3-YEUP>].

<sup>2</sup> See Drug Price Competition and Patent Term Restoration Act of 1984 § 101, 21 U.S.C. § 355(j) (1984).

<sup>3</sup> See *id.* § 201, 35 U.S.C. § 156 (1984); *id.* § 101.

<sup>4</sup> See *id.* § 202, 35 U.S.C. § 271(e).

<sup>5</sup> Kevin E. Noonan, *Lex Machina Looks at ANDA Cases*, PATENT DOCS (Nov. 5, 2014), <http://www.patentdocs.org/2014/11/lex-machina-looks-at-anda-cases.html> [<https://perma.cc/RPM7-X5JR>]; Brian C. Howard, *2014 Patent Litigation Year in Review*, LEX MACHINA 1, 13 (Mar. 26, 2015), [http://pages.lexmachina.com/rs/lexmachina/images/2014 Patent Litigation Report.pdf](http://pages.lexmachina.com/rs/lexmachina/images/2014%20Patent%20Litigation%20Report.pdf) [<https://perma.cc/T2ZR-D7Y7>] (“ANDA litigation is heavily concentrated in the Districts of New Jersey and Delaware.”). The most litigation occurs in the District of Delaware, followed by the District of New Jersey. Noonan, *supra* note 5.

<sup>6</sup> See *Judges’ Info*, U.S. DISTRICT. CT. DISTRICT. DEL., <http://www.ded.uscourts.gov/judges-info> [<https://perma.cc/6SXT-W2JQ>].

has adopted uniform local patent rules with Hatch-Waxman-specific provisions that govern all ANDA cases in the district, regardless of which of its twenty-five Article III judges presides over the case.<sup>7</sup> Additionally, Delaware's judges seldom allow ANDA litigants to bring motions for summary judgment.

¶4 The Hatch-Waxman Act seeks to accelerate the process of bringing low-cost generic drugs to consumers. This article explores some of the District of Delaware's practices and procedures in handling ANDA cases to see whether those practices frustrate the purpose behind the Hatch-Waxman Act by delaying the release of these low-cost drugs to the market. Part I presents the important provisions of the Hatch-Waxman Act that give rise to ANDA litigation, as well as the policies behind the Act. Part II explores the local rules and local practice in the District of Delaware and compares it with the District of New Jersey. This article focuses specifically on the District of Delaware but references the District of New Jersey's local rules and procedures to contrast with Delaware. Part III presents an empirical study of summary judgment motion practice in ANDA cases in those two districts. Part IV concludes that while the District of Delaware's local rules and procedures may seem disjunctive and inefficient at first glance, the district does not need uniform local patent rules because the judges are extremely experienced and efficient in handling patent cases, and of most relevance, in ANDA cases. However, Part IV further explains that the District of Delaware could improve its handling of ANDA cases by requiring early disclosure of the ANDA in litigation.

## I. BACKGROUND OF THE HATCH-WAXMAN ACT

¶5 The Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetic Act, and "effectively created the modern generic pharmaceutical industry."<sup>8</sup> By enacting the Hatch-Waxman Act, Congress provided the FDA with a new complex regulatory scheme to govern the approval of generic drugs.<sup>9</sup> The approval process allows generics to get their lower-cost alternatives on the market more quickly than under the previous FDA regime.

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<sup>7</sup> See D.N.J. L. CIV. R. App. T. In 2011, New Jersey was selected to participate in the congressionally enacted Patent Pilot Program, see *Pilot Program in Certain District Courts*, Pub. L. No. 111-349 § 1, 124 Stat. 3674 (2011), and has adopted procedures for the allocation of patent cases in its district, see D.N.J. L. CIV. R. 40.1(f); D.N.J. L. PAT. R. 1.5. Delaware was not selected to participate in the pilot program. See Ron Vogel, *The Patent Pilot Program: Reassignment Rates and the Effect of Local Patent Rules*, NYIPLA 13, 13 (Oct./Nov. 2013), <http://www.fr.com/files/Uploads/Documents/Vogel.NYIPLABulletin.Pilot-Patent-Program-Reassignment-Rates-and-Effects-of-Local-Rules.OctNov2013.pdf> [<https://perma.cc/BY2J-B45B>]. The Patent Pilot Program allows judges to transfer patent cases on their docket to a judge in the district who has opted to participate in the program. See *id.* "Delaware was the only patent-intense district not included in the Program." *Id.* Since Delaware has only four Article III judges, its non-participation in the program is not unusual.

<sup>8</sup> Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 175 (2008).

<sup>9</sup> Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417 (2011).

### A. ANDA Approval Process

¶16 Under the Hatch-Waxman Act, a generic seeking FDA approval of its drug may file an ANDA with the FDA<sup>10</sup> rather than a New Drug Application (“NDA”).<sup>11</sup> In comparison, before a research-based pharmaceutical company can market its pioneer drug, it must submit an NDA containing extensive pre-clinical and clinical data establishing the drug’s safety and efficacy.<sup>12</sup> Before the Hatch-Waxman Act, a generic seeking FDA approval had to submit an NDA. This meant that if an NDA submitted by the pioneer pharmaceutical company of the same drug had already been approved, the FDA still required the generic to file a lengthy NDA containing clinical data of the generic version of the approved drug even though the FDA had already concluded that the drug was safe and effective by approving the first NDA.<sup>13</sup> This regulatory system slowed the development of marketable generic equivalents.<sup>14</sup> Under the current system, rather than requiring the generic to submit full clinicals on safety and efficacy of the generic drug, the Hatch-Waxman Act instead requires that a generic submit an ANDA containing scientific data showing that the drug is the “bioequivalent”<sup>15</sup> of a drug approved in an NDA.<sup>16</sup>

¶17 The Hatch-Waxman regulatory scheme ensures that generic drugs meet FDA quality standards, while simplifying the generic drug approval process. This encourages the development of generic drugs, thereby accelerating consumer access to these affordable drugs.<sup>17</sup> An ANDA applicant can rely entirely on the pioneer pharmaceutical company’s lengthy and costly clinical data provided in the approved NDA and has no obligation to provide the FDA with its own proof of safety and efficacy as long as the generic can prove bioequivalency.<sup>18</sup>

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<sup>10</sup> 21 U.S.C. § 355(j) (2015).

<sup>11</sup> *Id.* § 355(a).

<sup>12</sup> See Avery, *supra* note 8, at 174–75 (discussing the extensive testing and analysis pharmaceutical companies perform in order to prove the drug’s safety and efficacy in an NDA).

<sup>13</sup> *Id.*

<sup>14</sup> See *id.* In fact, “just before the Hatch-Waxman Act was passed, the FDA estimated there were approximately 150 brand-name drugs on the market with expired patents but no generic equivalents.” *Id.*

<sup>15</sup> Under the Hatch-Waxman Act:

A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

21 U.S.C. § 355(j)(8)(B).

<sup>16</sup> Kelly, *supra* note 9, at 417. When filing an ANDA with the FDA, a generic need only “demonstrate that its generic drug has the same active ingredient, the same basic pharmacokinetics, and is bioequivalent to the pioneer drug.” Avery, *supra* note 8, at 176; see 21 U.S.C. § 355(j)(2)(A)(ii)–(iv). This does not suggest that the generic need only prove bioequivalency in its ANDA. A generic must submit a variety of information to the FDA in its ANDA, including chemistry manufacturing and controls. See 21 U.S.C. § 355(j)(b)(2)(A)(vi). Therefore, while the amount of information submitted in an ANDA is substantially less than an NDA, there is still some meat to an ANDA.

<sup>17</sup> Avery, *supra* note 8, at 176.

<sup>18</sup> *Id.*; see *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008) (“Generic

¶8 This eliminates duplicative research and clinical trial costs previously required of generics.<sup>19</sup>

¶9 Even if a generic proves that its generic drug is the “bioequivalent” of a drug approved in an NDA, there are limits to the FDA’s approval power. The FDA cannot approve an ANDA for a generic drug that will infringe a valid patent.<sup>20</sup> When filing an ANDA, the generic must certify that the drug it seeks to market is (I) not patented, (II) the patent has expired, (III) the generic drug will not go on the market until the patent expires, or (IV) the “patent is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug . . . .”<sup>21</sup> These are referred to as Paragraph I, II, III, and IV certifications respectively. By filing a Paragraph IV certification, a generic seeks to market an equivalent of a patented drug before the patent has expired when it believes the patent is invalid, not infringed, or unenforceable.<sup>22</sup> But the Hatch-Waxman Act prohibits the FDA from approving an ANDA “until all patent protection and market exclusivity periods have expired.”<sup>23</sup>

¶10 Once the FDA approves an ANDA containing a Paragraph IV certification, the generic receives 180-day marketing exclusivity for its approved generic drug.<sup>24</sup> The exclusivity period seeks to encourage and reward the first Paragraph IV challenger “for undertaking the costs and risks of patent litigation” in filing an ANDA challenging the validity of the patent.<sup>25</sup> Thus, a successful Paragraph IV challenger is given six months to market its generic drug without any generic competition.<sup>26</sup>

### B. Purpose and Policy of the Hatch-Waxman Act

¶11 The Hatch-Waxman Act was designed as a compromise between competing policy objectives.<sup>27</sup> On the one hand, Congress sought to increase the availability of low cost,

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drug companies are not required to conduct their own independent clinical trials to prove safety and efficacy, but can instead rely on the research of the pioneer pharmaceutical companies.”).

<sup>19</sup> See Avery, *supra* note 8, at 176. And by not requiring generics to undertake duplicative clinical trials, the Act allows for safe, previously patented generic drug equivalents to reach consumers, while saving Americans billions of dollars. See Kelly, *supra* note 9, at 426.

<sup>20</sup> See 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV).

<sup>21</sup> *Id.*

<sup>22</sup> Michael R. Herman, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1795 (2011).

<sup>23</sup> Kelly, *supra* note 9, at 418. By including this requirement, Congress sought to encourage generics to challenge stale patents on the market, while also giving valid patents the utmost protection to encourage innovation. See *Janssen Pharmaceutica*, 540 F.3d at 1355–56.

<sup>24</sup> 21 U.S.C. § 355(j)(5)(B)(iv).

<sup>25</sup> Avery, *supra* note 8, at 178 (quoting Representative Henry Waxman, Speech at the Generic Pharmaceutical Association’s First Annual Policy Conference: Securing the Future of Affordable Medicine (Sept. 20, 2005)).

<sup>26</sup> Avery, *supra* note 8, at 178. This period may be cut short. For example, the “180-day exclusivity can begin to run—with a court decision—even before an applicant has received approval for its ANDA. In that case, some, or all of the 180-day period, could expire without the ANDA applicant marketing its generic drug.” *FTC Study: Generic Drug Entry Prior to Patent Expiration: Before the Senate Committee on the Judiciary* (2003) (statement of Daniel E. Troy, Chief Counsel, FDA), <http://www.fda.gov/NewsEvents/Testimony/ucm161034.htm> [https://perma.cc/2QSW-ZCKQ].

<sup>27</sup> See *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230 (4th Cir. 2002) (citations and internal quotation marks and omitted) (discussing how the Hatch-Waxman Act was an “effort to strike a balancing between two conflicting policy objectives”).

generic drugs for American consumers.<sup>28</sup> On the other hand, in doing so, Congress did not want to discourage research-based pharmaceutical companies from investing in the research and development of new drugs.<sup>29</sup> Legislators wanted to continue to incentivize pharmaceutical companies to research and invent new drugs to treat medical conditions.<sup>30</sup> To achieve these objectives, Congress created the ANDA approval process for non-infringing generic drugs to increase competition among generics and research-based pharmaceutical drug companies, as well as competition between generics, thereby lowering costs to consumers.<sup>31</sup> Additionally, to provide incentives for research-based pharmaceutical companies to continue invest in research and development, the Hatch-Waxman Act included “patent term extensions of up to five years to compensate for marketing delays during the regulatory review period prior to the first permitted commercial marketing of a new drug.”<sup>32</sup>

### C. Paragraph IV Certifications

¶12 Litigation frequently arises under the Hatch-Waxman Act. Hatch-Waxman litigation arises when a generic files an ANDA with the FDA containing a “[P]aragraph IV certification challenging a brand drug manufacturer’s patent(s)”.<sup>33</sup> Filing an ANDA with a Paragraph IV certification is *itself* an act of patent infringement.<sup>34</sup> Therefore, the Hatch-Waxman Act requires all Paragraph IV ANDA filers to provide notice to the challenged patent holder (“patentee”), which should “include a detailed statement of the factual and legal basis” of why the applicant believes “that the patent is invalid or will not be infringed.”<sup>35</sup> Upon receipt of the notice, the patent holder can bring an infringement action against the ANDA applicant within forty-five days.<sup>36</sup> However, if the patent holder fails to file a suit within that time, “the approval [of the ANDA] shall be made effective immediately” upon the FDA’s completion of substantive review of the ANDA.<sup>37</sup>

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<sup>28</sup> See H.R. REP. NO. 98–857, pt. 1, at 14 (1984) (“The purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962.”); Avery, *supra* note 8, at 172 (noting that such a balance of rights is necessary to prevent pharmaceutical pioneers from reaping “monopoly profits indefinitely”).

