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EFFECTS OF THE FEDERAL CIRCUIT JUDGES ON HATCH-WAXMAN LITIGATION

I. INTRODUCTION

Many, if not all, patent lawyers have pre-conceptions on how patent litigation works. For example, many patent lawyers believe certain district courts are more patentee-friendly than others or that a jury trial would provide a more favorable outcome than a bench trial. Many patent lawyers hold a variety of beliefs about the Federal Circuit and its effect on patent law. A commonly held belief amongst patent litigators is that the outcome of their Federal Circuit case depends on the panel of judges that hear their arguments.¹ This knowledge is highly anecdotal – personal experiences and stories from other lawyers convince many patent attorneys that the draw of the Federal Circuit panel is outcome determinative. However, the effect of this belief results in attorney time and client money spent on preparing for the panel draw. For example, oral arguments are often tailored to particular judges.²

In addition to “war stories,” social scientists have developed an “attitudinal model” of judicial behavior through empirical studies.³ These studies attempt to establish links between various judicial characteristics and outcomes. Voting behavior and ideology by reference to nominating President or some other indicator has been the focus of most of these studies.⁴ In addition to ideology, studies

¹. See, e.g., Paul R. Michel, The Court of Appeals for the Federal Circuit Must Evolve to Meet the Challenges Ahead, 48 AM. U. L. REV. 1177, 1191 (1999). Judge Michel’s reply to this criticism was: “I believe that these complaints are exaggerated. By informal monitoring, I estimate that in ninety percent of these cases the result would be the same with any combination of three judges from among the court’s present complement of ten judges in full-time service.” Id.

². The Federal Circuit appears to be aware of this practice because the court does not release the panel composition until the morning of the oral argument. See Mary L. Jennings, Should Advocates Be Informed of the Identities of Members of Judicial Panels Prior to Hearings?, 6 FED. CIR. B. J. 41 (1996).


⁴. See, e.g., ROBERT A. CARP & C.K. ROWLAND, POLICYMAKING AND
have analyzed correlations between voting behavior and other judicial characteristics, including geography,\(^5\) age,\(^6\) gender,\(^7\) religion,\(^8\) tenure,\(^9\) and past experience.\(^{10}\) Most, but not all, of these studies claim to find positive correlations between judicial


\(^10\) See Eisenberg & Johnson, *supra* note 9, at 1189-91 (finding a correlation between voting in racial equal protection cases and prior prosecutorial experience); Goldman, *supra* note 6, at 211.
characteristics and voting patterns.

Some scholars have studied voting patterns of the individual judges of the Federal Circuit and the effects of panel composition in decisions involving different areas of patent law. These studies have not resulted in a clear trend of panel dependency. However, both studies have shown that the presence of certain judges on a panel or writing an opinion can increase the likelihood of a particular outcome. While the methodology employed in these two and the other empirical studies has been the source of some debate, their cumulative effect solidifies the notion that judicial characteristics matter to legal outcomes. Even if not accurate, the attitudinal model of judging has become prevalent, and prevalence is enough to support the claim that litigants might view the identity of the judge as a relevant factor in the prediction of a case’s outcome.

While some commentators believe it is not necessarily


14. See Jules L. Coleman & Brian Leiter, Determinacy, Objectivity, and Authority, 142 U. PA. L. REV. 549, 581 (1993) (“Not surprisingly, according to the realist, the ideal lawyer is the one who is in the best position to counsel his clients about what to expect from litigation. That lawyer will need to know what leads judges to decide as they do, not what legal reasons, if any, would justify their decisions. . . . The best explanation of judicial decisions may include the set of binding legal reasons, but cannot be limited to them. Instead, explanations will point to psychological and sociological facts about judges as part, if not all, of the causal story.”).
troubling, panel dependency can be problematic. If the outcome of a case depends on the judges on the panel, uniformity of decisions may suffer even where the underlying facts are similar. Furthermore, different panels can create or employ competing doctrines to resolve cases, which decrease the predictability of outcomes and limits businesses’ and individuals’ ability to prepare and plan future courses of action. Also, problems are especially likely to develop where the dependency is due to judges’ preconceptions about a certain class of litigants and the underlying legal framework has multiple competing doctrines that allow flexibility in order to find for their favored party. Due to the Federal Circuit’s nearly absolute appellate jurisdiction of patent issues and the presence of multiple conflicting doctrines, further studies into panel dependency and judicial voting patterns are of interest.

This study will focus on how the Federal Circuit judges vote and write in cases involving Food and Drug Administration (“FDA”) regulated pharmaceuticals, with an emphasis on Abbreviated New Drug Application (“ANDA”) cases. The recent changes to the process for obtaining FDA approval for marketing drugs were intended to balance two important public policy goals. First, drug manufacturers need meaningful market-protecting incentives to encourage the development of valuable new drugs. Second, once the statutory patent protection and marketing exclusivity for these new drugs has expired, the public benefits from the rapid

15. See, e.g., Wagner & Petherbridge, supra note 11, at 1169 (arguing that dependency implies some predictability in Federal Circuit behavior – a positive development and in accord with Congress’ mandate for the Federal Circuit); Samuel P. Jordan, Early Panel Announcement, Settlement, and Adjudication, 2007 BYU L. REV. 55 (2007) (arguing that panel dependency coupled with early announcement of panels can lead to settlements).

16. For example, the distinction between “interpreting the claims in light of the specification” and “reading limitations from the specification into the claims” constantly causes consternation among the members of the Federal Circuit as well as the rest of the patent bar. Other doctrines that allow for malleable decisions include de novo review of claim construction, inherent anticipation, and the doctrine of equivalents.

availability of lower priced generic versions of the drug. Because these goals are on-going and statutory language is hardly ever drafted perfectly, loopholes and unexpected consequences have arisen that have required solutions. Legislation, with its associated lag time, may be the imperfect vehicle for achieving a good balance. However, the courts can be an ideal place for filling the holes and undefined areas of the statute, as long as judges do not overstep their judicial role. As such, the Federal Circuit, as sole appellate court for patent issues, will play a large role in maintaining the balance of these competing interests.

This study provides insight into whether the Federal Circuit is properly balancing the competing interests that Congress recognized in enacting the Hatch-Waxman and Medicare Modernization Amendments to the FDA-drug approval process, while providing a jurisprudence that is clear, coherent, and predictable as dictated by Congress’ mandate in the Federal Courts Improvement Act. In Section II, the theoretical and doctrinal background of the Federal Circuit and the amendments to the FDA-approval process, as well as the Congressional intentions behind all of the relevant Acts, are discussed.

The design of the study is set forth in detail in Section III, which describes the research methods used, including the development of the case-coding instrument, the selection of the case population, the coding techniques, and the limitations. In Section IV, the results are presented, consisting of three basic inquiries: 1) is the Federal Circuit as a whole responding to Congressional intent behind the Hatch-Waxman Act in drug cases, measuring the total content of the relevant jurisprudence; 2) are individual judges, as well as combinations and panels of judges, following these mandates and if not, which specific judges are voting predominately for either the brand name companies or the generic companies; 3) whether the Congressional intent behind the Medicare Modernization Act has affected the judges voting. Section V describes policy implications and Section VI contains concluding remarks.
II. BACKGROUND INTO FEDERAL PHARMACEUTICAL DRUG REGULATION AND THE FEDERAL CIRCUIT’S INFLUENCE.

A. The Hatch-Waxman and Medicare Modernization Amendments to the Federal Food, Drug and Cosmetic Act (FDCA).\(^{18}\)

The Food and Drug Administration is the regulatory body that controls nearly every aspect of the development and marketing of pharmaceuticals, including clinical testing, and the safety and effectiveness of new drugs.\(^ {19}\) No new drug can be marketed in the United States without FDA approval.\(^ {20}\) A manufacturer seeking to market a drug that has not previously been approved by the FDA is required by the FDCA to submit a New Drug Application ("NDA") to the FDA.\(^ {21}\) NDAs are usually long and detailed and must include, among other things, evidence regarding the drug’s safety and effectiveness. Additionally, information about any patents held by the NDA that could reasonably be asserted to cover the drug in question must be listed.\(^ {22}\) After the NDA is approved, the FDA is required to publish the submitted patent information in a report called "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly referred to as "the Orange Book."\(^ {23}\)

In the early 1980s, bills were introduced in Congress to expedite generic drug approvals and to stimulate competition between brand-name manufacturers and generics.\(^ {24}\) As a result of

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22. Id.


negotiations between members of the brand and generic drug industries and involvement of Representative Henry Waxman and Senator Orrin Hatch, the Hatch-Waxman legislation was enacted on September 24, 1984.\textsuperscript{25} The Hatch-Waxman legislation "was predicated on the desire to enhance the growth of the generic drug industry while simultaneously extending patent protection for brand name drugs developed by the research-based industry."\textsuperscript{26} In the Hatch-Waxman Amendments, Congress attempted to strike a balance between two competing policy interests: (i) encouraging the research and development of new drugs and (ii) enabling generics to bring low-cost copies of those drugs to market.\textsuperscript{27}

For the generics, the Hatch-Waxman Act creates an efficient regulatory method of bringing a drug to market known as an Abbreviated New Drug Application ("ANDA").\textsuperscript{28} In an ANDA, a generic company must demonstrate its drug's "bioequivalence" with the previously approved brand-name product.\textsuperscript{29} However, ANDA applicants may rely on the brand's previous studies of safety and efficacy and do not need to repeat the clinical trials that had been required by the FDCA.\textsuperscript{30} As a result, generics are able to shorten the time period for approval and avoid much of the research and development costs that would otherwise be necessary to bring a new drug to market.

