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Hatch-Waxman in the Federal Courts: From 1994–2004

S. Peter Ludwig, Kristin Behrendt Kosinski, and Jonathan Harris
Darby & Darby, P.C., USA

ABSTRACT Decisions of the federal courts play a crucial role in drug development. Litigation related to drug development and approval under the abbreviated new drug application ("ANDA") process over the past 10 years was evaluated, examining over 300 written decisions from 22 U.S. District Courts and the U.S. Court of Appeals for the Federal Circuit. These written decisions represent the majority of patent litigation between brand and generic drug manufacturers. The reported data set provides critical information for the drug development and litigation strategies of both brand and generic manufacturers. The examination also provides a realistic portrayal of the anticipated outcome if a legal action is initiated.

KEYWORDS Hatch-Waxman, ANDA, Litigation, Drug approval

INTRODUCTION

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. No. 98–417, 1984 Stat. 1538 [codified in various sections of Titles 15, 21, 28, and 35 of the United States Code, U.S.C.]) popularly known as the Hatch-Waxman Act, ("the Act."), intended, in part, to expedite the marketing of generic drugs and medical devices. Although it restores to the patent holder a portion of the patent term lost during the regulatory [Food and Drug Administration (FDA)] approval process, the Act provides an avenue that can enable competing generic drugs to come to market sooner. The Act also encourages litigating the validity and breadth of pharmaceutical patents.

The Hatch-Waxman Act

The Act eliminates the de facto patent term extension that existed under the prior legal regime by providing that is not infringement to make, use, or sell a patented invention as long as the activity is reasonably related to obtaining FDA approval [35 U.S.C. 271(e)(1) (2004)]. Previously, experiments using a patented invention were infringing uses, even if only for the purpose of obtaining FDA approval to market a drug once the patent expired (*Roche Prod. Inc. v. Bolar Pharm. Co.* 733 F.2d 858 [Fed Cir.], *cert. denied*, 469 U.S. 856[1984]). As a result of the Act's reforms, the day after a patent on a

Address correspondence to S. Peter Ludwig, Darby & Darby, P.C., New York, NY, USA; E-mail: pludwig@darbylaw.com

brand name drug expires, it is now possible for generic drug makers to have a competing product on pharmacy shelves.

Congressional testimony prior to Hatch-Waxman reported that there were 150 drugs off-patent for which no generic existed because the cost of FDA approval was too great (H.R. Rep. No. 98–857, pt. 1 [1984]). Under the Act, generic manufacturers can now file abbreviated new drug applications (ANDAs) for generic versions of previously approved drugs. An ANDA significantly decreases the time and expense of the process for new drug approval because it requires a limited set of data for approval (21 U.S.C. 355[j] [2004]). The ANDA can be approved based upon evidence that the active ingredient of the generic version of a previously approved drug is "bioequivalent," i.e., has the same therapeutic effect, as the previously approved drug. The extensive safety and effectiveness studies required of a full new drug application are not required for ANDA approval (21 U.S.C. 355[j][2][A][iv][2004]). Therefore, generic drug makers need no longer spend the time and money for clinical trials that might otherwise impede the marketing of generic drugs (Mossinghoff, 1999).

Besides removing legal and administrative roadblocks to FDA approval, the Hatch-Waxman Act effectively puts a bounty on pioneer drug patents. An applicant seeking FDA approval to market a generic version of an approved drug must file its ANDA with a certification as to the status of the patents, if any, related to the innovator version of the generic drug listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") (21 U.S.C. 355[j][2][A][vii][2004]). The Orange Book is a list of all FDA approved drugs and the marketing exclusivities and patents covering such drugs. One of the following patent certifications maybe made by the ANDA applicant: 1) a patent has not been filed, 2) the patent has expired, 3) the drug will not be marketed until the date the patent expires, or 4) the patent is invalid or will not be infringed (21 U.S.C. 355[j][2][A][vii][2004]). A paragraph IV certification certifies that the patent at issue (presumably the patent that is "listed" in the Orange Book by the innovator as covering the original "branded" drug) is either invalid or the marketing of the generic drug will not infringe on the innovators "listed" patent (21 U.S.C. 355[j][2][A][vii][IV][2004]).