<sup>29</sup> Kelly, *supra* note 9, at 417; see Avery, *supra* note 8, at 171 (noting that “[t]he pharmaceutical industry is one of the few industries that requires patent protection to ensure the profitability of its innovative products” due to the enormous costs that companies must sink into research and development).

<sup>30</sup> Kelly, *supra* note 9, at 417.

<sup>31</sup> *Id.*

<sup>32</sup> Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 357–58 (2007); see Drug Price Competition and Patent Term Restoration Act of 1984 § 201, 35 U.S.C. § 156 (1984).

<sup>33</sup> 2014 Patent Litigation Study, PRICEWATERHOUSECOOPERS 1, 20 (2014), [http://www.pwc.com/en\\_US/us/forensic-services/publications/assets/2014-patent-litigation-study.pdf](http://www.pwc.com/en_US/us/forensic-services/publications/assets/2014-patent-litigation-study.pdf) [<https://perma.cc/PP35-S5ZF>].

<sup>34</sup> See 35 U.S.C. § 271(e)(2)(A) (2015) (“It shall be an act of infringement to submit . . . [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . .”).

<sup>35</sup> 21 U.S.C. § 355(j)(2)(B)(iv)(II).

<sup>36</sup> *Id.* § 355(j)(5)(B)(iii); see also 35 U.S.C. § 271(e)(5) (allowing a generic to bring a declaratory judgment action against the patentee if the patentee fails to bring an infringement action within the forty-five day period).

<sup>37</sup> 21 U.S.C. § 355(j)(5)(B)(iii). While the statute uses the “immediately” language, it is a bit misleading. If no suit is filed within forty-five days, that does not mean that the ANDA will be approved on day forty-six. It may take years for the FDA to complete its substantive review of the ANDA.



¶13 If the patent holder *does* assert its patent against the ANDA filer within the forty-five day time period, it automatically triggers a thirty-month stay.<sup>38</sup> During the thirty-month stay, “the FDA is barred from approving the ANDA” but may tentatively approve the application, which “become[s] effective immediately upon expiration of the stay.”<sup>39</sup> The stay is intended to protect patent holders with valid drug patents,<sup>40</sup> but if the patent expires or if a district court finds the patent invalid or not infringed by the ANDA, the FDA can immediately approve the ANDA before expiration of the thirty-month stay.<sup>41</sup>

¶14 The litigation between patentees and ANDA filers are bench trials that rarely award damages.<sup>42</sup> Damages are rare in these suits because the alleged infringer has not put the drug on the market yet, and thus, usually has not made any infringing sales prior to the suit.<sup>43</sup> Instead, patentees seek injunctive relief from the court to prevent a generic from putting their drug on the market.<sup>44</sup> Because patentees risk losing patent protection on their highly profitable brand-name drugs, the potential economic implications of ANDA litigation are significant.

## II. LOCAL RULES AND SUMMARY JUDGMENT PRACTICE IN THE DISTRICT OF DELAWARE

¶15 At first glance, in comparing the two most favored ANDA litigation districts, the District of Delaware’s rules and procedures in handling ANDA cases appear disjunctive and inefficient compared to the District of New Jersey’s rules and practice. ANDA litigation has grown substantially in the past decade, and Delaware and New Jersey are the most active districts for ANDA litigation by far.<sup>45</sup> These two districts combined have handed down almost half of all ANDA court decisions since 1995,<sup>46</sup> which is not surprising since these districts are home to many pharmaceutical companies. However, the local court rules governing ANDA cases in the District of Delaware and the District of New Jersey are significantly different. Also, the local procedures in ANDA cases, specifically summary judgment practice, differ considerably between these two districts. While this article focuses specifically on ANDA litigation in the District of Delaware, New Jersey’s local rules and practice are referred to for comparison. It is worth comparing the districts’ procedures in handling ANDA cases to evaluate whether the District of Delaware’s rules and practice are efficient in furthering the objectives of the Hatch-Waxman Act.

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<sup>38</sup> *See id.*

<sup>39</sup> Avery, *supra* note 8, at 177; *see* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd).

<sup>40</sup> Avery, *supra* note 8, at 177.

<sup>41</sup> *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I)–(II).

<sup>42</sup> *See* Brian D. Coggio et al., *The Right to a Jury Trial in Actions Under the Hatch-Waxman Act*, 79 J. PAT. & TRADEMARK OFF. SOC’Y 765, 767 (1997).

<sup>43</sup> *See id.*

<sup>44</sup> *See id.*; *see* 35 U.S.C. § 271(e)(4).

<sup>45</sup> Noonan, *supra* note 5; *see* Howard, *supra* note 5, at 13; 2013 *Patent Litigation Study*, PRICEWATERHOUSECOOPERS 1, 28 (2013), [http://www.pwc.com/en\\_US/us/forensic-services/publications/assets/2013-patent-litigation-study.pdf](http://www.pwc.com/en_US/us/forensic-services/publications/assets/2013-patent-litigation-study.pdf) [<https://perma.cc/7N4E-SA88>]. The “most ANDA litigation occurs in the District of Delaware (678 cases),” followed by “the District of New Jersey (481 cases) . . . .” Noonan, *supra* note 5.

<sup>46</sup> *See* 2013 *Patent Litigation Study*, *supra* note 45, at 28; *see also* Noonan, *supra* note 5. Since 1995, there have been 137 ANDA court decisions, and sixty-two of those decisions were handed down by judges in Delaware or New Jersey. 2013 *Patent Litigation Study*, *supra* note 45, at 28

### A. *The Local Rules: Delaware vs. New Jersey*

¶16 Over the last decade, patent rules have become an integral part of patent litigation.<sup>47</sup> At least twenty-four U.S. district courts have formally adopted local patent rules to govern patent litigation.<sup>48</sup> The District of New Jersey is one of those many districts.<sup>49</sup> The District of New Jersey has also amended its local patent rules to include unique disclosure provisions exclusive to patent cases arising under the Hatch-Waxman Act.<sup>50</sup> The District of Delaware has not followed suit. Delaware has adopted neither rules to govern Hatch-Waxman cases nor any local patent rules.<sup>51</sup> New Jersey's bench has twenty-five Article III judges<sup>52</sup> while the District of Delaware has four.<sup>53</sup> The purpose of local patent rules is to increase predictability and efficiency by promoting uniformity among the district,<sup>54</sup> so uniform local patent rules may be more important in districts with more district court judges, such as the District of New Jersey. However, like several other districts, the District of Delaware's individual judges do have standing orders similar to local patent rules.<sup>55</sup>

### B. *The District of Delaware's Local Rules*

¶17 The District of Delaware's local rules differ significantly from the District of New Jersey's local patent rules and Hatch-Waxman provisions. Most apparent is the fact that Delaware has not adopted local patent rules, let alone Hatch-Waxman provisions.<sup>56</sup> In fact, among its Local Civil Rules, Delaware has only one rule specifically directed at patent cases.<sup>57</sup>

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<sup>47</sup> See Travis Jensen, *Basics*, LOCAL PATENT RULES, <http://www.localpatentrules.com/basics/> (last visited Mar. 5, 2016) [<https://perma.cc/J799-E4YB>]. The Northern District of California was the first to adopt local patent rules in 2001. Arthur Gollwitzer III, *Local Patent Rules—Certainty and Efficiency or a Crazy Quilt of Substantive Law?*, 13 ENGAGE: J. FEDERALIST SOC'Y PRAC. GROUPS 94, 94 (2012).

<sup>48</sup> Gollwitzer, *supra* note 47, at 94; see generally D.N.J. L. PAT. R.; E.D. TEX. P.R.; N.D. ILL. LPR. District courts have authority to adopt local patent rules under Federal Rule of Civil Procedure 83. Gollwitzer, *supra* note 47, at 95; see FED. R. CIV. P. 83.

<sup>49</sup> See generally D.N.J. L. PAT. R. These rules govern all civil actions “which allege infringement of a patent in a complaint, counterclaim, cross-claim or third party claim, or which seek a declaratory judgment that a patent is not infringed, is invalid or is unenforceable.” D.N.J. L. PAT. R. 1.2.

<sup>50</sup> See D.N.J. L. PAT. R. 3.6 (“Disclosure Requirements for Patent Cases Arising Under 21 U.S.C. § 355 (commonly referred to as “the Hatch-Waxman Act”).

<sup>51</sup> See generally D. DEL. LR.

<sup>52</sup> At the time this article was written, the District of New Jersey had fourteen active Article III judges, eight Article III judges with senior status, and three judicial vacancies. *United States District Court for the District of New Jersey*, BALLOTPEDIA, [https://ballotpedia.org/United\\_States\\_District\\_Court\\_for\\_the\\_District\\_of\\_New\\_Jersey](https://ballotpedia.org/United_States_District_Court_for_the_District_of_New_Jersey) (last visited Feb. 26, 2016) [<https://perma.cc/LYC3-JK77>]; see *Our Judges*, U.S. DISTRICT CT. DISTRICT N.J., <http://www.njd.uscourts.gov/our-judges> (last visited Feb. 26, 2016) [<https://perma.cc/Y7HY-TRGV>].

<sup>53</sup> *Judges' Info*, U.S. DISTRICT CT. DISTRICT DEL., <http://www.ded.uscourts.gov/judges-info> (last visited Mar. 9, 2016) [<https://perma.cc/VV2R-WVE7>].

<sup>54</sup> See Gollwitzer, *supra* note 47, at 94. With more judges, there is more potential for variation between judges.

<sup>55</sup> See Jensen, *supra* note 47; see e.g., *Standing Orders*, U.S. DISTRICT CT. DISTRICT DEL., <http://www.ded.uscourts.gov/court-info/local-rules-and-orders/general-orders> (last visited Mar. 9, 2016) [<https://perma.cc/7TA4-9VVN>].

<sup>56</sup> See generally, D. DEL. LR.

<sup>57</sup> See D. DEL. LR 3.2 (“In all patent cases, copies of the patents at issue shall be attached and filed with the complaint.”).

## 1. Delaware's ANDA Procedures and Its Judges' Idiosyncrasies

¶18 Since the District of Delaware has not adopted local patent rules, the procedures governing ANDA cases in Delaware are “courtroom specific.” The District of Delaware has one division, and its bench comprises only four Article III judges—Chief Judge Leonard P. Stark, Judge Sue L. Robinson, Judge Gregory M. Sleet, and Judge Richard G. Andrews.<sup>58</sup> While Delaware has not adopted local patent rules, its individual judges have standing orders and guidelines that operate in effect like local patent rules.<sup>59</sup> However, unlike *uniform* local patent rules, the standing orders and guidelines are specific to the *individual* judge.<sup>60</sup> For example, each judge has his or her own model scheduling order for patent cases that sets out his or her general default procedures.<sup>61</sup> But the pertinent procedures for each judge vary considerably, and thus, the procedures governing ANDA cases in Delaware depend on to whose courtroom the parties are assigned.

¶19 In June 2014, Chief Judge Leonard P. Stark implemented new patent procedures for handling patent cases in his courtroom.<sup>62</sup> Those revised procedures include provisions governing almost all aspects of litigation, including: discovery, scheduling and case management, motions, invalidity and infringement contentions, *Markman* hearings,<sup>63</sup> summary judgment, *Daubert* motions,<sup>64</sup> pretrial orders, and trial.<sup>65</sup> However, these patent procedures govern only “all *non-ANDA* patent cases” assigned to Chief Judge Stark.<sup>66</sup> The Chief Judge also has two different scheduling orders for patent cases: (1) Patent Scheduling

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<sup>58</sup> See *Comparison of the Most Popular Patent Venues*, LAW360 (Dec. 10, 2009), [http://www.cooley.com/files/Law360.Patent Venue Article. Mitchell.Tilly.pdf](http://www.cooley.com/files/Law360.Patent%20Venue%20Article.Mitchell.Tilly.pdf) [<https://perma.cc/9FUA-FVUT>]; see also *Judges Info*, *supra* note 53.

<sup>59</sup> See *Standing Orders*, *supra* note 55. Each judge also has procedures and guidelines to govern patent cases in their courtroom that they post on their individual pages on the district's website. See also *Judges Info*, *supra* note 53.

<sup>60</sup> See *Judges Info*, *supra* note 53.