For the brands, the Hatch-Waxman Amendments continue to provide protection to the innovator whose patent rights have yet to expire through an array of notice provisions, among other incentive-creating provisions.\textsuperscript{31} In order to secure FDA approval,

\begin{itemize}
\item \textsuperscript{25} See id. at 780-82.
\item \textsuperscript{26} \textit{Bill to Ease Way for Generics is Introduced in the House}, \textit{CHAIN DRUG REV.}, June 4, 2001, at RX11.
\item \textsuperscript{27} See Andrx Pharm., Inc. v. Biovail Corp., 276 F.3d 1368, 1370-71 (Fed. Cir. 2002).
\item \textsuperscript{29} See § 355(j)(4)(F).
\item \textsuperscript{30} See § 355(j); see also 21 C.F.R. § 314.94(a)(3) (2008).
\item \textsuperscript{31} The Hatch-Waxman Amendments provide a number of other incentives including: (i) patent term extensions to compensate for delays during regulatory review of the brand-name product; (ii) mandatory notice by generics seeking to challenge patents covering the brand-name drug; (iii) up to a thirty-month stay of generic approval during patent litigation; and (iv) market exclusivity of three and five-year periods under special circumstances. See § 355(j)(2)(B)(i),
\end{itemize}
the ANDA applicant must certify that its generic version of the approved drug will not interfere with any patents that the NDA holder has listed. These are commonly referred to as paragraph I, II, III and IV certifications. Paragraph IV certification requires a court’s involvement to determine whether the patent is valid or whether it will be infringed by the generic drug product. Under Hatch-Waxman, filing a Paragraph IV certification is considered an act of infringement, although nothing has been made, used, or sold.

After filing a Paragraph IV certification with the FDA, an ANDA applicant who wishes to challenge the patent during the patent term, must give notice to the NDA-holder/patentee within twenty days of the filing. The notice must include a statement detailing the ANDA applicant’s factual and legal basis of invalidity, unenforceability, and/or non-infringement. If the brand does not file an infringement action within forty-five days of receiving the notice, “the approval [of the ANDA] shall be made effective immediately” by the FDA. If the patent holder files suit, the FDA approval is delayed thirty months from receipt of the notice unless the district court rules on the infringement claim within the thirty-month period or the patent expires. If the district court issues a ruling during the thirty-month stay period, the ANDA approval date is determined by the decision of the district court, or by the decision of the appellate court, if it is appealed. In short, litigation stays the FDA’s ability to grant approval of the generic’s ANDA for thirty months, which prevents the generic from marketing its drug, unless there is a holding of non-infringement, invalidity, or unenforceability.

In the years following enactment of the Hatch-Waxman legislation, both goals of the Act were being fulfilled to a certain extent.

39. Id.
extent. However, the terms of the original Hatch-Waxman Amendments created incentives for anticompetitive behavior, including late Orange Book listings of patents unrelated to the basic functioning of the drug, frivolous patent infringement lawsuits, and collusive arrangements between brand and generic companies. In response to these abuses, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act ("Medicare Amendments" or "MMA"), which became law on December 8, 2003.\textsuperscript{41} Title XI of the Medicare Amendments, entitled "Access to Affordable Pharmaceuticals," implemented significant changes to the Hatch-Waxman Act. Some of the changes include new remedies for the generic applicant, new requirements for the events that trigger the generic applicant’s 180-day exclusivity period, and restrictions on brand-name drug manufacturers’ thirty-month stay necessary to resolve infringement disputes involving patents listed in the Orange Book.\textsuperscript{42} It is clear from the legislative history\textsuperscript{43} that the MMA was passed with the idea that generic drug competition should be encouraged and enhanced.\textsuperscript{44} This can be viewed as an indication that the Hatch-Waxman act did not achieve the intended balance between competing goals. The MMA can also be seen as another attempt by Congress to achieve that balance by encouraging more robust generic competition.

\begin{footnotesize}


\textsuperscript{43} See 149 CONG. REC. S15882-03, S15885 (2003) (statement of Sen. Kennedy, ranking member of the Senate HELP committee regarding the “civil action to obtain patent certainty” provision under 21 U.S.C. § 355(j)(5)(C)) ("[I]n recent years both brand-name and generic drug companies have exploited certain aspects of the Hatch-Waxman Act to delay generic competition. The changes to the ... Act ... will stop these abuses.").

\textsuperscript{44} Commentators also view the MMA as allowing generics to compete more effectively. See, e.g., Stephanie Greene, A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs, 30 IOWA J. CORP. L. 309 (2005).
\end{footnotesize}
As evidenced by the MMA, legislation to define the balance between generic competition and new drug innovation is a difficult and inexact task. The inherent delay between identification of a loophole or other problems in an existing statute and the enactment of an amendment suggests that legislation may not be the best route to regulating the drug industry. Another option for Congress is to draft a broad statute and allow the courts to define the contours of the law.\footnote{Regardless of whether Congress will continue to tinker with drug regulation through legislation or not, the courts will play a substantial and critical role in interpreting and applying the statute. Given its role in patent law, the Federal Circuit has the ability to impact the outcome in pharmaceutical cases more than any other court.}


In the last two decades, Federal Circuit has become one of the most powerful and influential forces in the United States patent system.\footnote{47. See, e.g., Mark D. Janis, \textit{Patent Law in the Age of the Invisible Supreme Court}, 2001 U. ILL. L. REV. 387, 387 ("The Court of Appeals for the Federal Circuit . . . has become the de facto supreme court of patents.").} As the patent system has grown in economic importance,\footnote{48. \textit{See generally} Fred Warshofsky, \textit{The Patent Wars: The Battle to Own the World's Technology} (1994) (noting the critical nature of patents in economic development).} technological complexity,\footnote{49. See, e.g., John R. Allison & Mark A. Lemley, \textit{The Growing Complexity of the United States Patent System}, 82 B.U. L. REV. 77, 79 (2002) ("By almost any measure . . . the patents issued in the late 1990s are more complex than those issued in the 1970s.").} and public awareness, the administration of the entire enterprise increasingly depends

\footnote{45. A good example of this methodology is found in antitrust law where the Sherman Act provides a broad prohibition against anti-competitive behavior while allowing the courts to hash out the details. \textit{See} Lawerence A. Sullivan & Wolfgang Fikentscher, \textit{On the Growth of the Antitrust Idea}, 16 BERKELEY J. INT'L L. 197, 200 (1998).}
upon the judges of the Federal Circuit.