Each claim of a patent is presumed valid unless it can be shown that a claim fails to comply with a section of Title 35 of the United States Code governing patents (35 U.S.C. 282). Accordingly, if the ANDA applicant asserts that the patent is invalid, it alleges that each claim fails to comply with the patent statute. Alternatively, if the applicant contends that the marketing of the generic drug will not infringe, the applicant alleges that its drug does not meet the elements of any of the patent claims either literally or under the Doctrine of Equivalents. While a paragraph IV certification standing alone does not assert "unenforceability" of a patent, the generic applicant may also allege that the patent is unenforceable due to inequitable conduct before the U.S. patent and Trademark Office.

The first ANDA applicant to file a paragraph IV certification is given a 180-day exclusive marketing period beginning from the first commercial marketing of the generic drug (or beginning from a favorable court decision under the pre-December 8, 2003 law) (21 U.S.C. 355[j][5][B][iv][2004]). Thus, a drug maker who seeks approval for a generic version of a patented brand name drug stands to profit from supracompetitive pricing during the roughly 6 months of exclusivity if it obtains a favorable court decision or settlement thereby removing the patent as a barrier to entry.

Accordingly, the Act provides an avenue that can enable competing generic drugs to come to market sooner by way of the ANDA approval process; however, the Act also encourages litigating pharmaceutical patents covering brand-name drugs. This article focuses on litigation related to ANDA filings under the Hatch-Waxman Act, and the corresponding patent challenges raised by the ANDA filings.

MATERIALS AND METHODS

An Empirical Review of ANDA Litigation

This article takes an in-depth look at litigation related to ANDA filings under the Hatch-Waxman Act during the 10-year period from 1994 to 2004. It presents the results of an examination of over 300 written decisions from 22 U.S. District Courts and the

U.S. Court of Appeals for the Federal Circuit ("CAFC").

The population studied consists of all written decisions of patent cases from July 1, 1994 to July 1, 2004 that cite an ANDA filing. The population was obtained from a LEXIS® search for all patent cases from federal courts containing the term "ANDA."

The population also includes four district court opinions from an earlier date that were the subject of appeals decided by the CAFC during the time frame of the study. This was done for completeness in analyzing the appellate court's affirmance and reversal rates. As of July 1, 2004, there were nine decisions of district courts within the last year for which an appeal is possibly pending (four in favor of the innovator–all motions for summary judgment, and five in favor of the generic–three bench trials and two motions for summary judgment). A motion for summary judgment is a procedural device that allows fast disposition of a claim or defense without the need for trial. A court will grant the motion if it finds that the claim or defense presents no genuine issue of material fact.

During the course of the study, decisions were found that, though dealing with an ANDA, did not mention this term "ANDA" (*Bristol-Myers Squib v. Boehringer Ingelheim*, 86 F. Supp. 2d 433, D.N.J. 2000). However, these appear to be exceptions, and it is believed that reviewing the prior and subsequent histories of the cases that do reference the ANDA filing has produced a population of essentially all written decisions concerning generic ANDA filings.

Excluded from the study are decisions in cases where the infringement, validity, or unenforceability of a patent was not in issue (*Lousiana Wholesale Drug Co. v. Hoechst Marion Roussel*, 332 F.3d 896 [6th Cir. 2003] and *SmithKline Beecham v. Watson Pharms.*, 211 F.3d 21 [2d Cir.] *cert. denied*, 531 U.S. 872 [2000]) and orders certifying an issue for appeal, denying rehearing, or issuing a judgment order. Typically, such a study would fail to include jury trials, since they often lack a written opinion; and, in fact, only one motion for a judgment as a matter of law ("JMOL") following a jury trial was discovered (*Upjohn v. Mova Pharm.*, 31 F. Supp. 2d 211 [D.P.R. 1998], *aff'd in part, rev'd in part*, 225 F.3d 1306 [Fed. Cir. 2000]). However, it is unlikely that many disputes over an ANDA filing are ever tried before a jury. Though patent holders might be more likely to favor jury trials because it has been found that patent holders prevail in 68% of suits tried before a jury compared to 51% of suits before judges (Moore, 2000) they usually do not have the right to a jury trial in the customary ANDA litigation because the only relief being sought is equitable in nature (*Glaxo Wellcome v. Geneva Pharm.*, 45 U.S.P.Q. 2d 1702 [D.N.J.], *aff'd*, 110 F.3d. 1562 [Fed. Cir. 1997]. Therefore, the population as defined likely represents the vast majority of Hatch-Waxman litigation between brand and generic manufacturers. Out of the 300 Hatch-Waxman cases reviewed, the majority of the analysis reported below is based on a smaller subset of about 65 disputes that were resolved by one or more decisions.