<sup>61</sup> See e.g., *Revised Patent Form Scheduling Order (ANDA)*, U.S. DISTRICT CT. DISTRICT DEL. (July 1, 2014), <http://www.ded.uscourts.gov/sites/default/files/Chambers/LPS/PatentProcs/LPS-PatentSchedOrder-ANDA.pdf> [<https://perma.cc/22VY-FAVX>] [hereinafter *Chief J. Stark's ANDA Patent Scheduling Order*]; *Patent Case Scheduling Order*, U.S. DISTRICT CT. DISTRICT DEL. (Feb. 5, 2015), <http://www.ded.uscourts.gov/sites/default/files/Chambers/SLR/Forms/Sched-Order-Patent2-05-15.pdf> [<https://perma.cc/228C-TU3N>] [hereinafter *J. Robinson's Patent Scheduling Order*].

<sup>62</sup> See Honorable Leonard P. Stark, *Revised Procedures for Managing Patent Cases*, U.S. DISTRICT CT. DISTRICT DEL. 1, 1 (June 18, 2014), <http://www.ded.uscourts.gov/sites/default/files/Chambers/LPS/PatentProcs/LPS-PatentProcedures.pdf> [<https://perma.cc/5WQW-XCJG>] [hereinafter *Chief J. Stark's Patent Procedures*].

<sup>63</sup> In *Markman v. Westview Instruments, Inc.*, the U.S. Supreme Court held that in patent cases, the issue of claim construction is a matter of law reserved for the district court judge, not the jury. 517 U.S. 370, 388–89 (1996). The Supreme Court recently reaffirmed this aspect of *Markman*. See *Teva Pharm. v. Sandoz, Inc.*, 135 S. Ct. 831, 835 (2015). Thus, judges now hold a pretrial claim construction hearing, or a “*Markman* hearing,” to hear the parties' arguments on how to construe the claims in the asserted patent. Frank M. Gasparo, *Markman v. Westview Instruments, Inc. and its Procedural Shock Wave: The Markman Hearing*, 5 J.L. & POL'Y 723, 724–25 (1997).

<sup>64</sup> Trial judges, including those presiding over ANDA cases, are charged with the task of acting as gatekeepers to expert testimony and must determine the reliability and relevance of an expert's testimony before it is admissible. See *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). Parties can seek to exclude unreliable expert testimony by filing a pretrial motion known as a “*Daubert* motion.” See Andrew Jurs, *Gatekeeper with a Gavel: A Survey Evaluating Judicial Management of Challenges to Expert Reliability and Their Relationship to Summary Judgment*, 83 Miss. L.J. 325, 326 (2014).

<sup>65</sup> See generally *Chief J. Stark's Patent Procedures*, *supra* note 62.

<sup>66</sup> *Id.* at 1 (emphasis in original).

Order (non-ANDA)<sup>67</sup> and (2) Patent Scheduling Order (ANDA).<sup>68</sup> The non-ANDA patent scheduling order contains a section for Chief Judge Stark to set a deadline for all case dispositive motions, such as motions for summary judgment.<sup>69</sup> In comparison, his ANDA patent scheduling order states: “[a]bsent agreement between the parties, the Court will generally not hear case dispositive motions in ANDA cases.”<sup>70</sup>

¶20 Unlike Chief Judge Stark, Judge Sue L. Robinson has only one patent case scheduling order, which appears to apply to ANDA cases as well as non-ANDA.<sup>71</sup> Judge Robinson’s patent scheduling order allows parties to file summary judgment motions with no explicit constraint on parties to ANDA cases.<sup>72</sup> Judge Robinson also provides patent litigants with certain guidelines that govern her courtroom; but again, she makes no distinction between normal patent cases and ANDA cases.<sup>73</sup> For example, she permits each party to file “one motion relating to infringement and one motion relating to validity.”<sup>74</sup>

¶21 Judge Gregory M. Sleet has implemented his own procedural rules to govern his courtroom as well. Like Judge Robinson, he has only one scheduling order to govern all patent cases.<sup>75</sup> However, his scheduling order requires that “[p]rior to filing any summary judgment motion, the parties must submit letter briefs seeking *permission* to file the motion.”<sup>76</sup> Also unique to Judge Sleet are his patent standing orders, which provide for appointment of “special masters” to hear discovery disputes in patent cases.<sup>77</sup>

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<sup>67</sup> *Revised Patent Form Scheduling Order*, U.S. DISTRICT CT. DISTRICT DEL. (June 2014), <http://www.ded.uscourts.gov/sites/default/files/Chambers/LPS/PatentProcs/LPS-PatentSchedOrder-Non-ANDA.pdf> [<https://perma.cc/65QV-DY7U>] [hereinafter *Chief J. Stark’s non-ANDA Patent Scheduling Order*].

<sup>68</sup> *Chief J. Stark’s ANDA Patent Scheduling Order*, *supra* note 61.

<sup>69</sup> *See Chief J. Stark’s non-ANDA Patent Scheduling Order*, *supra* note 67, at 11.

<sup>70</sup> *Chief J. Stark’s ANDA Patent Scheduling Order*, *supra* note 61, at 10.

<sup>71</sup> *See J. Robinson’s Patent Scheduling Order*, *supra* note 61.

<sup>72</sup> *See id.*

<sup>73</sup> *See, e.g., Additional Civil Trial Guidelines for Patent Cases*, U.S. DISTRICT CT. DISTRICT DEL. (Dec. 21, 2010), [http://www.ded.uscourts.gov/sites/default/files/Chambers/SLR/Misc/Additional\\_Civil\\_Trial\\_Guidelines-Patent\\_Cases\\_12-21-10.pdf](http://www.ded.uscourts.gov/sites/default/files/Chambers/SLR/Misc/Additional_Civil_Trial_Guidelines-Patent_Cases_12-21-10.pdf) [<https://perma.cc/FA69-WR6W>] [hereinafter *J. Robinson’s Additional Guidelines*]; *Briefing Guidelines in Complex Cases*, U.S. DISTRICT CT. DISTRICT DEL. (Dec. 3, 2013), [http://www.ded.uscourts.gov/sites/default/files/Chambers/SLR/Misc/Briefing\\_Guidelines-Complex\\_Cases-12-3-13.pdf](http://www.ded.uscourts.gov/sites/default/files/Chambers/SLR/Misc/Briefing_Guidelines-Complex_Cases-12-3-13.pdf) [<https://perma.cc/3QAG-G7HC>] [hereinafter *J. Robinson’s Briefing Guidelines*]; *Guidelines for Claim Construction Rulings in Patent Cases*, U.S. DISTRICT CT. DISTRICT DEL. (Dec. 21, 2010), [http://www.ded.uscourts.gov/sites/default/files/Chambers/SLR/Misc/Claim\\_Construction\\_Guideline\\_12-21-10.pdf](http://www.ded.uscourts.gov/sites/default/files/Chambers/SLR/Misc/Claim_Construction_Guideline_12-21-10.pdf) [<https://perma.cc/Y9ZC-TZKE>] [hereinafter *J. Robinson’s Claim Construction Guidelines*].

<sup>74</sup> *J. Robinson’s Briefing Guidelines*, *supra* note 73, at 2.

<sup>75</sup> *Scheduling Order [Patent]*, U.S. DISTRICT CT. DISTRICT DEL. (Feb. 25, 2014), [http://www.ded.uscourts.gov/sites/default/files/Chambers/GMS/Forms/Sched\\_Order\\_Patent\\_Rev02-25-14.pdf](http://www.ded.uscourts.gov/sites/default/files/Chambers/GMS/Forms/Sched_Order_Patent_Rev02-25-14.pdf) [<https://perma.cc/C6RH-5Q79>] [hereinafter *J. Sleet’s Patent Scheduling Order*].

<sup>76</sup> *Id.* at 4 (emphasis added).

<sup>77</sup> *See, e.g., Special Master Standing Order*, U.S. DISTRICT CT. DISTRICT DEL. (June 13, 2011), [http://www.ded.uscourts.gov/sites/default/files/Chambers/GMS/Orders/PDF/Special\\_Masters\\_Standing\\_Order\\_6-8-11.pdf](http://www.ded.uscourts.gov/sites/default/files/Chambers/GMS/Orders/PDF/Special_Masters_Standing_Order_6-8-11.pdf) [<https://perma.cc/A8CR-LRZ2>] [hereinafter *J. Sleet’s Special Master Standing Order*]; *Procedures – Appointment of Special Masters to Hear Discovery Disputes in Intellectual Property Cases*, U.S. DISTRICT CT. DISTRICT DEL. (Sept. 2004), <http://www.ded.uscourts.gov/sites/default/files/Chambers/GMS/Orders/PDF/spmasproc.pdf> [<https://perma.cc/T5CV-KWNY>] [hereinafter *J. Sleet’s Special Master Procedures*]; *Panel – Appoint of Special Masters to Hear Discovery Disputes in Intellectual Property Cases*, U.S. DISTRICT CT. DISTRICT DEL. (Sept. 2004),

¶22 Among Delaware’s four Article III judges, Judge Richard G. Andrews has the fewest patent-specific procedures and guidelines. Like Judge Robinson and Judge Sleet, he has only one scheduling order for patent cases.<sup>78</sup> Similarly, his patent scheduling order allows parties to file case dispositive motions without reference to ANDA cases,<sup>79</sup> but his scheduling order is the only explicit guideline applicable to patent cases in his courtroom.<sup>80</sup> What is unique about Judge Andrews’s scheduling order is that he has a unique procedure for claim construction.<sup>81</sup> Instead of having the parties file separate claim construction charts and briefs for the *Markman* hearing, he requires the parties to exchange their proposed claim terms for construction, exchange their proposed constructions, confer, and file a Joint Claim Construction Chart, as well as a Joint Claim Construction Brief.<sup>82</sup>

### III. EMPIRICAL STUDY: SUMMARY JUDGMENT PRACTICE IN DELAWARE VS. NEW JERSEY

¶23 Along with the local rules, the local procedures for handling ANDA cases in the District of Delaware and the District of New Jersey vary notably. Specifically, the two districts differ significantly in how they handle summary judgment motions in ANDA cases. This article presents an empirical study that compares the summary judgment practice in the two districts. Like most litigation, the majority of ANDA cases end in settlement.<sup>83</sup> Therefore, the number of final decisions on the merits to evaluate for this study was limited. Nevertheless, the results of this empirical study show the general way in which the two districts handle motions for summary judgment and the variance between the districts’ practices. The data also reveals that the four Article III judges in Delaware rarely allow parties to ANDA cases to bring motions for summary judgment.

#### A. Data Collection for the Empirical Study

¶24 This empirical study was conducted by collecting data from ANDA cases filed in the Districts of Delaware and New Jersey between 2009 and 2013. The author searched the dockets of the two districts for cases filed during the relevant time period using Bloomberg Law’s docket search feature. The study was limited to ANDA cases filed on or after January 1, 2009 through December 31, 2013. The dockets were searched using the keywords “ANDA AND summary judgment” and “Hatch-Waxman AND summary judgment.” The search found every case in those districts where a document on the docket

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<http://www.ded.uscourts.gov/sites/default/files/Chambers/GMS/Orders/PDF/spmaspanel.pdf> [<https://perma.cc/4HAX-WBA7>] [hereinafter *J. Sleet’s Special Masters Panel*].

<sup>78</sup> See *Scheduling Order*, U.S. DISTRICT CT. DISTRICT DEL. (Apr. 2012), [http://www.ded.uscourts.gov/sites/default/files/Chambers/RGA/Forms/Rule16\\_Scheduling\\_Order-Patent.pdf](http://www.ded.uscourts.gov/sites/default/files/Chambers/RGA/Forms/Rule16_Scheduling_Order-Patent.pdf) [<https://perma.cc/SSH5-L8TS>] [hereinafter *J. Andrews’s Patent Scheduling Order*].

<sup>79</sup> See *id.* at 6.

<sup>80</sup> See *Judge Richard G. Andrews*, U.S. DISTRICT CT. DISTRICT DEL., <http://www.ded.uscourts.gov/judge/judge-richard-g-andrews> (last visited Mar. 10, 2016) [<https://perma.cc/DR7X-JJ9A>].

<sup>81</sup> See *J. Andrew’s Patent Scheduling Order*, *supra* note 78, at 3–4.

<sup>82</sup> See *id.* at 3–5.

<sup>83</sup> See *2014 Patent Litigation Study*, *supra* note 33, at 21.

contained the word “summary judgment” and either “ANDA” or “Hatch-Waxman” in its title or body.<sup>84</sup>

¶25 The author subsequently analyzed every docket sheet within those search parameters and recorded whether a motion for summary judgment, request for leave to file a motion for summary judgment, or both were filed within each case.<sup>85</sup> In analyzing those cases in which a party filed a motion for summary judgment or sought leave to file a motion for summary judgment, the author also recorded the judge’s decision.