Even after twenty-five years, Congressional intent behind creating the Federal Circuit is not open to debate. By the enactment of the Federal Courts Improvement Act ("FCIA") of 1982, 50 Congress unified in the Federal Circuit the appellate jurisdiction for patent cases, 51 whether from the U.S. Patent and Trademark Office, the U.S. district courts, the Court of Federal Claims, or the Court of International Trade (ITC). At the time of enactment, the legal landscape of patent law was widely thought to be inefficient and unpredictable. Legislators were confronted with information that the interpretation of the patent law differed in different parts of the country. 52 Studies predating FCIA revealed that a patent was more "likely to be held valid and infringed in the Fifth Circuit than in the Seventh Circuit, and almost four times more likely to be enforced in the Seventh Circuit than in the Second Circuit." 53

After hearing this and other testimony, Congress determined that national uniformity in the patent law of the United States was desirable. National uniformity would bring uniformity of doctrinal development, 54 doctrinal stability, 55 and predictability to the law. 56 The solution was the unification of patent appeals under a single appellate jurisdiction. 57 In sum, the vesting in the Federal Circuit

53. See Dreyfuss, supra note 46, at 7 (citing Thomas Cooch, The Standard of Invention in the Courts, in DYNAMICS OF THE PATENT SYSTEM 34, 56–59 (William B. Ball ed., 1960)).
55. See id. ("The Federal Circuit also provides a forum that will increase doctrinal stability in the field of patent law.").
56. See id. at 6, as reprinted in 1982 U.S.C.C.A.N. 11, 16 (stating that stable and predictable law is better for the national economy).
57. See id. at 4, as reprinted in 1982 U.S.C.C.A.N. 11, 14 ("The Court of Appeals for the Federal Circuit provides such a forum for appeals from
of exclusive jurisdiction of patent appeals has been based on a consistent and transparent line of reasoning. First, the Federal Circuit, playing a unitary judicial role, will manage, develop, and police the patent law. Second, the imposition of this institutional design will promote a clearer, more stable and predictable patent doctrine, which in turn will reduce forum shopping and improve the economic usefulness of important property rights.

It is clear that Congress’s structural goals have been met. The Federal Circuit has moved swiftly into its role as manager, developer, and enforcer of the patent doctrine. Without a doubt, it has expanded its influence over the jurisprudence in a number of doctrinal areas, including claim interpretation,\(^{59}\) the standard for obviousness,\(^ {60}\) remedies,\(^ {61}\) procedural issues,\(^ {62}\) anticipation,\(^ {63}\) and inequitable conduct.\(^ {64}\) As such, the judges of the Federal Circuit have a profound impact on patent law in general. As Hatch-Waxman litigation is a subset of patent law, the Federal Circuit judges and their policies and decisions have a large influence in the pharmaceutical drug arena as well.

C. Questions Presented

Given the intent of Congress to improve generic-brand competition in the drug market while also providing incentives to the brand-name manufacturers to continue to bring new and innovative drugs to market and the prominence of the Federal Circuit’s influence on patent law, the question becomes whether

\(^{58}\) Id. at 5–6, as reprinted in 1982 U.S.C.C.A.N. 11, 15–16; Dreyfuss, supra note 46, at 7.

\(^{59}\) See Wagner & Petherbridge, supra note 11 (discussing the Federal Circuit’s development of claim-interpretation jurisprudence).


\(^{61}\) Dreyfuss, supra note 46, at 18–19.

\(^{62}\) See id. at 30–52 (discussing some areas where the court has wielded jurisprudential influence and concluding that the court’s success was mixed).

\(^{63}\) Id. at 10–11.

\(^{64}\) Id. at 21–22.
the Federal Circuit is correctly balancing the competing interests that motivated Congress to pass the Hatch-Waxman Act in the first place. Ideally, these goals would be reflected in the court’s decisions. For example, a clear preference for generic companies or brand companies in the outcome of the cases would suggest that Congressional intent has gone unheeded. To the contrary, outcomes not favoring one party over the other would suggest that the Act is being properly applied in light of Congress’s wishes.

Even if the Federal Circuit as a whole is fulfilling the intent behind Hatch-Waxman, individual judges may not be. Individual judges who are voting for one side with regularity could cause a number of significant consequences. First, these individuals could be overstepping their bounds as judges and taking on roles that are more appropriate for legislators. Second, the outcome of a case could be dependent on the members of the panel assigned to the case and litigators can alter strategies to play to the judges assigned to their cases. Third, knowledge of panels could affect the parties standing in settlement talks. Finally, questions of judicial craftsmanship arise as, ideally, judges should apply the law impartially.

Congress’ enactment of the Medicare Amendments could be viewed as a signal that generic competition should be more vigorously protected. The question then becomes whether the Federal Circuit and its judges have taken this enactment as a signal. For instance, did the outcome of the court’s decisions start to favor generics more after enactment? Also, have individual judges taken the signal to begin favoring generics more or have they favored brands more, perhaps because they feel Congress has gone too far in enabling generics?

III. DESCRIPTION OF STUDY

A. Court Opinions as Data

A key design choice faced at the outset concerned the identification of a source of information that allowed the sort of systematic analysis needed for this study. This study utilizes the court’s jurisprudence itself as the relevant data source, measuring
aspects of the Federal Circuit’s decision making as expressed in written judicial decisions and voting patterns.\textsuperscript{65} Unlike traditional legal research, the data was collected and analyzed more systematically and by more rigid criteria. Given the object of the study – to analyze whether the court is balancing the competing interests of generic and brand name pharmaceutical manufacturers while developing a clear, coherent, and predictable jurisprudence – measuring the jurisprudence and voting patterns is likely to provide the necessary insights.

\textbf{B. Population}

The population for this study includes all Federal Circuit decisions that involve a pharmaceutical ANDA filer being sued for infringement under § 271(e) reported from the enactment of the Hatch-Waxman Act on September 24, 1984 through March 26, 2009. This is a population, as opposed to a sample, because every opinion is included, whether or not it was designated “for publication” under the Federal Circuit Rules. However, the population is limited to decisions involving the Hatch-Waxman Act and pharmaceuticals. It includes all aspects of § 271(e) infringement suits, including jurisdictional\textsuperscript{66} and substantial rulings, as well as suits against the FDA involving application of the Act. It does not include the §271(e)(1) research exception for

\textsuperscript{65} This is a commonly used method. See Allison & Lemley, \textit{supra} note 11, at 746; Wagner & Petherbridge, \textit{supra} note 11, at 1126 & n.82.

\textsuperscript{66} A majority of the included jurisdictional rulings were requests for declaratory judgments that would allow the generic to challenge patents in order to enter the market for a given drug. As such, these rulings are included in the study because a judge that favors either side of the pharmaceutical argument can use jurisdiction to allow generic competition (by allowing the challenge) or prevent it (by dismissing the case on jurisdictional grounds). On this front, the Federal Circuit as a whole has moved from normally disallowing these challenges towards allowing challenges by generics. Compare Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324 (Fed. Cir.2005) (affirming district court’s holding of no Article III standing because there was no reasonable apprehension of suit) \textit{with} Caraco Pharm. Labs. v. Forest Labs., 527 F.3d 1278 (Fed. Cir. 2008) (reversing and remanding district court’s dismissal for lack of subject matter jurisdiction because there was a case or controversy under all circumstances test). This may be due to an intervening ruling in the Supreme Court. See Medimmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007).
medical device cases or cases that were purely related to civil procedure matters. Finally, the measure of this study is by opinion, not by case or patent. In all, this population contains 176 different written opinions from 136 titled cases decided by 110 different three-judge panels. The 176 opinions include 126 majority opinions (including 5 per curium opinions and 2 opinions written by judges sitting by designation), 12 concurrences, 30 dissents (including 11 dissents from denial of rehearing or rehearing en banc), and 8 concurring-dissenting opinions.

C. Data Collected

For each case, the following was cataloged:

- Case name, citation, and date of decision
- Precedential weight
- Patentee and ANDA Filer
- Patent(s)-at-issue
- Brand and generic name of the patented drug
- Federal Circuit judges on the panel
- Opinion-writing judge
- Any concurring or dissenting opinions, their authors, and outcomes
- Issue(s) on appeal, including: jurisdiction; preliminary injunction; claim construction; infringement (literal and doctrine of equivalents); obviousness; anticipation; on-sale bar; §112 issues ((best mode, enablement, written description, or indefiniteness); double patenting; inequitable conduct; reissue problems; term extension; Hatch-Waxman interpretation issues

- Whether the finder of fact was a jury, judge in a bench trial, a judge ruling on a pre-trial motion, or a judge granting judgment as a matter of law

67. See, e.g., Pfizer, Inc. v. Dr. Reddy’s Labs., Ltd., 359 F.3d 1361, 1365-66 (Fed. Cir. 2004) (reversing district court’s holding of non-infringement because patent extension under Hatch-Waxman amendments applied to the drug’s active ingredient, not only the identified salt). But see id. at 1367 (Mayer, J., dissenting) (would have affirmed district court because Hatch-Waxman statute should be interpreted to limit the patent term extension to the specific product that was subject to FDA approval).
• Whether the lower court was reversed or affirmed
• Who the outcome favored (generic or patentee)
• A short synopsis of the outcome and reasoning of the case

Some of this data is of little importance to the current study but was collected to enable additional studies in the future.