RESULTS AND DISCUSSION

Final Decisions

The population of decisions includes 65 disputes that were resolved by one or more decisions at the district court level. Of those, 41 resulted in review and a written decision by the CAFC. One of four types of decision resolved the dispute: 1) dismissal, 2) summary judgment on the merits, 3) JMOL, or 4) trial verdict with the judge sitting as the finder of fact. The results of these decisions are presented in Table 1. Note that the abbreviations "Aff/Rev" in the tables below refer to decisions that were either "affirmed" or "reversed."

TABLE 1 **Final Decisions of Innovator-Generic Disputes**

Type of decision	Innovator prevails	Aff/Rev	Generic prevails	Aff/Rev
Motion to dismiss	0	–	1	0/1
Summary judgment	7	3/0	30	13/8
JMOL	1	1/0	1	1/0
Bench trial	14	7/0	11	6/1
All decisions	22	11/0	43	20/10
Final disposition	26		33	

In 66% of the disputes, the generic applicant prevailed in district court. Upon review, one-third of these decisions were reversed or vacated, leaving generic applicants with a 56% success rate in all disputes that have reached final disposition. The generic applicant was successful in only 24% of arguments before the court of appeals. As discussed above, as of July 1, 2004, district courts decided nine of these disputes within the last year. It is likely that appeals are pending for at least some of these. If these decisions were excluded from the results above, the generic win rate would remain unchanged.

In 34% of the disputes, the innovator prevailed in district court. In the court of appeals, the innovator won in 76% of arguments before the court. Of the 10 district court decisions overturned in favor of the innovator, six summary judgment motions were vacated and remanded for further action by the district court. The remainder (four cases) were reversed with judgment for the innovator. Most of these four cases overturned motions for summary judgment granted in favor of the generic applicant. Thus, the resulting final disposition after appeal where the innovator prevailed totaled 26 (i.e., 22 favorable district court decisions minus zero reversals of these decisions plus four cases reversing a judgment for the innovator), providing a 40% success rate of the innovator in all disputes that have reached a final disposition.

The decrease in the success rate of the generic litigant from the district court to the CAFC and the corresponding increase in the success rate of the innovator in all disputes that have reached a final disposition demonstrates that while generics may fare well in district court proceedings, the score is evened when the cases are reviewed on appeal. The high success rate of the innovator over the generic in arguments before the court of appeals further supports this conclusion.

Grounds for Decision

In the 43 district court decisions in which the generic applicant prevailed, the court based its decision on noninfringement in 74% of cases. In 26% of cases, the patents or claims were found invalid. Seven percent of the decisions relied on unenforceability of the patent to find in the generic's favor. Occasionally, a court would rule that in addition to no infringement occurring, a patent was invalid or that a patent was invalid and unenforceable; thus, the total percentage of decisions reported on noninfringement, invalidity, and unenforceability is greater than 100%. In no instance did a court find a patent valid but unenforceable. Table 2 summarizes the grounds for decision and how they fared on appeal.

Decisions by Type of Patent Claim

The final decisions required construing numerous patent claims that were classified as covering either 1) a new chemical entity, e.g., a chemical compound that was not previously approved by the FDA, 2) a pharmaceutical formulation, 3) a method of treatment, or 4) a method of manufacturing a pharmaceutical composition. Table 3 breaks down the final disposition of those claims following any appeal with respect to validity, infringement, and enforceability of the claims.

The validity of new chemical entity patents was affirmed in 73% of the cases challenging validity. The courts upheld the validity of patents claiming formulations, methods of treatment, and methods of manufacturing a drug in 66% of the cases challenging validity.