### B. *The Results of the Study*

¶26 The data collected from the empirical study is presented in Table I. Table I shows the number of cases where a party brought at least one motion for summary judgment, the number of cases where a motion was granted, and the number of cases where the judge issued a summary judgment decision and that decision was case dispositive. Table I further shows the number of cases where a party requested leave to file a motion for summary judgment and whether that request was granted. Table I displays the data from the empirical study by district. The data for the District of Delaware is further broken down by judge since the procedures governing ANDA cases in Delaware vary by judge.<sup>86</sup> The results for the District of New Jersey were not separated by judge because New Jersey has six times the number of judges as the District of Delaware and has uniform patent rules governing ANDA cases. Therefore, the author presumed that New Jersey was less likely to have wide divergence between judges. The data presented in Table I was also organized into Chart I to compare the summary judgment practice between the two districts. The data for the District of Delaware was further arranged in Chart II to show the variance among its four Article III judges.

**TABLE I. SUMMARY JUDGMENT DATA FOR ANDA CASES 2009–2013<sup>87</sup>**

	Delaware					New Jersey
	Stark	Robinson	Sleet	Andrews	All Judges	All Judges
Summary Judgment Motions	2	1	0	4	7	31
Granted Summary Judgment Motions <sup>88</sup>	1	1	0	2	4	10

<sup>84</sup> The author acknowledges that the results are dependent upon the search terms used and Bloomberg Law’s algorithm and is cognizant that there may be relevant cases that did not meet the search parameters. However, the objective of the empirical study was to compare the general summary judgment practice in the two districts in ANDA cases. Therefore, even if the data is not complete, the results are still useful for showing this point.

<sup>85</sup> If an ANDA case was filed before December 31, 2013 but the case had not reached the dispositive motion stage, no data for that case was recorded.

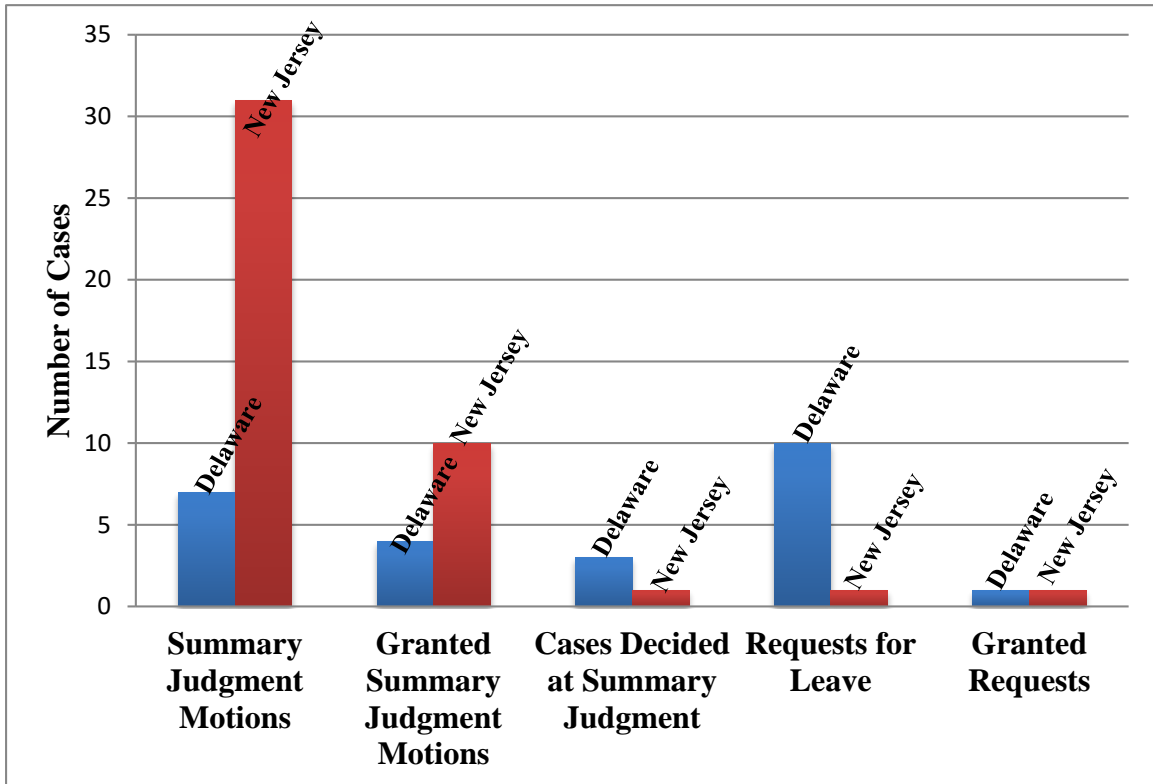
<sup>86</sup> See *supra* Section II(B).

<sup>87</sup> For the data used to compile Table I, see *Empirical Study Data*, *infra* Appendix A.

<sup>88</sup> If a motion for summary judgment was not granted, that does not necessarily mean that the motion was denied. The results reflect only those cases where the judge reached a decision on the summary judgment motion(s). There were two summary judgment motions filed in the District of Delaware and recorded in Table I—one before Judge Andrews and the other before Judge Stark—that were neither granted nor denied. See *Medicis Pharm. Corp. v. Actavis Mid Atlantic LLC*, No. 11-409 (D.

Cases Decided at Summary Judgment	0	1	0	2	3	1
Requests for Leave to File a Motion for Summary Judgment <sup>89</sup>	2	0	4	4	10	1
Granted Requests for Leave to File Motion for Summary Judgment <sup>90</sup>	0	0	0	1	1	1

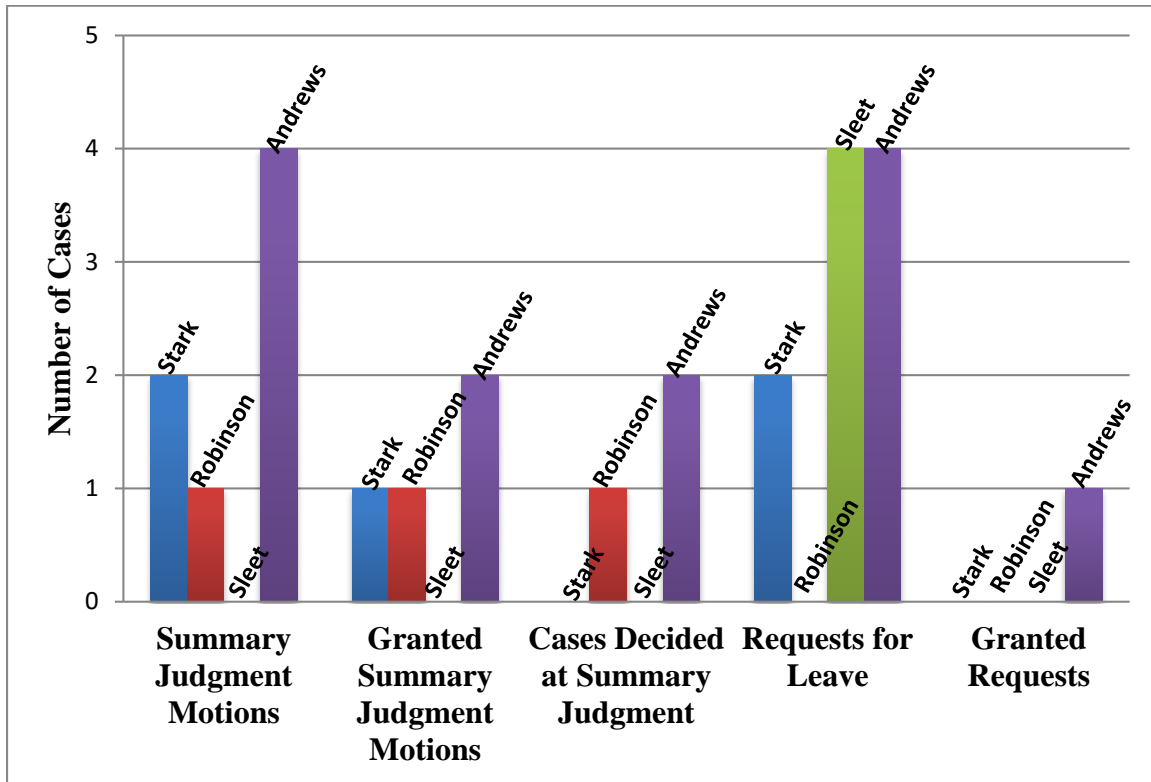
**CHART I. SUMMARY JUDGMENT DATA: DELAWARE & NEW JERSEY**



Del. Apr. 12, 2013) (order granting parties’ joint stipulation of dismissal with prejudice); *Novartis Pharm. Corp. v. Alvogen Pine Brook Inc.*, No. 13-52 (D. Del. July 7, 2013) (order granting the parties’ joint stipulation of noninfringement and dismissing the case).

<sup>89</sup> This data includes formal requests for leave as well as letters to judges requesting permission to file a motion for summary judgment or to alter their usual practice of not allowing dispositive motions. The author notes that there may have been informal requests that were not reflected on the dockets.

<sup>90</sup> If a request for leave was not granted, that does not mean that the request was necessarily denied. The results reflect only those cases where the judge reached a decision on the request. There was one request for leave before Judge Andrews that was withdrawn before he rendered a decision. *See Novartis Pharm. Corp. v. Noven Pharm. Inc.*, No. 13-527 (D. Del. Oct. 22, 2014) (notice of withdrawal of request for leave to file summary judgment).

**CHART II. SUMMARY JUDGMENT DATA IN DELAWARE BY JUDGE**

¶27 Two things are apparent from the results of the empirical study: (1) the judges in the District of Delaware rarely allow parties to bring motions for summary judgment, and (2) there appears little uniformity among Delaware’s judges as to whether the motions will be allowed.

### C. Summary Judgment Is Rare in the District of Delaware

¶28 One thing is apparent from the results of the empirical study: the four judges in the District of Delaware entertain few summary judgment motions in ANDA cases. From 2009–2013, litigants filed only seven motions for summary judgment before judges in the District of Delaware.<sup>91</sup> This may be because litigants know Delaware judges rarely entertain these motions or have realized that such motions are not successful in ANDA cases in the district. Of those seven motions, four were granted<sup>92</sup> and three were case

<sup>91</sup> *Summary Judgment Data for ANDA Cases 2009–2013, supra* Table I; see *Motion for Summary Judgment of Noninfringement by Upsher-Smith Labs. Inc., Auxilium Pharm. Inc. v. Upsher-Smith Labs. Inc.*, No. 13-148 (D. Del. Apr. 5, 2013); *Motion for Summary Judgment of Noninfringement by Alvogen Grp. Inc., Novartis Pharm. Corp. v. Alvogen Pine Brook Inc.*, No. 13-52 (D. Del. June 24, 2014); *Motion for Summary Judgment of Invalidity by Mylan Institutional Inc., Spectrum Pharm. Inc. v. InnoPharma Inc.*, No. 12-260 (D. Del. Oct. 17, 2014); *Motion for Partial Summary Judgment of Noninfringement by Actavis Mid Atlantic LLC, Medicis Pharm. Corp. v. Actavis Mid Atlantic LLC*, No. 11-409 (D. Del. Mar. 1, 2013); *Motion for Summary Judgment by Anchen Inc., Shire LLC v. Teva Pharm. USA Inc.*, No. 10-329 (D. Del. June 20, 2012); *Motion for Summary Judgment of Invalidity by Sandoz Inc., Wyeth Holdings Corp. v. Sandoz Inc.*, No. 09-955 (D. Del. Feb. 10, 2012); *Motion for Summary Judgment of Invalidity by Lupin Ltd., Abbott Labs. v. Lupin Ltd.*, No. 09-152 (D. Del. Mar. 25, 2011).

<sup>92</sup> *Auxilium Pharm. Inc. v. Upsher-Smith Labs. Inc.*, No. 13-148 (D. Del. Dec. 4, 2013) (order granting



dispositive.<sup>93</sup> In comparison, the District of New Jersey's judges entertained thirty-one motions and granted a third of those motions.<sup>94</sup> However, only one of those thirty-one motions was case dispositive.<sup>95</sup> Since 2009, there have been 678 ANDA cases filed in the District of Delaware and 481 filed in the District of New Jersey.<sup>96</sup> That means the District of New Jersey handles thirty percent fewer ANDA cases than Delaware<sup>97</sup> but entertains over four times the number of motions for summary judgment.<sup>98</sup> And while the District of New Jersey entertains over four times the number of summary judgment motions, its judges resolved fewer cases at summary judgment than Delaware's judges between 2009 and 2013.<sup>99</sup>

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In the District of Delaware, parties sometimes seek leave to file a motion for summary judgment. The requests, when made, are rarely granted. There were ten such requests for leave filed between 2009 and 2013,<sup>100</sup> but only one of those requests was

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motion for summary judgment of noninfringement); Spectrum Pharm. Inc. v. InnoPharma Inc., No. 12-260 (D. Del. Aug. 4, 2015) (order granting motions for summary judgment of noninfringement and invalidity); Novartis Pharm. Corp. v. Alvogen Pine Brook Inc., No. 13-52 (D. Del. June 24, 2014) (order granting defendants' motion for summary judgment); Abbott Labs. v. Lupin Ltd., No. 09-152 (D. Del. May 19, 2011) (order denying defendants' motion for summary judgment of invalidity and granting plaintiffs' motion for summary judgment of validity).