D. Methodology

As this study contained a well-defined population and all the members of that population were included in the data set, the normal tests designed to evaluate the statistical significance of data do not apply.68 Within the population, all the numbers reproduced here are by definition "statistically significant."69 Thus, the majority of the data discussed are descriptive statistics about the population; such as what percentage of the time that a particular judge’s vote favored generic or brand companies. These descriptive statistics also include data relating one variable to another, for example, comparing how judges’ voting patterns changed over time. These statistics are interesting for what they reveal about the population of Federal Circuit ANDA decisions in the past twenty-five years. As a matter of statistical inference, however, they do not predict anything about future cases. Methods that would enable predictions about future decisions were beyond the scope of this paper, but may be done in the future.70

Outcome was determined to be “pro-generic” when the decision allowed the FDA to grant the generic’s ANDA and “pro-brand” if the decision prevented the generic from entering the market. For example, in Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories., Inc.,71 the Federal Circuit (Rader, Michel, Linn, JJ.) affirmed the district court’s holdings of no inequitable conduct,

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69. However, such differences may nevertheless be small enough to have no practical significance to lawyers.

70. Two examples of predictive methodologies are the “superpopulation” approach and binary logistic regression analysis. See Allison & Lemley, supra note 11, at 749 (for the “superpopulation” approach); Wagner & Petherbridge, supra note 11, at 1164 (for the binary logistic regression analysis).

71. 520 F.3d 1358 (Fed. Cir. 2008).
non-obviousness and enablement. All of these holdings favor the brand, as they keep the patent valid which bars the FDA from approving the generic’s ANDA. As such, this case was coded as pro-brand and the opinion writer (Rader, J.) and those who joined it (Michel & Linn, JJ.) were scored accordingly in the database.

As another example, in *Pfizer, Inc. v. Apotex, Inc.*, the Federal Circuit (Michel, Mayer, Linn, JJ.) reversed the district court’s holding of infringement and non-obviousness and held the claims obvious. This case was coded pro-generic because the holding of invalidity would allow the FDA to approve the generic’s ANDA, which, in turn, allows them to market their drug.

Cases that were not the final determination of the issues (e.g. remands) were coded based on whether the decision made it more or less likely for the generic’s ANDA to be granted. More specifically, if the district court held the patent invalid, not infringed, or unenforceable and the Federal Circuit panel reversed and remanded, the opinion would be classified as pro-brand. For example, in *SmithKline Beecham Corp. v. Excel Pharmaceuticals, Inc.*, the Federal Circuit (Rader, Plager, Gajarsa, JJ.) vacated and remanded the district court’s summary judgment of non-infringement because a factual question related to the scope of surrendered equivalents existed. This opinion was coded pro-brand because the decision could allow the brand to prevent the generic’s ANDA from granting if they could win on remand. In other words, the decision is pro-brand because the FDA could have granted the generic’s ANDA but for the Federal Circuit panel reversing the district court. On the other hand, if the district court held the patent infringed, not invalid, and not unenforceable, and the Federal Circuit panel reversed and remanded on all of these issues, the opinion would be classified as

72. 480 F.3d 1348 (Fed. Cir. 2007).
73. Any one of these holdings would allow the FDA to grant the generic’s ANDA application, which would allow the generic to market its drug as long as other patents were not barring market entry.
74. 356 F.3d 1357 (Fed. Cir. 2004).
75. The actual outcomes below on remand, while interesting, do not provide any insight into how the Federal Circuit judges decide ANDA cases. As such, the actual outcomes on remand were not studied.
76. All three holdings would be necessary to bar a generic’s ANDA from being approved, assuming each ground was asserted in the litigation.
For example, in Bristol-Myers Squibb Co. v. Pharmachemie B.V., the Federal Circuit (Bryson, Michel, Newman, JJ.) vacated the district court's holding of obviousness-type double patenting and remanded because of a convoluted factual scenario. This opinion was coded pro-generic because it was possible for the generic company to invalidate the patent on remand, which would allow for the FDA to approve its ANDA. These classifications are appropriate because the focus of this study is on the Federal Circuit judges in ANDA litigations. By reversing and remanding in the above scenarios, the panel enabled a party who was disadvantaged by the district court to have another chance to win the case. Therefore, the opinion is properly classified as favoring the party who was previously disadvantaged by the district court's opinion.

Certain opinions held for the brand on some issues and the generic on others. These cases cause some analytical problems, as they may be a result of compromise between the panelists, an indication of the panel's interpretation and application of the law, or a way for the author to "split the baby" and favor neither side. However, the focus of this paper is whether the competing goals of Congress are being met. With this focus, these split issue opinions can be classified based on whether generic competition is increased (by allowing FDA approval of the ANDA) or decreased (thereby enhancing the brands incentive to innovate). Given these considerations, split-issue opinions were classified as pro-generic if they allowed the generic to market the drug and pro-brand if the decision barred the FDA from approving the generic's ANDA. For example, in Pharmacia Corp. v. Par Pharmaceutical, Inc., the Federal Circuit (Rader, Schall, Linn, JJ.) affirmed the district
court's holding of inequitable conduct in prosecuting one patent, but did not find that it infected a related patent that was terminally disclaimed to the unenforceable patent. Although one patent was held unenforceable (a pro-generic result), the generic would still be barred from entering the market because of the valid patent (a pro-brand result). As such, this decision was classified as "split (pro-brand)" because the FDA would not be able to approve the generic's ANDA.\(^{81}\) On the other hand, in \textit{In re Omeprazole Patent Litigation}, \(^{82}\) the Federal Circuit (Rader, Schall, Newman, JJ.) affirmed the district court's holding of infringement (pro-brand) but also affirmed the invalidity of the patent under the inherent anticipation doctrine (pro-generic).\(^{83}\) The majority opinion was classified as "split (pro-generic)" because the FDA would be able to approve the generic's ANDA as the patent listed in the Orange Book was held invalid.\(^{84}\)

All of the opinions in the study were classified according to this coding method. Each judge's voting and writing patterns were tabulated in a spreadsheet. Various numerical and statistical manipulations were performed using a standard spreadsheet program to arrive at the data and representations presented herein.\(^{85}\)

\textbf{E. Limitations}

A challenge to this methodology is that judges may not be "pro-brand" or "pro-generic" at all and may be simply following the law. However, even if they are "following the law," many patent law issues have conflicting doctrines and case law that allows a

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\(^{81}\) In all, fourteen other majority opinions were classified as split (pro-brand).

\(^{82}\) 483 F.3d 1364 (Fed. Cir. 2007).

\(^{83}\) Judge Newman dissented from this part of the opinion and would have reversed the inherent anticipation holding. \textit{See id.} at 1376 (Newman, J., concurring in part and dissenting in part). As such, her concurring/dissenting opinion in this case was classified as pro-brand.

\(^{84}\) In all, eleven other majority opinions were classified as split (pro-generic).

\(^{85}\) The most complex calculation done in the software was determining standard deviations. Other manipulations include averaging and calculating percentages.
judge with a particular view can choose a doctrine or case that favors his/her viewpoint. Voting records over a large enough data set should demonstrate the individual judge’s stance in the ANDA arena. Also, this methodology provides a relatively objective method of determining a judge’s viewpoint, rather than reading into the tealeaves or psychoanalyzing a judge’s position of the words and phrases in judicial opinions. 86 Furthermore, judge’s agendas are rarely written into their opinions. 87 Finally, this approach allows for the management of the large amount of data generated in this study.

There are inherent limitations in converting written opinions into numbers and statistics. 88 For example, how a case should be characterized sometimes requires an exercise of judgment (as described above). Others may disagree with some assignments one way or the other. However, there is no reason to believe that evaluations of these cases are biased in any systematic way.

The data set is limited by the inherent nature of the litigation process as well. The skill of the lawyers on each side, the procedural posture of the case, the interest and skill of the judges, adequacy of the record, financial resources of the parties, and quality of the patent itself are all likely to affect the outcome in at least some cases. In analyzing the output of judicial opinions, this study did not seek to account for various inputs that might have affected the outcome or reasoning, such as the quality of arguments, strategic choices by parties, or even strategic behavior by judges. 89

86. See Allsion & Lemley, supra note 11, at 745 n.1 ("It isn’t necessary to notify counsel regarding who will be sitting; and it is a little demeaning, frankly . . . when lawyers go running around psychoanalyzing judges by reading the tea leaves in their opinions ahead of time" (quoting Hon. Howard T. Markey, Judge, United States Court of Appeals for the Federal Circuit, Address at The First Annual Judicial Conference of the United States Court of Appeals for the Federal Circuit (May 20, 1983), in 100 FED. RULES DECISIONS 499, 511-12)).