In final dispositions of court actions where infringement was an issue, 50% of decisions found new chemical entity patents infringed, 43% found formulation patents infringed, 45% found method of

TABLE 2 Grounds for Decision in Favor of Generic Applicant

Proceeding	Noninfringement	Invalid	Unenforceable
District court	32	14	3
Federal circuit			
Vacated	6	0	0
Reversed	2	3	1
Final disposition	24	11	2

TABLE 3 Decisions of Validity, Infringement, and Unenforceability by Claim Type

Type of patent claim	Decisions	Valid	Invalid	Infringement	Noninfringement	Enforceable	Unenforceable
New chemical entity	21	11	4	6	6	4	1
Formulation	29	10	5	10	13	5	1
Method of treatment	15	6	3	5	6	2	0
Method of manufacture	7	2	1	2	4	0	0
All claims	72	29	13	23	29	11	2

treatment claims infringed, and 33% found method of manufacture patents infringed.

Where enforceability was an issue, the courts found new chemical entity patents unenforceable 20% of the time, while formulation patents were unforceable 17% of the time. In actions involving enforceability of patents with method of treatment claims, 100% of the patents were found enforceable. Enforceability of patents claiming method of manufacture was not challenged.

Accordingly, the courts were most likely to find patents claiming new chemical entities valid and infringed. However, while only one such patent was found unenforceable, the rate of unenforceability of patents claiming new chemical entities was the highest of all types of patents reviewed.

Results by District Court

A perception that some circuit courts were "pro-patent" while others were "anti-patent" in part prompted the 1982 creation of the U.S. Court of Appeals for the Federal Circuit and its grant of exclusive appellate jurisdiction over appeal of patent infringement decisions (*Florida Prepaid Postsecondary Educ, Expense Bd. v. College Sav. Bank*, 527 U.S. 627,

TABLE 4 Likelihood of Success by District

District court	Decisions	Innovator prevails	Aff/Rev	Generic prevails	Aff/Rev
Northern District of Illinois	12	3	1/0	9	4/4
District of New Jersey	10	2	1/0	8	4/1
Southern District of New York	9	5	3/0	4	1/0
Southern District of Florida	5	0	–	5	1/3
Eastern District of Pennsylvania	4	1	0/0	3	2/0
District of Delaware	3	2	1/0	1	0/0
Eastern District of North Carolina	3	2	2/0	1	1/0
Central District of California	2	0	–	2	0/0
District of Massachusetts	2	1	0/0	1	0/0
District of Maryland	2	2	1/0	0	–
Eastern District of Virginia	2	0	–	2	1/1
Northern District of Georgia	2	0	–	2	1/1
Southern District of Indiana	2	2	1/0	0	–
District of Connecticut	1	0	–	1	1/0
District of Minnesota	1	0	–	1	1/0
District of Puerto Rico	1	0	–	1	1/0
District of Vermont	1	1	0/0	0	–
Northern District of California	1	0	–	1	1/0
Northern District of West Virginia	1	0	–	1	1/0
Southern District of California	1	1	1/0	0	–
All decisions	65	22	11/0	43	20/10

TABLE 5 Resolution of All Motions

		Motion by innovator				Motion by generic			
Type of motion	Decisions	Granted	Aff/Rev	Denied	Aff/Rev	Granted	Aff/Rev	Denied	Aff/Rev
Preliminary injunction	5	4	2/1	0	–	0	–	1	0/0
Motions to dismiss	22	4	0/0	4	0/0	7	0/1	7	0/0
Summary judgment (on the merits)	77	13	4/1	1	0/0	46	21/9	17	2/0
Summary judgment (not on the merits)	7	2	0/1	1	0/0	2	0/1	2	0/1
Other motions	44	12	1/1	12	0/0	9	0/0	11	0/0
All motions	155	35	7/4	18	0/0	64	21/11	38	2/1

651 n.3 [1999] [J. Slevens dissenting]). In 1992, the Advisory Commission on Patent Law Reform's recommendation that a single district in each circuit hold original jurisdiction in patent cases was adopted to further improve consistency in the application of patent law (Comer et al., Aug. 1992).

To evaluate whether trends remain in how the various district courts ruled in ANDA disputes, the results were compiled by district court. The 65 disputes reported above were disposed of in 20 different district courts. The number of favorable decisions for each litigant is presented by district in Table 4. With the exception on the Southern District of New York, the generic applicant was more likely to prevail in each of the most popular districts in which to litigate, including the Northern District of Illinois and the District of New Jersey. Given the differentiation of decisions in the district courts, forum shopping is a likely result of parties bringing suit.