<sup>93</sup> Auxilium Pharm. Inc. v. Upsher-Smith Labs. Inc., No. 13-148 (D. Del. Dec. 30, 2013) (final judgment of noninfringement); Spectrum Pharm. Inc. v. InnoPharma Inc., No. 12-260 (D. Del. Aug. 4, 2015) (order directing clerk to close the case after holding the patents-in-suit invalid and not infringed); Novartis Pharm. Corp. v. Alvogen Pine Brook Inc., No. 13-52 (D. Del. July 7, 2014) (final judgment of noninfringement).

<sup>94</sup> *Summary Judgment Data for ANDA Cases 2009–2013*, *supra* Table I; *see* Noven Pharm. v. Watson Labs., Inc., No. 11-5997 (D.N.J. Nov. 26, 2013) (order granting defendants' motion for summary judgment of invalidity and noninfringement and denying plaintiff's cross-motion for summary judgment of validity); Shire LLC v. Amneal Pharm., LLC, No. 11-3781 (D.N.J. June 23, 2014) (order granting plaintiffs' motions for summary judgment in part and denying in part and granting defendants' motions for summary judgment in part and denying in part); Gilead Scis., Inc. v. Natco Pharm. Ltd., No. 11-1455 (D.N.J. Dec. 21, 2012) (order granting plaintiffs' motion for summary judgment); Braintree Labs., Inc. v. Novel Labs., Inc., No. 11-1341 (D.N.J. Jan. 18, 2013) (order granting plaintiff's motions for summary judgment and denying defendant's motion for summary judgment); Prometheus Labs. Inc. v. Roxane Labs., Inc., No. 11-1241 (D.N.J. Dec. 16, 2013) (same); Prometheus Labs. Inc. v. Roxane Labs., Inc., No. 11-230 (D.N.J. Dec. 16, 2013) (same); Janssen Prods., L.P. v. Lupin Ltd., No. 10-5954 (D.N.J. Mar. 12, 2014) (order granting in part and denying in part parties' motions for summary judgment); Merck Sharp & Dohme Corp. v. Mylan Pharm. Inc., No. 09-6383 (D.N.J. Aug. 22, 2011) (order granting in part and denying in part plaintiff's motions for summary judgment); Reckitt Benckiser Inc. v. Tris Pharma, Inc., No. 09-3125 (D.N.J. Dec. 21, 2011) (order granting defendant's motion for summary judgment); Sunovion Pharm. Inc. v. Teva Pharm. USA, Inc., No. 09-1302 (D.N.J. Jan. 1, 2013) (order granting defendants' motion for summary judgment).

<sup>95</sup> *See* Shire LLC v. Amneal Pharma., LLC, No. 11-3781 (D.N.J. July 21, 2014) (order of final judgment).

<sup>96</sup> Noonan, *supra* note 5.

<sup>97</sup> *See id.*

<sup>98</sup> *See Summary Judgment Data for ANDA Cases 2009–2013*, *supra* Table I.

<sup>99</sup> *See id.*

<sup>100</sup> *See* Letter from Defendants Requesting Summary Judgment Practice, Fresenius Kabi USA, LLC v. Watson Labs. Inc., No. 13-1015 (D. Del. Mar. 4, 2014); Letter from Defendants Requesting Summary Judgment Practice, Fresenius Kabi USA, LLC v. Dr. Reddy's Labs. Ltd., No. 13-925 (D. Del. Mar. 4, 2014); Letter from Defendants Requesting Summary Judgment Practice, Novartis Pharm. Corp. v. Noven Pharm. Inc., No. 13-527 (D. Del. Oct. 15, 2014); Motion for Leave to File a Summary Judgment Motion, Novartis Pharm. Corp. v. Alvogen Pine Brook Inc., No. 13-52 (D. Del. May 29, 2014); Letter from Defendants Requesting Leave to File a Summary Judgment Motion, Cubist Pharm., Inc. v. Hospira, Inc., No. 12-367 (D. Del. Oct. 8, 2013); Letter from Defendants Requesting Leave to File a Summary Judgment Motion, Allergan Inc. v. Akorn Inc., No. 11-1270 (D. Del. May 24, 2012); Letter from Defendants Requesting Leave to File a Summary Judgment Motion, Galderma Labs. Inc. v. Amneal Pharm. LLC, No. 11-1106 (D. Del. Apr. 17, 2012); Letter from Defendant Seeking Permission to File a Motion for Summary

granted.<sup>101</sup> For example, Chief Judge Stark denied every request for leave during that time period.<sup>102</sup> In fact, Judge Andrews was the only judge to grant a party's request for leave.<sup>103</sup> In comparison, there was only one request for leave to file a motion for summary judgment in New Jersey, and that request was granted.<sup>104</sup> This may be because the judges in New Jersey regularly entertain motions for summary judgment in ANDA cases, and thus, parties need not seek permission before filing.

#### *D. Delaware's Practice: Disjunctive or Consistent and Predictable?*

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The results from the empirical study show that the judges in the District of Delaware do entertain motions for summary judgment occasionally, but the decision to hear such a motion appears discretionary to each individual judge.<sup>105</sup> At first glance, the District of Delaware's practice may seem unpredictable and inconsistent. For example, Judge Sleet's patent scheduling order requires parties to seek permission before filing motions for summary judgment,<sup>106</sup> but Judge Sleet denied every request between 2009 and 2013.<sup>107</sup> In comparison, between 2009 and 2013, Chief Judge Stark did not grant a single request for leave, yet he entertained motions for summary judgment in two cases where the parties did not first request leave to file the motions.<sup>108</sup> Similarly, Judge Andrews granted only one request for leave<sup>109</sup> but heard four motions for summary judgment.<sup>110</sup> On the other hand,

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Judgment, *AbbVie Inc. v. Hospira Inc.*, No. 11-648 (D. Del. Jan. 4, 2013); Letter from Defendants Seeking Permission to File a Motion for Summary Judgment, *Endo Pharm. Inc. v. Mylan Techs. Inc.*, No. 11-220 (D. Del. Apr. 15, 2013); Letter from Defendant Requesting Leave to File a Motion for Summary Judgment, *Roche Palo Alto LLC v. Endo Pharm. Inc.*, No. 10-261 (D. Del. June 4, 2010).

<sup>101</sup> See *Novartis Pharm. Corp. v. Alvogen Pine Brook Inc.*, No. 13-52 (D. Del. June 24, 2014) (order granting defendants' motion for leave to file a motion for summary judgment). Again, this study only looked at formal requests for leave or requests made through letters written to the judge. Requests for leave can also come through the scheduling order. See, e.g., *AstraZeneca AV v. Aurobindo Pharma Ltd.*, No. 14-664 (D. Del. Oct. 17, 2014) (consolidated) (granting a request for leave via the parties' proposed scheduling order). Requests for leave through the scheduling order were not looked at in this study, so there may be additional requests and grants that were made via the Rule 16 conference and scheduling order.

<sup>102</sup> See *Allergan Inc. v. Akorn Inc.*, No. 11-1270 (D. Del. June 21, 2012) (denying defendants' request); *Galderma Labs. Inc. v. Amneal Pharm. LLC*, No. 11-1106 (D. Del. Apr. 23, 2012) (same).

<sup>103</sup> See *Novartis Pharm.*, No. 13-52 (order granting defendants' motion for leave).

<sup>104</sup> See *Sunovion Pharm. Inc. v. Teva Pharm. USA, Inc.*, No. 09-1302 (D.N.J. Oct. 1, 2011) (order granting request for leave to file summary judgment motions).

<sup>105</sup> See *Summary Judgment Data for ANDA Cases 2009 – 2013*, *supra* Table I.

<sup>106</sup> See *J. Sleet's Patent Scheduling Order*, *supra* note 75, at 4.

<sup>107</sup> See *Summary Judgment Data for ANDA Cases 2009 – 2013*, *supra* Table I; *Cubist Pharm., Inc. v. Hospira, Inc.*, No. 12-367 (D. Del. Jan. 15, 2014) (order denying defendant's letter request to file a motion for summary judgment); *AbbVie Inc. v. Hospira Inc.*, No. 11-648 (D. Del. Mar. 25, 2013) (oral order denying letter request for permission to file a motion for summary judgment); *Endo Pharm. Inc. v. Mylan Techs. Inc.*, No. 11-220 (D. Del. May 3, 2013) (order denying letter request seeking leave to move for summary judgment); *Roche Palo Alto LLC v. Endo Pharm. Inc.*, No. 10-261 (D. Del. Feb. 23, 2011) (stating that there will be no summary judgment practice during a telephone conference with the parties).

<sup>108</sup> See *Motion for Partial Summary Judgment of Noninfringement by Actavis Mid Atlantic LLC, Medicis Pharm. Corp. v. Actavis Mid Atlantic LLC*, No. 11-409 (D. Del. Mar. 1, 2013); *Motion for Summary Judgment of Invalidity by Lupin Ltd., Abbott Labs. v. Lupin Ltd.*, No. 09-152 (D. Del. Mar. 25, 2011). The author recognizes that the parties may have requested leave through the Rule 16 conference and scheduling order, but no such request was present on the either case's docket sheet.

<sup>109</sup> See *Novartis Pharm. Corp. v. Alvogen Pine Brook Inc.*, No. 13-52 (D. Del. June 24, 2014) (order granting defendants' motion for leave to file a motion for summary judgment).

<sup>110</sup> See *Motion for Summary Judgment of Noninfringement by Alvogen Grp. Inc., Novartis Pharm.*

in the only case where Judge Robinson granted a party's request for leave, she also granted that same party's motion for summary judgment.<sup>111</sup> The results displayed in Chart II further illustrate that the practices in the District of Delaware are "courtroom specific."<sup>112</sup>

¶31 The District of Delaware's practice may seem inconsistent and discretionary, but Delaware's practice is actually quite uniform. While each judge has discretion over whether he or she will entertain a motion for summary judgment or a request for leave to file such a motion in an ANDA case, the four Article III judges are surprisingly consistent in how they handle summary judgment motions. The results of the empirical study show that, overall, the District of Delaware's judges entertain very few requests for leave and motions for summary judgment.<sup>113</sup> This practice is consistent across each of Delaware's four Article III judges. Therefore, the District of Delaware's tendency to exclude summary judgment practice in ANDA cases is actually consistent across the district. This gives parties predictability.

#### IV. NO NEED FOR DELAWARE TO CHANGE ITS PROCEDURES IN ANDA CASES

¶32 Notwithstanding the variations among the judges' standing orders, the investigation into the District of Delaware's practice and the empirical study highlights the remarkable consistency between the judges in Delaware in granting—or even hearing—summary judgment motions in ANDA cases. There are certainly differences in the judges' standing orders and summary judgment may not be an option for parties in ANDA cases in the District of Delaware, but litigants know what to expect in each judge's courtroom based on their detailed standing orders and overall preference for no summary judgment motion practice. The District of Delaware does not need to adopt uniform local patent rules or specific Hatch-Waxman provisions as the District of New Jersey has done. Delaware could be more receptive to summary judgment motions, but its current practice is efficient in moving ANDA cases to trial, which are ultimately bench trials before the judge. However, the District of Delaware could benefit by requiring early disclosure of the ANDA in these cases.

##### A. *The Purpose and Benefit of Local Patent Rules*

¶33 Patent litigation imposes a number of additional "substantive, procedural, and administrative challenges" on tribunals due to the highly technical and complex nature of the subject matter.<sup>114</sup> Former Chief Judge Rader of the U.S. Court of Appeals for the Federal Circuit acknowledged "that one of the greatest challenges in patent law is 'the

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Corp. v. Alvogen Pine Brook Inc., No. 13-52 (D. Del. June 24, 2014); Motion for Summary Judgment of Invalidity by Mylan Institutional Inc., Spectrum Pharm. Inc. v. InnoPharma Inc., No. 12-260 (D. Del. Oct. 17, 2014); Motion for Summary Judgment by Anchen Inc., Shire LLC v. Teva Pharm. USA Inc., No. 10-329 (D. Del. June 20, 2012); Motion for Summary Judgment of Invalidity by Sandoz Inc., Wyeth Holdings Corp. v. Sandoz Inc., No. 09-955 (D. Del. Feb. 10, 2012).