87. But see, Pfizer, Inc. v. Apotex, Inc., 488 F.3d 1377 (Fed. Cir. 2007) (dissenting from a denial of rehearing en banc, Newman, Lourie, and Rader, JJ., discuss the significance of the panel’s holding of obviousness on the conduct of R&D and brand companies not being able to commercialize new products).

88. See Allison & Lemley, supra note 68, at 203; Allison & Lemley, supra note 11, at 748-49; Wagner & Petherbridge, supra note 11, at 1128.

89. See, e.g., Richard A. Posner, What Do Judges and Justices Maximize?
An additional bias may result from the nature of the appellate process. Courts of appeals are more likely to write and publish opinions in cases in which they reverse the district court than in cases in which they affirm, for the simple reason that at least some affirmances can rely heavily on the prior opinion of the district court. To some extent this bias is controlled as this study includes written opinions designated "not for publication" as well as published opinions and "summary affirmances" under Federal Circuit Rule 36.90

Analyzing the content of judicial opinions assumes that the expression in a given opinion accurately reflects the actual process by which the result was reached. There is at least some reason to question this assumption,91 if for no other reason than the author of the opinion is primarily concerned with "justifying her conclusion by showing that it proceeds from accepted sources by legitimate, properly argued steps."92 The presence of multiple causative facts specific to particular cases cannot effectively be taken into account in a study of this type. The final outcome of the case is being tested. Judges may agree on the final outcome even though they

(See, e.g., William M. Sage, Judicial Opinions Involving Health Insurance Coverage: Trompe L'Oeil or Window on the World?, 31 IND. L. REV. 49, 61-68 (1998) (identifying small sample size, long time lags, selection bias, publication bias, and unstated rationales as the limitations of a judicial dataset).)

disagree on the reasoning (without writing a concurrence). As such, the concurring-in-silence judge would be lumped into whatever category the writer of the opinion was in this case. However, this limitation is less likely to burden this study because the Federal Circuit judges have shown little hesitancy in writing concurring or dissenting opinions, even though they are supposed to be unifying patent law.

Furthermore, any use of the voting patterns in this study as predictors will also be limited by the fact that they assume static laws. As the focus of the law changes, outcomes of previous cases are of less predictive value. For example, the Supreme Court recently disapproved of the Federal Circuit’s rigid test for obviousness. Many of the obviousness cases in this study were decided under this rigid regime. The outcome of these cases may be different if they were tried under the new KSR regime. This would undermine my thesis to a degree because a judge’s viewpoint should not shift based on changing law. However, judges take their responsibilities seriously and cannot outright disobey Supreme Court direction. As such, judges may begrudgingly apply the new test in a way that results in an outcome against their viewpoint. However, judges could find other avenues within the new regimes to arrive at a more palatable outcome. For example, in the obviousness context, a pro-brand judge may weigh secondary considerations (such as unexpected results) more heavily in a given case to overcome a presumption of obviousness.

While these limitations may couch this study, they do not eliminate its validity or its worth. Developing and using a relatively objective standard to code a relatively large set of cases overcome many of these limitations. Furthermore, some of these limitations will be present in any study using opinions as data and cannot be removed.

94. Some of the patents in these cases were deemed non-obvious solely because the rigid “Teaching, Suggestion, Motivation” (“TSM”) test was not met. See, e.g., Alza Corp. v. Mylan Labs., Inc., 391 F.3d 1365, 1372 (Fed. Cir. 2004); Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1344 (Fed. Cir. 2000).
IV. RESULTS

A. Judges in the Population

Twenty-five Federal Circuit judges (active or senior status) participated in at least one ANDA decision during the period of the study. As of this writing (March 2009), twelve active judges and four senior judges in the study remained on the bench. Some of the judges in the study participated in relatively few cases for a variety of reasons: some died or left the bench sometime after the study began; others were appointed during the period of the study; still others took senior status and did not have a full docket during this period. As a result, ten of the judges in the study participated in fewer than five decisions. The remainder participated in somewhere between thirteen and forty-one decisions in the population. Of the twenty-five participating judges, twenty-one wrote at least one opinion included in the study. The median number of written opinions (four) was fairly low, however. Only six judges wrote ten or more opinions. The full list of participations and writings is reprinted in Table 1.

One of the most striking findings about Federal Circuit decisions in ANDA cases is the apparent specialization of the court. A
relatively small number of judges have taken responsibility for writing a large proportion of the patent opinions produced by the court. This study includes 399 participations and 176 opinions altogether. Among the judges that participated in over ten cases, Judge Lourie wrote opinions in 23 of 30 cases in which he participated (76.7%). Also, Judge Rader wrote 26 opinions in 38 participations (68.4%), Judge Dyk wrote in 11 of 17 participations (64.7%), and Judge Newman wrote in 19 of 31 participations (61.3%). By contrast, Judge Friedman wrote only 3 opinions in 13 cases (23.1%), Judge Linn wrote 3 opinions in 14 cases (21.4%), and Judge Clevenger wrote 3 opinions in 19 participations (15.8%). If opinion writing is a measure of influence, a relatively small number of judges have a significant influence on the ANDA patent law. Collectively, Judges Rader, Lourie, and Gajarsa wrote 70 of the 176 opinions (39.8%) in the study; a group of six judges wrote over 63% of the opinions. Looking at binding outcomes, Judge Rader has written 20 majority opinions in the 129 binding decisions (15.5%) while three judges (Rader, Lourie, and Gajarsa) account for 52 of the majority opinions (40.3%). As such, it is fair to say that some judges have been more influential in the ANDA arena than others.

102. This includes majority, concurring, and dissenting opinions, including 8 dissents from denial of rehearing or rehearing en banc. The five per curium, three summary affirmances under R. 36, and two designee-written majority opinions are also included for voting determinations of the Federal Circuit as a whole.


104. See Allison & Lemley, supra note 11, at 753 (drawing a similar conclusion in patent validity cases).

105. Judges Rader (26), Lourie (24), Gajarsa (20), Newman (19), Schall (12), and Dyk (11) accounted for 112 of the 176 written opinions (63.6%).
Table 1. Participation and Authorship of Opinions by Federal Circuit Judges

<table>
<thead>
<tr>
<th>Judge</th>
<th># participate</th>
<th>Majority Opinion</th>
<th>Concurring Opinion</th>
<th>Dissenting Opinion</th>
<th>Total Authored</th>
</tr>
</thead>
<tbody>
<tr>
<td>Archer</td>
<td>15</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Baldwin</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Bennett</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
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<td>1</td>
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<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Bryson</td>
<td>27</td>
<td>6</td>
<td>1</td>
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<td>7</td>
</tr>
<tr>
<td>Clevenger</td>
<td>19</td>
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<td>0</td>
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</tr>
<tr>
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<td>0</td>
<td>0</td>
</tr>
<tr>
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<td>17</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
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<td>13</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
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<td>41</td>
<td>15</td>
<td>3</td>
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<td>20</td>
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<td>1</td>
<td>0</td>
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</tr>
<tr>
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<td>6</td>
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<td>0</td>
<td>1</td>
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<td>0</td>
<td>1</td>
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<td>19</td>
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<td>0</td>
<td>2</td>
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<tr>
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<td>1</td>
<td>0</td>
<td>6</td>
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<td>26</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Rader</td>
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<td>2</td>
<td>4</td>
<td>26</td>
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<td>Rich</td>
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<td>0</td>
<td>1</td>
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<td>9</td>
<td>1</td>
<td>2</td>
<td>12</td>
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<td>-</td>
<td>-</td>
<td>5</td>
</tr>
<tr>
<td>Designee</td>
<td>8</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

106. Includes concurring-in-part/dissenting-in-part opinions, as well as dissents from denial of rehearing petitions.
Looking at the panels as a whole, 110 distinct panels heard ANDA cases in the study. Only ten of the panels heard more than one ANDA case covered in the study. Two different panels heard four different ANDA cases, which was the most any panel heard together.\footnote{The two panels were: Judges Friedman, Gajarsa, and Mayer (holding for the brand in three cases) and Judges Gajarsa, Prost, and Rader (also holding for the brand in three cases).} Furthermore, 120 two-judge combinations heard at least one ANDA case with the average being 3.0 cases. Only three two-judge combinations heard ten or more cases together.\footnote{They are: Judges Gajarsa & Rader (11, 54.6\% pro-brand), Judges Gajarsa & Prost (12, 58.3\% pro-generic), and Judges Prost & Rader (13, 69.2\% pro-brand).} Any conclusions regarding panels or two-judge combinations, such as influence of one judge over another, are tenuous, at best, given the low recurrence of panels or two judge combinations.