<sup>111</sup> See *Auxilium Pharm. Inc. v. Upsher-Smith Labs. Inc.*, No. 13-148 (D. Del. Dec. 4, 2013) (order granting motion for summary judgment of noninfringement).

<sup>112</sup> See *Summary Judgment Data for ANDA Cases 2009 – 2013*, *supra* Chart II.

<sup>113</sup> See *Summary Judgment Data for ANDA Cases 2009 – 2013*, *supra* Table I.

<sup>114</sup> Pauline M. Pelletier, *The Impact of Local Patent Rules on Rate and Timing of Case Resolution Relative to Claim Construction: An Empirical Study of the Past Decade*, 8 J. BUS. & TECH. L. 451, 453 (2013).

expense and delay of the litigation system.”<sup>115</sup> However, the complex issues in patent litigation can usually be narrowed to a short, critical list of case dispositive issues, such as whether a patent claim is valid or whether the ANDA filer’s drug infringes the claim.<sup>116</sup> Thus, narrowing these issues early on in litigation reduces the complexity of the case.<sup>117</sup>

¶34 Local patent rules can assist with narrowing complex patent infringement claims. Such rules usually require patentees to serve and disclose to the alleged infringers their asserted claims and infringement contentions.<sup>118</sup> These disclosures are typically in the form of charts whereby the patentee compares its patent in detail — “claim-by-claim, element-by-element” — with the alleged infringer(s)’s product(s).<sup>119</sup> Normal procedural rules may be insufficient to handle complex patent litigation cases. For example, if a patentee brings an infringement suit for its complicated patent containing fifty claims, the defendant’s attorney—even if very knowledgeable in the specific art—“would have a difficult time defending his client if the [patentee’s] attorney only made ‘a short and plain statement of the claim showing that the pleader is entitled to relief.’”<sup>120</sup> Further, without clear and organized contentions presented by the parties, it is difficult for a judge and jury<sup>121</sup>—who do not have a background in the technology—to understand the important issues.<sup>122</sup>

¶35 Along with reducing the complexity of patent cases, another major benefit of local patent rules can be a quicker resolution of patent cases.<sup>123</sup> Patent rules can affect the timing of a case, as well as the outcome.<sup>124</sup> Uniform rules can lead to fairly standard case management within a district, relatively predictable case timelines, and overall “increased efficiency.”<sup>125</sup>

¶36 ANDA cases are unique from other forms of patent litigation. ANDA litigation begins when a generic files a Paragraph IV certification in its ANDA arguing that the patent is invalid, not infringed, or otherwise unenforceable.<sup>126</sup> The patent holder, usually a brand-name drug company, can then bring suit against the generic after the generic files the Paragraph IV certification because filing a Paragraph IV certification is a statutory-based

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<sup>115</sup> *Id.* at 462 (citations omitted).

<sup>116</sup> *See id.*

<sup>117</sup> Patent litigation issues do not become simple merely by narrowing the issues. The subject matter remains highly technical, though there remain fewer case dispositive issues. For example, a pharmaceutical patent may contain fifty claims, but judgment may turn on whether just one of those claims is valid. Thus, by narrowing the issues in the case to whether that one claim is valid, the litigation becomes more focused.

<sup>118</sup> Megan Woodhouse, *Shop ‘Til You Drop: Implementing Federal Rules of Patent Litigation Procedure to Wear Out Forum Shopping Patent Plaintiffs*, 99 GEO. L.J. 227, 248 (2010).

<sup>119</sup> *See id.* The patentee’s chart includes two columns. *Id.* The first column lists the asserted claim of the patent and separates the claim’s elements by rows, “and the second column [compares] specific information regarding the defendant’s product that allegedly infringes the elements of the [] patent.” *Id.* Patentees must also provide “the details regarding the legal theories [they] are using to assert the claims in the patent.” *Id.*

<sup>120</sup> *Id.* 247–28 (quoting FED. R. CIV. P. 8(a)(2)).

<sup>121</sup> While there are no juries in ANDA cases, there can be juries in other patent litigation suits. *See Coggio et al., supra note 42, at 767.*

<sup>122</sup> Woodhouse, *supra note 118, at 248.*

<sup>123</sup> *See Pelletier, supra note 114, at 463; Woodhouse, supra note 118, at 252–53.*

<sup>124</sup> *See Jensen, supra note 47.*

<sup>125</sup> Pelletier, *supra note 114, at 463.* When case schedules are predictable, attorneys can better estimate and stick to their clients’ case budgets. *See Gollwitzer, supra note 47, at 94.*

<sup>126</sup> *See 2014 Patent Litigation Study, supra note 33, at 20.*

act of infringement.<sup>127</sup> Frequently, the critical issue is whether the patent(s) on which the generic seeks to market its generic equivalent is valid.<sup>128</sup> Additionally, because the Hatch-Waxman Act requires all Paragraph IV ANDA filers to provide notice to the challenged patent holder, which “include[s] a detailed statement of the factual and legal basis” of why the applicant believes “that the patent is invalid or will not be infringed,” the ANDA filer is not in the same position as an accused infringer in a normal patent infringement action before litigation commences.<sup>129</sup> Instead, the ANDA filer is well aware of the risks associated with filing a Paragraph IV certification before it files the ANDA and has already established its noninfringement or invalidity position before the patentee files suit.<sup>130</sup>

### 1. Local Patent Rules Are Not Necessary in Delaware

¶37 It is no secret that the District of Delaware’s four Article III judges have extensive patent experience and are some of the most experienced in the country in handling patent infringement cases.<sup>131</sup> The District of Delaware leads all other district courts with the most patent case filings per *judge*, which results in an experienced bench.<sup>132</sup> In fact, Judge Andrews, Judge Robinson, Judge Sleet, and Chief Judge Stark are among the U.S. district court judges who hear the most patent cases,<sup>133</sup> and they are the four judges that hear the most ANDA cases in the country.<sup>134</sup> And when it comes to patent litigation, “[e]xperience leads to efficiency, uniformity, and better case management.”<sup>135</sup> All four Article III judges in the District of Delaware are extremely experienced and knowledgeable in patent issues despite the district’s lack of uniform patent rules. Unlike judges who “lack[] prior patent litigation experience [and] would benefit from patent trial rules,”<sup>136</sup> Delaware’s judges have extensive experience and it may be superfluous for Delaware to adopt uniform local patent rules.

¶38 The District of Delaware’s lack of local patent rules does not seem to have affected the district’s case efficiency or time-to-trial.<sup>137</sup> Research “suggests that districts with local

<sup>127</sup> See 35 U.S.C. § 271(e)(2)(A) (2015); 21 U.S.C. § 355(j)(5)(B)(iii) (2015).

<sup>128</sup> See *2014 Patent Litigation Study*, *supra* note 33, at 20.

<sup>129</sup> 21 U.S.C. § 355(j)(2)(B)(iv)(II).

<sup>130</sup> See *id.*

<sup>131</sup> See *Comparison of the Most Popular Patent Venues*, *supra* note 58.

<sup>132</sup> See *id.* The most patent cases are filed in the Eastern District of Texas, and the District of Delaware has the second most filings. *Patent Litigation Statistics*, IP LAW ALERT, <http://iplawalert.wp.lexblogs.com/wp-content/uploads/sites/242/2014/03/Patent-Litigation-Research.pdf> (last visited Mar. 13, 2016) [<https://perma.cc/4S3D-6V8L>]. These two districts “have nearly three times the number of patent cases as the third busiest district, the Central District of California.” Charles H. Chevalier et al., *New Patent Case Scheduling Order Seeks to Achieve Efficiencies in Delaware*, IP LAW ALERT (Mar. 26, 2014), <http://www.iplawalert.com/2014/03/articles/patent/new-patent-case-scheduling-order-seeks-to-achieve-efficiencies-in-delaware/> [<https://perma.cc/KU4Z-XNGK>]. However, the District of Delaware has only four district court judges in comparison to eight in the Eastern District of Texas, *Judges*, U.S. DISTRICT CT. E. DISTRICT TEX., <http://www.txed.uscourts.gov/page1.shtml?location=info> (last visited Mar. 13, 2016) [<https://perma.cc/99M3-HFND>], and therefore has the most patent case filings per judge.

<sup>133</sup> See *Patent Litigation Statistics*, *supra* note 132; see also *2014 Patent Litigation Study*, *supra* note 33, at 22.

<sup>134</sup> Noonan, *supra* note 5.

<sup>135</sup> Woodhouse, *supra* note 118, at 252.

<sup>136</sup> *Id.* at 247.

<sup>137</sup> See *2013 Patent Litigation Study*, *supra* note 45, at 30.

patent rules process patent cases faster than districts lacking such rules.”<sup>138</sup> However, this research is not dispositive.<sup>139</sup> Additionally, experienced judges can resolve cases more quickly.<sup>140</sup> The District of Delaware has an overall faster time-to-trial—time from the day the complaint is filed to the first day of trial—than the District of New Jersey for patent cases that do not settle.<sup>141</sup> While local patent rules can decrease the time-to-trial, Delaware’s experienced bench is efficient in resolving patent disputes.

¶39 Uniform local patent rules could still benefit Delaware’s experienced bench. Although the District of Delaware’s judges are among the most knowledgeable in patent issues, including ANDA cases, it may appear there is no uniformity among the judges. Each judge has different standing orders that apply to cases in his or her courtroom,<sup>142</sup> and the procedures governing ANDA cases in the District of Delaware are “courtroom specific” and vary among the individual judges.<sup>143</sup> Uniform local patent rules can increase judicial efficiency for inexperienced and experienced judges alike.<sup>144</sup> Local patent rules could only improve the district’s efficiency in handling patent cases. However, because the District of Delaware has only four Article III judges—all of whom are extremely knowledgeable in patent issues—and patent litigation in that district is already more efficient than in other districts that have adopted local patent rules, it is probably not necessary for the District of Delaware to adopt local patent rules.<sup>145</sup>

¶40 Even if the District of Delaware adopted local patent rules, thereby increasing uniformity across its bench, that would not create uniformity among all patent litigation, or more specifically, among ANDA litigation, in the United States. While many district courts have adopted uniform local patent rules, those rules only apply to that specific district.<sup>146</sup> Local patent rules vary widely among the twenty-four districts that have formally adopted them.<sup>147</sup> This disunity can “yield legal clutter, undue complexity, and unfairness” across patent litigation.<sup>148</sup>

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<sup>138</sup> Gollwitzer, *supra* note 47, at 95 (discussing a study by LegalMetric that found “in districts adopting local patent rules, the average time patent cases were pending decreased by 2 1/2 months when compared to the average time pending prior to adopting the rules”).

<sup>139</sup> *See id.* (noting that “[t]he two most notable patent ‘rocket-dockets,’ the Eastern District of Virginia and the Western District of Wisconsin, have not adopted local patent rules”).

<sup>140</sup> *See* Woodhouse, *supra* note 118, at 244 (“Experienced judges would be more familiar with the stages of patent litigation, and trials would be faster.”).

<sup>141</sup> *See 2013 Patent Litigation Study*, *supra* note 45, at 30. These statistics are not specific to ANDA litigation but instead are general statistics of patent litigation in those districts. *See id.*

<sup>142</sup> *See Standing Orders*, *supra* note 55.

<sup>143</sup> *See e.g., Chief J. Stark’s ANDA Patent Scheduling Order*, *supra* note 61; *J. Robinson’s Patent Scheduling Order*, *supra* note 61; *J. Sleet’s Patent Scheduling Order*, *supra* note 75; *J. Andrews’s Patent Scheduling Order*, *supra* note 78.

<sup>144</sup> *See* Woodhouse, *supra* note 118, at 252–53.

<sup>145</sup> Adding local patent rules certainly would not hurt the district, but the district may not see much benefit from adopting such rules. Local patent rules are designed to help judges inexperienced in patent issues, *see id.*, and that certainly is not the case on the District of Delaware’s bench.

<sup>146</sup> *See* Pelletier, *supra* note 114, at 464.

<sup>147</sup> *See id.*

<sup>148</sup> *Id.*

## 2. The Benefits of Early Disclosure in ANDA Cases

¶41 While the District of Delaware does not *need* local patent rules, it could consider requiring generics to disclose the ANDA submitted to the FDA earlier in the litigation. The Hatch-Waxman Act only requires that the ANDA filer give notice to the patentee when it files a Paragraph IV certification in its ANDA.<sup>149</sup> This notice does not require the generic to disclose the contents of its ANDA, but need only “include a detailed statement of the factual and legal basis” of why the applicant believes “that the patent is invalid or will not be infringed.”<sup>150</sup> Patent rules that require parties to make disclosures early on in the litigation “enhances the transparency, organization, and accuracy of the patent litigation process.”<sup>151</sup> This is especially true in ANDA cases where the generic has already submitted a Paragraph IV certification to the FDA in its ANDA.