In addition to analyzing the votes of individual judges, judges with some patent background or experience before joining the court were distinguished from judges without such a background.\footnote{See Allison & Lemley, \textit{supra} note 11, at 751 (employing the same grouping to study Federal Circuit judge voting in validity cases).} A judge is defined as having a patent background if they had regularly practiced patent law, or if they had a scientific or technical expertise. Nine of the twenty-five judges in the study have a patent background; sixteen did not.\footnote{The judges with patent law backgrounds are: Judge Baldwin, who has a degree in biology and served on the C.C.P.A from 1968 until 1982; Judge Gajarsa, who has a degree in electrical engineering and practiced patent law before his appointment; Judge Linn, who has a degree in electrical engineering and practiced patent law before his appointment; Judge Lourie, who has an advanced degree in chemistry, was corporate counsel for SmithKline Beecham, practiced and wrote about patent law before his appointment; Judge Markey, who has an advanced degree in patent law, practiced patent law before his appointment, wrote about patent law, and served on the C.C.P.A. from 1972 until 1982; Judge Moore, who has a degree in electrical engineering and taught and practiced patent law; Judge Newman, who has an advanced degree in chemistry, was a research chemist and a patent lawyer before her appointment; Judge Rader, who was counsel to the Senate subcommittee on patents, copyrights and trademarks, and has written on patent law; and Judge Rich, who helped draft the 1952 Patent Act, taught and practiced patent law, and served on the C.C.P.A. from 1956 until 1982. Judge Nies is not included in this group.} One could argue that
judges with a patent background could have a different viewpoint based on his or her experience than those without or that judges without patent law experience may be deferential to those with experience. Interestingly, these nine judges (24% of the judges in the study) accounted for 163 of 399 (40.9%) of the participations and wrote 96 of 176 (54.5%) opinions. This suggests that the non-patent experienced judges defer to the experienced judges for writing opinions.\(^\text{111}\) This deference is more pronounced if one considers that three of the nine judges (Baldwin, Markey, and Rich) dealt with relatively few ANDA cases and are no longer on the bench and that Judge Moore has had limited opportunity to participate in these cases as she was recently appointed (2006) to the Federal Circuit. Together, these four judges account for only nine participations and four opinions. Removing these four judges leaves five judges (20%) with patent law experience accounting for 38.6% of the participations and 52.3% of the opinions. Again, these five judges (Gajarsa, Linn, Lourie, Newman, and Rader) are quite influential in ANDA litigation.

**B. ANDA Cases**

A common assumption among patent lawyers in ANDA litigation is that different judges have different inclinations towards generic and brand pharmaceutical manufacturers. The individual judges, as well as the groups identified above, were tested to see if their voting and opinion writing demonstrated any patterns in ANDA cases.

Looking at binding outcomes (i.e., majority opinions and summary affirmances) from the Federal Circuit, 71 of the 129 cases (55.0%) have favored the brand/innovator. If all written opinions are included, 97 of 176 opinions (55.1%) have favored the brands. These numbers suggest that the Federal Circuit, as a

\(^{111}\) Allison & Lemley saw a similar phenomenon in validity cases. See Allison & Lemley, *supra* note 11, at 752-53. As in Allison & Lemley’s study, the results could be explained by the greater interest of such judges writing concurrences and dissents. However, these judges wrote 67 of 126 majority opinions (53.2%), which is similar to the amount of overall opinions (54.5%).
whole, has slightly favored brand pharmaceutical companies over generic companies in ANDA cases. This also suggests that the Federal Circuit is not straying too far from the Congressional intent behind the Hatch-Waxman and Medicare Amendments of providing generic competition while incentivizing innovation by the brands. However, the overall performance of the court does not necessarily mean that all the judges do not have their own individual voting patterns; the “pro-brand” and “pro-generic” judges could simply cancel each other out.

Comparing the voting patterns of patent-experienced judges versus non-experienced judges reveals an interesting trend. Judges with prior patent experience voted in favor of the brand companies 104 of 163 times (63.8%), while judges without patent experience voted in favor of brand companies 114 of 227 times (50.2%). As such, judges with patent experience were somewhat more likely (13.6%) to find in favor of brands than judges without such experience. This discrepancy may reflect the more pro-patentee stance that would be expected of prior practitioners and patent law professors. On the other hand, the non-experienced group may be less influenced by their backgrounds and may focus more on Congressional intent behind the acts that they are enforcing and interpreting, which is borne out in the nearly balanced voting record in ANDA cases. Coupled with their large amount of opinions and participations, the judges with patent-experience and “pro-brand” stance may have an interesting effect on future litigation considering that 50% of the current roster of active judges on the Federal Circuit has patent law experience.112

Looking at individual judges voting patterns, it was difficult to categorize judges as either “pro-generic” or “pro-brand.” Of the fifteen judges who participated in more than ten ANDA decisions,113 the majority came quite close to the average pro-brand voting rate of 55.6%.114 The

112. This assumes that trends will continue and that this study has a scintilla of predictive value. However, as discussed earlier, predictions made from the historical data in this study are tenuous, at best.

113. These fifteen judges accounted for 371 of the 399 participations (93.0%) in the study and, therefore, are representative of the entire study.

114. This percentage differs slightly from the overall percentages identified earlier in the study because participations are being measured, not cases or
complete list of votes and generic outcomes are detailed in Table 2. There were a few outliers as six judges (Rader, Newman, Linn, Friedman, Clevenger, and Mayer) fell outside one standard deviation from the mean. On the brand side, Judge Rader voted pro-brand in 30 of 38 cases (79.0%), Judge Newman voted pro-brand in 24 of 31 participations (77.4%), Judge Linn voted pro-brand in 10 of 14 cases (71.4%), and Judge Friedman voted pro-brand in 9 of 13 cases.

**Table 2. Pro_Generic Votes**

<table>
<thead>
<tr>
<th>Judge</th>
<th># participating</th>
<th># pro generic</th>
<th>% generic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Archer</td>
<td>15</td>
<td>7</td>
<td>46.7%</td>
</tr>
<tr>
<td>Baldwin</td>
<td>2</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Bennett</td>
<td>1</td>
<td>1</td>
<td>100.0%</td>
</tr>
<tr>
<td>Bissell</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Bryson</td>
<td>27</td>
<td>14</td>
<td>51.9%</td>
</tr>
<tr>
<td>Clevenger</td>
<td>19</td>
<td>11</td>
<td>57.9%</td>
</tr>
<tr>
<td>Cowen</td>
<td>3</td>
<td>1</td>
<td>33.3%</td>
</tr>
<tr>
<td>Dyk</td>
<td>17</td>
<td>9</td>
<td>52.9%</td>
</tr>
<tr>
<td>Friedman</td>
<td>13</td>
<td>4</td>
<td>30.8%</td>
</tr>
<tr>
<td>Gajarsa</td>
<td>41</td>
<td>23</td>
<td>56.1%</td>
</tr>
<tr>
<td>Linn</td>
<td>14</td>
<td>4</td>
<td>28.6%</td>
</tr>
<tr>
<td>Lourie</td>
<td>30</td>
<td>14</td>
<td>46.7%</td>
</tr>
<tr>
<td>Markey</td>
<td>1</td>
<td>1</td>
<td>100.0%</td>
</tr>
<tr>
<td>Mayer</td>
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<td>15</td>
<td>60.0%</td>
</tr>
<tr>
<td>Michel</td>
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<td>12</td>
<td>40.0%</td>
</tr>
<tr>
<td>Moore</td>
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<td>2</td>
<td>50.0%</td>
</tr>
<tr>
<td>Newman</td>
<td>31</td>
<td>7</td>
<td>22.6%</td>
</tr>
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<td>Nies</td>
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<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Plager</td>
<td>16</td>
<td>9</td>
<td>56.3%</td>
</tr>
<tr>
<td>Prost</td>
<td>26</td>
<td>12</td>
<td>46.2%</td>
</tr>
</tbody>
</table>

opinions, as the denominator. The ratios may differ because some decisions included a dissent, because some cases were decided en banc, and because some cases were decided with the participation of only two Federal Circuit judges.
(69.2%). On the generic side, Judge Mayer voted in favor of generics in 15 of 25 cases (60.0%), Judge Clevenger voted in favor of generics in 11 of 19 cases (57.9%). Judges Plager (56.3%) and Gajarsa (56.1%) favored generics in their voting as well, though within one standard deviation from the mean. Aside from the judges discussed above, the voting patterns of the other judges do not seem to support their characterization as necessarily “pro-generic” or “pro-brand” based on voting alone given the small deviation from the average.