¶42 Prior to litigation, as required under the Hatch-Waxman Act, the ANDA filer has already made certain contentions to the FDA in its Paragraph IV certification as to why the patent is invalid or not infringed<sup>152</sup> and has provided notice to the patent holder of its factual and legal theories behind its Paragraph IV certification.<sup>153</sup> The patent holder has forty-five days to review the Paragraph IV certification before initiating an infringement suit.<sup>154</sup> This puts the ANDA filer in a unique position before litigation commences and even before filing its ANDA. By filing a Paragraph IV certification, the generic essentially asserts: (1) that it has reviewed the patent(s), (2) that it believes the patent(s) is invalid or not infringed by the generic’s drug, and (3) that it has researched the legal theories to support its position. Requiring the ANDA filer to disclose the ANDA earlier in litigation, such as when it files its answer, could increase transparency in the litigation since the ANDA filer is uniquely situated and has already provided the FDA with substantially relevant information in its ANDA, specifically, in its Paragraph IV certification.

¶43 The District of New Jersey has recognized this unique position ANDA litigants stand in before litigation commences and has adopted unique early disclosure requirements that apply specifically to ANDA cases. In 2010, New Jersey amended its local patent rules to include specific disclosure provisions that govern all patents challenged by a Paragraph IV certification in cases arising under the Hatch-Waxman Act.<sup>155</sup> The amendments impose certain early disclosure requirements on both the party alleging patent infringement and the ANDA filer.<sup>156</sup> Of particular importance is the amendment relating to early disclosure of the ANDA.<sup>157</sup> The ANDA filer must produce the complete ANDA with its answer or motion in response to the complaint,<sup>158</sup> disclose its noninfringement and invalidity contentions for any patents referred to in its Paragraph IV certification within fourteen days

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<sup>149</sup> See 21 U.S.C. § 355(j)(2)(B)(iv)(II) (2015).

<sup>150</sup> *Id.*

<sup>151</sup> See Woodhouse, *supra* note 118, at 248.

<sup>152</sup> See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

<sup>153</sup> See *id.* § 355(j)(2)(B)(iv)(II).

<sup>154</sup> See *id.* § 355(j)(5)(B)(iii).

<sup>155</sup> See D.N.J. L. PAT. R. 3.6.

<sup>156</sup> See *id.*

<sup>157</sup> See *id.* 3.6(a).

<sup>158</sup> See *id.* 3.6(a) (“On the date a party answers, moves, or otherwise responds, each party who is an ANDA filer shall produce to each party asserting patent infringement the entire Abbreviated New Drug Application or New Drug Application that is the basis of the case in question.”).

after the initial Scheduling Conference,<sup>159</sup> produce all FDA communications pertaining to the ANDA, and inform the FDA of any injunctions and motions in the case.<sup>160</sup>

¶44 Due to the unique information the defendant in ANDA litigation acquires before commencement of the suit, it is fair to require that party—the ANDA filer—to make these early disclosures to the plaintiff. The ANDA filer has already made contentions in its Paragraph IV certification and argued why the patent is invalid or not infringed,<sup>161</sup> and the patentee has decided to refute those contentions. Like the District of New Jersey, the District of Delaware should consider adopting similar early disclosure rules that require the ANDA filer to (1) produce the complete ANDA with its answer or motion in response to the complaint, (2) disclose its invalidity and non-infringement contentions first, and (3) produce all FDA communications.<sup>162</sup>

### B. *Is Summary Judgment Proper in ANDA Litigation?*

¶45 Along with the District of Delaware’s predictable procedure governing ANDA cases, the district’s summary judgment practice is efficient and consistent with the Hatch-Waxman’s purpose and policies. The District of Delaware rarely allows parties to bring a summary judgment motion in ANDA cases. While the Federal Rules of Civil Procedure explicitly permits parties to move for summary judgment,<sup>163</sup> there is usually a question of fact in ANDA cases that should be decided at trial, not at summary judgment.<sup>164</sup>

#### 1. Summary Judgment Motions Are Not Necessary in ANDA Cases

¶46 Summary judgment motions are proper when “the movant shows that there is no genuine dispute as to any material fact.”<sup>165</sup> Patent cases frequently involve a disagreement over the facts, which is why “[i]t can be a significant waste of time and money to bring a

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<sup>159</sup> See *id.* 3.6(c) (“Not more than 14 days after the initial Scheduling Conference, each party opposing an assertion of patent infringement shall provide to each party asserting patent infringement the written basis for its ‘Invalidity Contentions,’ for all patents referred to in the opposing party’s Paragraph IV Certification . . . .”); *id.* 3.6(e) (“Not more than 14 days after the initial Scheduling Conference, each party opposing an assertion of patent infringement shall provide to each party asserting patent infringement the written basis for its ‘Non-Infringement Contentions,’ for any patents referred to in the opposing party’s Paragraph IV Certification which shall include a claim chart identifying each claim at issue in the case and each limitation of each claim at issue.”).

<sup>160</sup> See *id.* 3.6(j) (“Each party that has an ANDA application pending with the Food and Drug Administration (“FDA”) that is the basis of the pending case shall: (1) notify the FDA of any and all motions for injunctive relief no later than three business days after the date on which such a motion is filed; and (2) provide a copy of all correspondence between itself and the FDA pertaining to the ANDA application to each party asserting infringement . . . .”).

<sup>161</sup> See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2015); see also *Comparison of the Most Popular Patent Venues*, *supra* note 58 (recognizing that “[b]ecause of the triggers built into the [A]ct, . . . the potential defendant knows the patents that will be asserted, the identity of the plaintiff, and the time frame for filing the complaint”).

<sup>162</sup> This would benefit the patentee because he would receive the ANDA filer’s ANDA and noninfringement and invalidity contentions before having to narrow his claims asserted and infringement contentions.

<sup>163</sup> See FED. R. CIV. P. 56.

<sup>164</sup> Sara Stefanini, *Judges’ Top Four Pet Peeves in Patent Litigation*, LAW360 (May 1, 2008), <http://www.law360.com/articles/54905/judges-top-four-pet-peeves-in-patent-litigation> [<https://perma.cc/7XWF-FT2Q>].

<sup>165</sup> FED. R. CIV. P. 56(a).



summary judgment motion.”<sup>166</sup> Former Judge Joseph J. Farnan of the District of Delaware believes 90–95% of the time there is a dispute of facts, and thus summary judgment is improper in ANDA cases.<sup>167</sup> Delaware’s Judge Sleet has stated that summary judgment motions are unnecessary in ANDA cases, explaining that both parties usually “have experts who are ready, willing and able to come to court and dispute the facts . . . .”<sup>168</sup> He has asserted that in ANDA cases, a generic is usually attacking a patent for invalidly or noninfringement, which almost always involves a dispute of facts.<sup>169</sup> Judge Sleet believes ANDA cases are more effectively decided after hearing all the arguments, rather than at summary judgment.<sup>170</sup> Since the resolution of many patent cases turns on a question of fact, summary judgment may be unnecessary in most ANDA cases.

¶47

The data from the empirical study is illustrative of how few ANDA cases are resolved at summary judgment. From 2009–2013, the District of New Jersey entertained thirty-one motions for summary judgment and granted ten of those motions.<sup>171</sup> Two-thirds of those motions were denied, and only one of those thirty-one motions was case dispositive.<sup>172</sup> That means that in the cases where a party moved for summary judgment in the District of New Jersey, ninety-seven percent of those cases were not resolved at summary judgment and continued towards trial. In comparison, the District of Delaware entertained two-thirds

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<sup>166</sup> Stefanini, *supra* note 164 (quoting Delaware’s former Chief Judge Sleet).

<sup>167</sup> *See id.*

<sup>168</sup> *Id.*

<sup>169</sup> *See id.*

<sup>170</sup> *See id.* Judge Sleet’s procedures reflect his viewpoint on summary judgment motions in ANDA cases. For example, he requires parties to ask permission before filing a motion for summary judgment “[t]o clamp down on filing that will undoubtedly lack merit in [ANDA] cases . . . .” *Id.*; *see J. Sleet’s Patent Scheduling Order, supra* note 75. When a party seeks permission, Judge Sleet allows both parties to argue their positions to him via teleconference. *See* Stefanini, *supra* note 164. However, he has started taking the teleconferences off the case schedule and simply denying the requests generally because the facts are usually disputed. *See id.*

<sup>171</sup> *See Summary Judgment Data for ANDA Cases 2009–2013, supra* Table I; *Noven Pharm. v. Watson Labs., Inc.*, No. 11-5997 (D.N.J. Nov. 26, 2013) (order granting defendants’ motion for summary judgment of invalidity and noninfringement and denying plaintiff’s cross-motion for summary judgment of validity); *Shire LLC v. Amneal Pharm., LLC*, No. 11-3781 (D.N.J. June 23, 2014) (order granting plaintiffs’ motions for summary judgment in part and denying in part and granting defendants’ motions for summary judgment in part and denying in part); *Gilead Scis., Inc. v. Natco Pharm. Ltd.*, No. 11-1455 (D.N.J. Dec. 21, 2012) (order granting plaintiffs’ motion for summary judgment); *Braintree Labs., Inc. v. Novel Labs., Inc.*, No. 11-1341 (D.N.J. Jan. 18, 2013) (order granting plaintiff’s motions for summary judgment and denying defendant’s motion for summary judgment); *Prometheus Labs. Inc. v. Roxane Labs., Inc.*, No. 11-1241 (D.N.J. Dec. 16, 2013) (same); *Prometheus Labs. Inc. v. Roxane Labs., Inc.*, No. 11-230 (D.N.J. Dec. 16, 2013) (same); *Janssen Prods., L.P. v. Lupin Ltd.*, No. 10-5954 (D.N.J. Mar. 12, 2014) (order granting in part and denying in part parties’ motions for summary judgment); *Merck Sharp & Dohme Corp. v. Mylan Pharm. Inc.*, No. 09-6383 (D.N.J. Aug. 22, 2011) (order granting in part and denying in part plaintiff’s motions for summary judgment); *Reckitt Benckiser Inc. v. Tris Pharma, Inc.*, No. 09-3125 (D.N.J. Dec. 21, 2011) (order granting defendant’s motion for summary judgment); *Sunovion Pharm. Inc. v. Teva Pharm. USA, Inc.*, No. 09-1302 (D.N.J. Jan. 1, 2013) (order granting defendants’ motion for summary judgment).

<sup>172</sup> *See Shire LLC v. Amneal Pharm., LLC*, No. 11-3781 (D.N.J. July 21, 2014) (order of final judgment).

fewer summary judgment motions than New Jersey<sup>173</sup> but resolved three times the number of cases at summary judgment.<sup>174</sup>

¶48 If a case ultimately involves a question of fact, the case proceeds more quickly to trial by skipping the summary judgment stage. When a party or parties move for summary judgment, there are usually lengthy motions and briefing by both parties on the issues.<sup>175</sup> This is burdensome on litigants and the court—in terms of resources, cost, and time—if the case ultimately comes down to a question of fact that must be decided at trial.<sup>176</sup> In other patent litigation disputes, parties may see summary judgment as the last opportunity to have the judge decide and resolve the case before it goes to an unpredictable jury.<sup>177</sup> However, since ANDA cases are bench trials, the judge ultimately decides all issues at trial. The risk of leaving those issues to an unpredictable jury if the case is not resolved at summary judgment is not present in ANDA cases. If the judge is going to decide the case anyway, then why not skip the lengthy summary judgment briefing and just have a trial?

¶49 The District of Delaware does not entertain many motions for summary judgment, but that district does have an overall faster time-to-trial than the District of New Jersey in patent litigation.<sup>178</sup> When Delaware’s four Article III judges skip the summary judgment stage in ANDA cases altogether, the court does not waste time and resources on hearing issues that the judge will ultimately need to decide at trial. Further, Delaware’s bench is experienced and knowledgeable in patent issues, and specifically in ANDA issues, and those judges are the ultimate decision makers at trial.<sup>179</sup> The District of Delaware’s summary judgment practice in ANDA cases may be more efficient because then the judges

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<sup>173</sup> See *Summary Judgment Data for ANDA Cases 2009–2013*, *supra* Table I; Motion for Summary Judgment of Noninfringement by Upsher-Smith Labs. Inc., Auxilium Pharm. Inc. v. Upsher-Smith Labs. Inc., No. 13-148 (D. Del. Apr. 5, 2013); Motion for Summary Judgment of Noninfringement by Alvogen Grp. Inc., Novartis Pharm. Corp. v. Alvogen Pine Brook Inc., No. 13-52 (D. Del. June 24, 2014); Motion for Summary Judgment of Invalidity by Mylan Institutional Inc., Spectrum Pharm. Inc. v. InnoPharma Inc., No. 12-260 (D. Del. Oct. 17, 2014); Motion for Partial Summary Judgment of Noninfringement by Actavis Mid Atlantic LLC, Medicis Pharm. Corp. v. Actavis Mid Atlantic LLC, No. 11-409 (D. Del. Mar. 1, 2013); Motion for Summary Judgment by Anchen Inc., Shire LLC v. Teva Pharm. USA Inc., No. 10-329 (D. Del. June 20, 2012); Motion for Summary Judgment of Invalidity by Sandoz Inc., Wyeth Holdings Corp. v. Sandoz Inc., No. 09-955 (D. Del. Feb. 10, 2012); Motion for Summary Judgment of Invalidity by Lupin Ltd., Abbott Labs. v. Lupin Ltd., No. 09-152 (D. Del. Mar. 25, 2011).