As judges appear to relax their preferences somewhat when joining opinions, 115 looking at opinion writing may provide a better insight into the judges’ stances in ANDA cases. Of the eleven judges who wrote more than five opinions, 116 the majority came quite close to the average pro-brand opinion writing rate of 50.8%. The complete list of opinions and generic outcomes are detailed in Table 3. Five judges (Bryson, Newman, Dyk, Mayer, and Gajarsa) opinions favoring one side or the other fell outside one standard deviation from the mean. On the brand side, Judge Bryson wrote pro-brand in 6 of 7 opinions (85.7%) and Judge Newman wrote pro-brand in 16 of 19 opinions (84.2%). On the generic side, Judge Gajarsa wrote pro-generic opinions 15 out of 20 total (75.0%), Judge Mayer wrote 6 of 8 opinions (75.0%) favoring generics, and Judge Dyk wrote pro-generic in 8 of 11 opinions (72.7%). Notably, Judge Rader wrote 19 of 26 opinions (73.1%) favoring the brand, which was approximately one standard deviation from the mean.

Given their large deviation from the average in both voting and

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<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Rader</td>
<td>38</td>
<td>8</td>
</tr>
<tr>
<td>Rich</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Schall</td>
<td>29</td>
<td>14</td>
</tr>
<tr>
<td>Skelton</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Smith</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

115. Another commentator has seen this trend in choices between claim construction methodologies in Federal Circuit judges. See Wagner & Petherbridge, supra note 11, at 1158.

116. These eleven judges accounted for 149 of the 176 participations (84.7%) in the study and, therefore, are representative of the entire study.
opinion writing as shown in Figure 1, Judges Newman (pro-brand: 77.4% votes, 84.2% opinions) and Mayer (pro-

117. Judges with ten or more participations were included in Figure 1. The trendline is drawn to voting records. Because of the limited number of opinions written by some of the judges, the writing data series may appear to give disparate results in some cases.
Table 3. Pro-Generic Opinions.

<table>
<thead>
<tr>
<th>Judge</th>
<th># opinions</th>
<th># pro generic</th>
<th>% pro generic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Archer</td>
<td>4</td>
<td>3</td>
<td>75.0%</td>
</tr>
<tr>
<td>Baldwin</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Bennett</td>
<td>0</td>
<td>0</td>
<td>n/a</td>
</tr>
<tr>
<td>Bissell</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Bryson</td>
<td>7</td>
<td>1</td>
<td>14.3%</td>
</tr>
<tr>
<td>Clevenger</td>
<td>3</td>
<td>2</td>
<td>66.7%</td>
</tr>
<tr>
<td>Cowen</td>
<td>0</td>
<td>0</td>
<td>n/a</td>
</tr>
<tr>
<td>Dyk</td>
<td>11</td>
<td>8</td>
<td>72.7%</td>
</tr>
<tr>
<td>Friedman</td>
<td>3</td>
<td>1</td>
<td>33.3%</td>
</tr>
<tr>
<td>Gajarsa</td>
<td>20</td>
<td>15</td>
<td>75.0%</td>
</tr>
<tr>
<td>Linn</td>
<td>3</td>
<td>1</td>
<td>33.3%</td>
</tr>
<tr>
<td>Lourie</td>
<td>23</td>
<td>11</td>
<td>47.8%</td>
</tr>
<tr>
<td>Markey</td>
<td>1</td>
<td>1</td>
<td>100.0%</td>
</tr>
<tr>
<td>Mayer</td>
<td>8</td>
<td>6</td>
<td>75.0%</td>
</tr>
<tr>
<td>Michel</td>
<td>9</td>
<td>4</td>
<td>44.4%</td>
</tr>
<tr>
<td>Moore</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Newman</td>
<td>19</td>
<td>3</td>
<td>15.8%</td>
</tr>
<tr>
<td>Nies</td>
<td>2</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Plager</td>
<td>6</td>
<td>3</td>
<td>50.0%</td>
</tr>
<tr>
<td>Prost</td>
<td>8</td>
<td>4</td>
<td>50.0%</td>
</tr>
<tr>
<td>Rader</td>
<td>26</td>
<td>7</td>
<td>26.9%</td>
</tr>
<tr>
<td>Rich</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Schall</td>
<td>12</td>
<td>7</td>
<td>58.3%</td>
</tr>
<tr>
<td>Skelton</td>
<td>0</td>
<td>0</td>
<td>n/a</td>
</tr>
<tr>
<td>Smith</td>
<td>0</td>
<td>0</td>
<td>n/a</td>
</tr>
</tbody>
</table>

generic: 60.0% votes, 75.0% opinions) have displayed a propensity for favoring one side in ANDA litigations in past cases.
Furthermore, the past performances of Judges Rader (pro-brand) and Gajarsa (pro-generic) appear to favor one side when one considers the combination of their voting and opinion writing records and the large number of cases that they have been involved in. For example, Judge Rader participated in thirty-eight cases and voted for brands in 78.9% of his cases and wrote pro-brand in 73.1% of his opinions. Similarly, Judge Gajarsa participated in forty-one cases and voted pro-generic in 56.1% of his cases and wrote pro-generic in 75.0% of his opinions. In addition, Judges Clevenger (pro-generic), Linn (pro-brand), and Friedman (pro-brand) have shown a moderate preference for one side in a lesser number of cases. For example, in nineteen cases, Judge Clevenger voted pro-generic 57.9% and wrote pro-generic 66.7% of the time, Judge Linn voted pro-brand 71.4% and wrote pro-brand 66.7% in fourteen participations, and Judge Friedman voted pro-brand 69.2% and wrote pro-brand 66.7% of the time in thirteen cases. However, none of these three judges have either their voting or writing patterns outside one standard deviation from the respective means. Also, each judge has written only three opinions. As such, any inference of a preference is less so than the other judges identified. The other nine judges with ten or more participations have not shown a strong preference for one side or the other when looking at their voting records and opinion writing. Instead of focusing on the entire dataset, a number of interesting trends arise when the data set is separated into pre- and post-Medicare Amendments time frames. Most, if not all, of the cases in this study do not apply the law under the Medicare Amendments (MMA) because a majority of the provisions of the MMA are not retroactive and the ANDAs were filed prior to the enactment date set in the MMA. However, the reasoning and goals behind the act (i.e., to further aid generic competition with brands) may be influencing the judges. A comparison of pre- and post-MMA voting, opinion writing and outcomes are detailed in Table 4. Overall, the voting of the court went from 52.8% pro-brand prior to the MMA to 57.3% pro-brand after enactment. Interestingly, the number of binding opinions favored brands 56.7% of the time post-MMA, up from 52.7% pre-MMA. Overall opinions favored

118. This table includes all twelve active status judges and all four senior status judges that comprise the current Federal Circuit.
brands 54.4% of the time pre-MMA as to 54.7% post-MMA. These results show that the court has shifted pro-brand in its binding outcomes and suggests the number of dissents and concurrences are being written supporting generics has risen since 2003.

Looking at the ten judges\(^\text{119}\) that had seven or more participations pre- and post-enactment of the MMA,\(^\text{120}\) some judges have solidified their stance on one side of the debate or the other in recent years. For example, Judge Gajarsa has voted pro-generic in 66.7% of his cases since the MMA compared to 35.7% pre-MMA and has written pro-generic in 85.7% of his opinions post-MMA compared to 40.0% pre-MMA. Judge Mayer has also moved more strongly pro-generic since the MMA: voting 72.7% post-MMA vs. 56.3% pre-MMA. On the brand side,

### Table 4. Comparison of Pre- and Post-Medicare Modernization Act Jurisprudence\(^\text{121}\)

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Archer</td>
<td>37.5% (8)</td>
<td>57.1% (7)</td>
<td>100.0% (1)</td>
<td>66.7% (3)</td>
</tr>
<tr>
<td>Bryson</td>
<td>53.9% (13)</td>
<td>50.0% (14)</td>
<td>0.00% (2)</td>
<td>20.0% (5)</td>
</tr>
<tr>
<td>Clevenger</td>
<td>72.7% (11)</td>
<td>37.5% (8)</td>
<td>66.7% (3)</td>
<td>n/a</td>
</tr>
</tbody>
</table>

119. These judges are: Bryson (13 pre, 14 post); Clevenger (11, 8); Gajarsa (14, 27); Lourie (14, 16); Mayer (16, 11); Michel (14, 17); Newman (13, 17); Plager (9, 7); Rader (13, 24); and Schall (13, 16).