<sup>174</sup> See *Auxilium Pharm. Inc. v. Upsher-Smith Labs. Inc.*, No. 13-148 (D. Del. Dec. 30, 2013) (final judgment of noninfringement); *Spectrum Pharm. Inc. v. InnoPharma Inc.*, No. 12-260 (D. Del. Aug. 4, 2015) (order directing clerk to close the case after holding the patents-in-suit invalid and not infringed); *Novartis Pharm. Corp. v. Alvogen Pine Brook Inc.*, No. 13-52 (D. Del. July 7, 2014) (final judgment of noninfringement).

<sup>175</sup> See D. Theodore Rave, *Questioning the Efficiency of Summary Judgment*, 81 N.Y.U. L. REV. 875, 894 (2006) (discussing how “the parties have an incentive to engage the merits of the case with full briefing and presentation of evidence—in essence, a dress rehearsal of the trial”).

<sup>176</sup> See *id.* at 876 (“Modern summary judgment, however, is a frequently used motion that is costly to oppose and, if not granted often enough, may be a net drain on society.”)

<sup>177</sup> See Jennifer F. Miller, *Should Juries Hear Complex Patent Cases?*, 4 DUKE L. & TECH. REV. 1, 32 (2004) (discussing the concerns that decisions by juries in complex patent cases “are arbitrary, unpredictable, and based on considerations other than the relevant law”); *but see* Michael J. Mazzeo et al., *Explaining the “Unpredictable”: An Empirical Analysis of U.S. Patent Infringement Awards*, 35 INT’L REV. L. & ECON. 58, 69 (presenting an empirical study showing the fear and concern of unpredictable patent infringement awards by juries may be unfounded).

<sup>178</sup> See *2013 Patent Litigation Study*, *supra* note 45, at 30.

<sup>179</sup> See *Comparison of the Most Popular Patent Venues*, *supra* note 58; *see also Patent Litigation Statistics*, *supra* note 132; Chevalier et al., *supra* note 132.

do not waste time hearing and ruling on ultimately pointless summary judgment motions that they will ultimately have to decide at trial.

¶150 However, summary judgment can be practical in some ANDA cases. While Hatch-Waxman cases commonly involve questions of fact, there are situations in which there is no dispute of fact. Of the seven motions for summary judgment filed between 2009 and 2013 in the District of Delaware, over half of those motions were granted.<sup>180</sup> Those motions could not have been granted if there was a “genuine dispute as to any material fact.”<sup>181</sup>

## 2. Delaware’s Practice Is Consistent with the Purpose of the Hatch-Waxman Act

¶151 The District of Delaware’s practice does not undermine the goal of the Hatch-Waxman Act: to get non-infringing, low-cost generic equivalents on the market faster.<sup>182</sup> Commencement of ANDA litigation halts the FDA’s approval process until resolution of the case, and this stay can last up to thirty months.<sup>183</sup> With little to no chance of being able to bring a summary judgment motion and dispose of the case before trial, it may seem like the District of Delaware’s practice is contrary to the purpose of the Hatch-Waxman Act. However, bypassing the summary judgment stage for ANDA cases may increase case efficiency and quicken the time-to-trial if most ANDA cases ultimately come down to a question of fact. When ANDA litigation is resolved more quickly, the generic drugs subject to litigation are put in the hands of American consumers more quickly.

## CONCLUSION

¶152 ANDA litigation is on the rise. The number of ANDA cases filed increases each year,<sup>184</sup> and “the number of court decisions from ANDA litigation has grown substantially . . . .”<sup>185</sup> Since the District of Delaware hears the most ANDA cases of any district court, its local rules and summary judgment practice affects a substantial amount of ANDA litigation. Thus, the District of Delaware’s procedures can affect more than just the ANDA parties before the court; it can have a dramatic effect on the entire pharmaceutical industry.

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<sup>180</sup> See *Auxilium Pharm. Inc. v. Upsher-Smith Labs. Inc.*, No. 13-148 (D. Del. Dec. 4, 2013) (order granting motion for summary judgment of noninfringement); *Spectrum Pharm. Inc. v. InnoPharma Inc.*, No. 12-260 (D. Del. Aug. 4, 2015) (order granting motions for summary judgment of noninfringement and invalidity); *Novartis Pharm. Corp. v. Alvogen Pine Brook Inc.*, No. 13-52 (D. Del. June 24, 2014) (order granting defendants’ motion for summary judgment); *Abbott Labs. v. Lupin Ltd.*, No. 09-152 (D. Del. May 19, 2011) (order denying defendants’ motion for summary judgment of invalidity and granting plaintiffs’ motion for summary judgment of validity).

<sup>181</sup> See FED. R. CIV. P. 56(a).

<sup>182</sup> See H.R. REP. NO. 98-857, pt. 1, at 14 (1984) (“The purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962.”); Avery, *supra* note 8, at 172.

<sup>183</sup> See 21 U.S.C. § 355(j)(5)(B)(iii) (2015).

<sup>184</sup> See Howard, *supra* note 5, at 13 (noting that “ANDA case filings have risen slightly in 2014”). This trend is “consistent with the upward trend of overall patent litigation . . . .” *2014 Patent Litigation Study*, *supra* note 33, at 20.

<sup>185</sup> *2014 Patent Litigation Study*, *supra* note 33, at 20. Courts handed down an average of eighteen ANDA decisions per year from 2010 to 2013 as compared to only eight decisions per year from 2005 to 2009. *Id.* That is a 225% increase in decisions in just four years! See *id.*

The district's procedures and summary judgment practice does not delay consumer access to affordable generic drugs.

¶53 The District of Delaware does not need to adopt local patent rules because its four Article III judges are already knowledgeable and efficient in handling ANDA cases. While procedures governing ANDA cases vary between Delaware's four Article III judges, once a litigant knows which judge his or her case is before, the case schedule is predictable. However, due to the unique information the defendant in ANDA litigation acquires before litigation commences, the District of Delaware could consider adopting early disclosure provisions that require that party—the ANDA filer—to (1) produce the complete ANDA with its answer or motion in response to the complaint, (2) disclose its invalidity and noninfringement contentions first, and (3) produce all FDA communications.

¶54 The District of Delaware should continue with its practice of only hearing summary judgment motions in the exceptional case because most ANDA cases involve questions of fact. If a party brings a summary judgment motion, it can be a waste of court resources and time when the motion is eventually denied and the case progresses towards trial. By skipping summary judgment, ANDA cases proceed more quickly to trial where ultimately a judge, and not a jury, will decide the issues. The District of Delaware's judges are efficient in handling and resolving ANDA cases, so this practice does not keep those low-cost alternatives off the shelf and out of reach of American consumers.

**APPENDIX A: Empirical Study Data****Table II. Delaware Cases Used in the Empirical Study**

<b>Parties</b>	<b>Docket Number</b>	<b>Date Filed</b>
Fresenius Kabi USA LLC v. Watson Labs. Inc.	No. 13-1015	June 6, 2013
Fresenius Kabi USA LLC v. Dr. Reddy's Labs. Ltd.	No. 13-925	May 23, 2013
Novartis Pharm. Corp. v. Noven Pharm. Inc.	No. 13-527	Apr. 3, 2013
Auxilium Pharm. Inc. v. Upsher-Smith Labs. Inc.	No. 13-148	Jan. 28, 2013
Novartis Pharm. Corp. v. Alvogen Pine Brook Inc.	No. 13-52	Jan. 4, 2013
Cubist Pharm. Inc. v. Hospira Inc.	No. 12-367	Mar. 21, 2012
Spectrum Pharm. Inc. v. InnoPharma Inc.	No. 12-260	Mar. 2, 2012
Allergan Inc. v. Akorn Inc.	No. 11-1270	Dec. 21, 2011
Galderma Labs. Inc. v. Amneal Pharm. LLC	No. 11-1106	Nov. 8, 2011
AbbVie Inc. v. Hospira Inc.	No. 11-648	July 21, 2011
Medicis Pharm. Corp. v. Actavis Mid Atlantic LLC	No. 11-409	May 11, 2011
Abbott Prods. Inc. v. Teva Pharm. USA Inc.	No. 11-384	Apr. 29, 2011
Endo Pharm. Inc. v. Mylan Tech. Inc.	No. 11-220	Mar. 14, 2011
Shire LLC v. Teva Pharm. USA Inc.	No. 10-329	Apr. 22, 2010
Wyeth Holdings Corp. v. Sandoz Inc.	No. 09-955	Dec. 11, 2009
Roche Palo Alto LLC v. Endo Pharm. Inc.	No. 10-261	Mar. 31, 2009
Abbott Labs. v. Lupin Ltd.	No. 09-152	Mar. 6, 2009

**Table III. New Jersey Cases Used in the Empirical Study**

<b>Parties</b>	<b>Docket Number</b>	<b>Date Filed</b>
United Therapeutics Corp. v. Sandoz, Inc.	No. 13-316	Jan. 16, 2013
AstraZeneca AB v. Dr. Reddy's Labs., Inc.	No. 13-91	Jan. 4, 2014
Auxilium Pharm., Inc. v. Watson Labs., Inc.	No. 12-3084	May 23, 2012
Warner Chilcott Co. v. Amneal Pharm., LLC	No. 12-2928	May 16, 2012
United Therapeutics Corp. v. Sandoz, Inc.	No. 12-1617	Mar. 14, 2012
Shire LLC v. Watson Labs. Inc.	No. 12-83	Jan. 5, 2012
Santarus, Inc. v. Zydus Pharm. (USA) Inc.	No. 11-7441	Dec. 21, 2011
MSD Consumer Prods., Inc. v. Zydus Pharm. (USA) Inc.	No. 11-7437	Dec. 21, 2011
Noven Pharm. v. Watson Labs., Inc.	No. 11-5997	Oct. 13, 2011
Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd.	No. 11-3962	July 8, 2011
Shire LLC v. Amneal Pharm., LLC	No. 11-3781	June 30, 2011
Hoffmann-La Roche Inc. v. Teva Pharm. USA, Inc.	No. 11-3635	June 23, 2011
The Medicines Co. v. Dr. Reddy's Labs. Ltd.	No. 11-2456	Apr. 28, 2011
AstraZeneca AB v. Dr. Reddy's Labs. Inc.	No. 11-2317	Apr. 21, 2011
Gilead Scis., Inc. v. Natco Pharma Ltd.	No. 11-1455	Mar. 15, 2011
Braintree Labs., Inc. v. Novel Labs., Inc.	No. 11-1341	Mar. 9, 2011
Prometheus Labs. Inc. v. Roxane Labs., Inc.	No. 11-1241	Mar. 4, 2011
Prometheus Labs. Inc. v. Roxane Labs., Inc.	No. 11-230	Jan. 14, 2011
Janssen Prods., L.P. v. Lupin Ltd.	No. 10-5954	Nov. 15, 2010
Abbott Labs. v. Lupin Ltd.	No. 10-1578	Mar. 26, 2010
Teva Women's Health, Inc. v. Mylan Pharm., Inc.	No. 10-1234	Mar. 9, 2010

Graceway Pharm., LLC v. Perrigo Co.	No. 10-937	Feb. 23, 2010
Teva Women's Health, Inc. v. Lupin, Ltd.	No. 10-80	Jan. 6, 2010
Merck Sharp & Dohme Corp. v. Mylan Pharm. Inc.	No. 09-6383	Dec. 16, 2009
Merck Sharp & Dohme Corp. v. Apotex Inc.	No. 09-6373	Dec. 18, 2009
Hospira, Inc. v. Sandoz Int'l GmbH	No. 09-4591	Sept. 4, 2009
Reckitt Benckiser Inc. v. Tris Pharma, Inc.	No. 09-3125	June 26, 2009
Hoffmann-La Roche Inc. v. Mylan Inc.	No. 09-1692	Apr. 8, 2009
Sunovion Pharm. Inc. v. Teva Pharm. USA, Inc.	No. 09-1302	May 20, 2009
Merck & Co., Inc. v. Sandoz Inc.	No. 09-890	Feb. 27, 2009
Dr. Reddy's Labs., Ltd. v. Eli Lilly & Co.	No. 09-192	Jan. 8, 2009