120. The dividing line was December 8, 2003, the date of enactment. This may be a bit arbitrary, as this requires the Federal Circuit judges had knowledge that the act passed and the Congressional intent behind the act. This is especially true in the two cases decided in December 2003. See Pharmacia & Upjohn Co. v. Ranbaxy Pharmas., Inc., 85 F. App'x 205 (Fed. Cir. Dec. 23, 2003); In re Omeprazole Patent Litigation, 84 F. App'x 76 (Fed. Cir. Dec. 11, 2003). However, any line would be arbitrary due to the fact that the influence of the act is being implied and is not a direct correlation to the law being in effect.

121. The number in parentheses represents the number of votes or opinions for the judge in that category.
Judge Newman has voted pro-brand in 88.2% of her cases post-MMA versus 61.5% pre-MMA and 90.0% of her opinions are favorable to the brand companies since the MMA compared to 75.0% pre-MMA. Also, Judge Rader has voted pro-brand 83.3% of the time post-MMA versus 69.2% of the time pre-MMA, and 75.0% of his opinions have favored brands post-MMA as opposed to 66.7% pre-MMA.

Other judges who appear relatively impartial from their entire voting and writing records show a severe trend shift when their decisions are examined pre- and post-MMA. Judge Lourie

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</tr>
</thead>
<tbody>
<tr>
<td>Judge Newman</td>
<td>88.2%</td>
<td>61.5%</td>
<td>90.0%</td>
<td>75.0%</td>
</tr>
<tr>
<td>Judge Rader</td>
<td>83.3%</td>
<td>69.2%</td>
<td>75.0%</td>
<td>66.7%</td>
</tr>
</tbody>
</table>

Other judges who appear relatively impartial from their entire voting and writing records show a severe trend shift when their decisions are examined pre- and post-MMA.
is a prime example as shown in Figure 2. Looking at his entire record, Judge Lourie has voted pro-brand 53.3% of the time. However, since December 2003, he has voted pro-brand in 81.3% of his participations. Obviously, Judge Lourie voted heavily in favor of the generic (78.6%) prior to that time. His opinion writing has mirrored that trend: 52.2% pro-brand overall but 75.0% pro-brand post-MMA and 72.7% pro-generic pre-MMA. Judge Clevenger has followed a similar trend in his voting: overall he has voted pro-generic 57.9% of the time, however, post-MMA enactment he has voted pro-brand 62.5% of the time versus 72.7% pro-generic pre-MMA.

Looking at the changes in voting patterns, Judge Gajarsa showed the largest pro-generic shift (Δ 31.0%) since 2003, followed by Judge Mayer (Δ 16.5%). Meanwhile, Judge Lourie showed the largest pro-brand shift (Δ 59.8%), followed by Judges Clevenger (Δ 35.2%), Newman (Δ 26.7%), Schall (Δ 24.0%), Plager (Δ 23.8%), and Rader (Δ 8.6%). Only three judges (Lourie, Mayer, and Gajarsa) were more than one standard deviation from the average shift of the court. The behavior of these judges may...
be surprising in light of Congress' intent to improve generic competition with the MMA. Perhaps the judges that swung towards the brand side felt that Congress went too far in enabling generics or that incentives for the brand companies to bring new drugs to market would be too diminished.¹²²

V. IMPLICATIONS

A major implication of this study is that four or five of the judges that are currently on the Federal Circuit have decided cases with a strong viewpoint towards one side in ANDA litigations. Judges Gajarsa and Mayer have consistently voted and written pro-generic, especially since late 2003. On the other side, Judges Newman and Rader have clearly and consistently voted and written pro-brand. Judge Newman has moved further towards the brand in the years since the MMA was enacted. In addition, Judge Lourie's voting and writing pattern since 2003 has strongly favored brand companies.

From this major implication, a secondary implication is that these judges have not followed the intent Congress had in enacting the Hatch-Waxman Act – to provide a balance between generic competition and brand innovation. Judicial activism becomes a concern when a judge constantly flouts the intentions of Congress. From Judge Newman's viewpoint, "divergence [of viewpoints] also reflects the court's 'activism,' as new facts lead it into areas of uncertain public policy, and the court brings its own viewpoints to bear on the jurisprudence assigned to it."¹²³ She has also "caution[ed] against a retrenchment from that elegant simplicity [effective Federal Circuit opinions], into a policy-driven activism whereby the application of the law will not be known until the Federal Circuit hears the case."¹²⁴ However, Judge Newman's quest for simplicity is misplaced and predictability is

¹²². Interestingly, Judges Lourie and Newman have prior experience at brand pharmaceutical companies both as researchers and in their IP departments, which may explain their strong pro-brand voting and writing patterns.
¹²⁴. Id.
not the only or the primary goal of patent law jurisprudence, especially where Congress has dictated a desire for balancing competing interests. Under the United States Constitution, judges are supposed to follow Congressional mandates and only substitute their own judgments when the language and legislative history from Congress is not clear. Congress was clear in its intentions in the ANDA context. As such, Judges Newman, Rader, Lourie, Gajarsa, and Mayer may have allowed their own preferences to enter into their decisions in spite of the intentions of balance from Congress. Judges Gajarsa and Mayer may be somewhat excused for this behavior in light of the intention behind the MMA, namely, to further allow generic competition. However, Judges Lourie, Newman, and Rader may be acting as advocates for their views and venturing into an area that is reserved for members of Congress.

Another secondary implication is that the outcome of an ANDA case may be determined by the panel that hears the case. For example, it seems unlikely that a generic would have much of a chance to win a close case when Judges Newman, Rader, and Lourie are on the panel. However, the paucity of panel data does not lend this hypothesis to empirical analysis. As a general matter, the Federal Circuit does not reveal the identity of the judges assigned to a particular case until oral argument. Assuming that the composition of panels may affect the outcome in ANDA cases, this policy has important effects, both positive and negative.

On the negative side, keeping panel membership a secret until oral argument dramatically decreases the chances of settlement while an appeal is pending. By the time the parties know of the identity of the panel, all costs of the appeal (writing briefs, filing fees, argument preparation, etc.) have been expended, perhaps removing the primary impetus for settlement. In contrast,


126. Similarly, the lack of the same two-judge combinations hearing multiple cases prevents objective analysis in this regard.
a rule that allows parties to know panel membership months in advance would increase both the time and the cost-incentives to settle the appeal.\textsuperscript{127} More settlements mean lower social costs and free the Federal Circuit to spend additional time on the more difficult (and less predictable) cases. A policy change by the court to release panel composition as soon as possible would be a simple, cost-free way for the court to increase the settlement rate.

On the other hand, there are jurisprudential benefits to the Federal Circuit’s current panel secrecy policy. One important finding of this study is that while several members of the Federal Circuit have voted distinctly for one side in ANDA cases, about half of the court has not. This in turn means that some panels will be more predictable than others - for example, those with a majority of “swing” judges or a combination of all three types (pro-generic, pro-brand, and swing) would be harder to predict. Given this understanding, settlement rates will likely be unequally distributed when panel composition is known with less settlement of panels that are relatively less predictable.\textsuperscript{128} This, then, has the potential of affecting the jurisprudence, with a larger proportion of opinions being decided by panels (and written by judges) that are less predictable. This, obviously, could have long-term negative effects on the overall performance of the court.

VI. CONCLUSIONS

Overall, the Federal Circuit has come close to meeting the Congressional goals embodied in the Hatch-Waxman Act based on the nearly 50% split in binding decisions in ANDA cases. However, a significant number of judges have voted and written opinions in a manner that could be viewed as inconsistent with the intentions of Congress. Judges Gajarsa and Mayer have sided with the generics in their voting and opinions while Judges Rader and Newman have supported the brands. Recently, Judge Lourie has voted and written pro-brand nearly exclusively. Unfortunately,

\textsuperscript{127} Cf. George L. Priest & Benjamin Klein, The Selection of Disputes for Litigation, 13 J. LEGAL STUD. 1, 15-16 & fig.6 (1984) (depicting how expectations can affect the likelihood of settlement).

\textsuperscript{128} See id. at 15-16 (demonstrating the relationship between settlement rates and predictability).
there is insufficient data to determine the effects of these individual judges on each other and the other judges of the Federal Circuit when empanelled together. However, this study raises concerns that these judges could be becoming more like advocates and also that they could be flouting Congressional intent by disregarding a balanced approach to ANDA jurisprudence. Finally, any advantage in furthering settlements coming from the predictably of these judges is lost due to the Federal Circuit’s policy of not announcing panels prior to oral argument.

Martin S. Masar III