The number of decisions in each district that were affirmed and reversed (or vacated) on appeal is also presented. Of those labeled as "reversed" on appeal, two decisions each of the Northern District of Illinois and the Southern District of Florida were actually reversed for a total of four reversals where the innovator prevailed; the remainder were vacated and remanded for further proceedings. Accordingly, Table 4 further supports the conclusion drawn from Table 1 that while generics were more successful than innovators in the district courts, the balance was evened on appeal.

All Combined Judicial Decisions

In addition to final resolution of the disputes between innovators and generics, the results of numerous interlocutory decisions were collected. Interlocutory decisions are nonfinal, "intermediate" decisions made during the course of an action. The data include decisions not only in the disputes finally adjuncted, but also in disputes that settled or which have not yet produced a final decision on the merits. Also, the resolution of some of the decisions reported above required the court to rule on multiple motions or make conclusions with respect to distinct sets of claims or more than one patent. Table 5 reports the results of all distinct issues before the district court on motion and how they were, if at all, resolved on appeal. Similarly, the courts' conclusions of law are summarized in Table 6.

Innovators were more successful than generics in requesting a preliminary injunction from the district courts. The innovator had a 75% success rate upon

TABLE 6 Conclusions of Law

Conclusions of law	Innovator prevails	Aff/Rev	Generic prevails	Aff/Rev
JMOL	2	1/1	1	1/0
Claim of construction	2	2/0	0	–
Bench trial	19	0/0	17	10/1
All conclusions	23	3/1	18	11/1

TABLE 7 Average Time Between ANDA Filing and Final Court Decisions

	District court		Federal circuit	
Type of decision	Decisions	Time (months)	Decisions	Time (months)
Motion to dismiss	1	13.9	1	16.1
Summary judgment	18	27.7	12	35.7
JMOL	2	31.9	2	56.6
Bench trial	14	31.3	8	47.4
All decisions	35	29.0	23	40.7

filing a motion for a preliminary injunction, while the generic had a 100% failure rate.

Motions to dismiss were equally granted and denied for both innovators and generics.

A high percentage of decisions granted summary judgment on the merits with respect to both the innovator and generic. Summary judgment on the merits was granted in favor of the innovator movant in 17% of decisions and was granted in favor of the generic movant in 59% of decisions. Summary judgment not on the merits was equally granted and denied for innovators and generics.

While the unique facts of each case will impact each motion before the district court, the results demonstrate that the innovator has a high rate of success in requesting a preliminary injunction. Furthermore, both the innovator and the generic were highly successful in requesting a motion to grant summary judgment on the merits.

In 41 decisions involving conclusions of law, the innovator prevailed in 56% of cases and the generic was successful in the remaining 44% of cases. While the unique facts of each case may be a better barometer of the courts conclusions of law, the rate of success on conclusions of law was slightly higher for the innovator.

Duration of Legal Proceedings

Once an infringement suit is brought against a generic applicant, the FDA approval process is stayed until the earlier of 30 months from the notice of filing or a court decision in favor of the applicant (21 U.S.C. 355[j][5][B][iii][2004]). However, experience has shown that generic applicants are reluctant to enter the market prior to a favorable court decision, even though the 30-month stay had expired (*Generic Drug Entry Prior to Patent Expiration: An FTC Study*, Federal Trade Commission, July 2002).

Table 7 reports the average time between ANDA filings and final district court and Federal Circuit decisions on the merits of the 58 (paragraph IV) cases that reported the date of the ANDA filing. Note that where the decision only reported the month of the ANDA filing, the 15th day of that month was recorded as the filing date. In a few instances, only the date of the notice given to the innovator of the ANDA filing was reported; accordingly, it was used as an approximation of the filing date.

The average duration of an action before the district court from ANDA filing to final decision is 29 months, or almost 2 1/2 years. An appeal to the CAFC has an average duration from district court decision to final disposition of 11 months, or about one year. In some instances, the appeal of a decision may result in an additional one-year delay in generic market entry.

Actions having the shortest time from ANDA filing to final disposition involve motions to dismiss, while actions having the longest duration are those before a jury.

CONCLUSION

While each patent case is unique and presents its own set of difficult questions concerning validity and breadth, viewing the results of many cases in the aggregate can help to identify trends that can assist in formulating litigation strategy. The results of the study support the perception that generic drug makers fare well in district court, but the playing field appears to be leveled when the cases are reviewed on appeal.

REFERENCES

Bristol-Myers Squib v. Boehringer Ingelheim, 86 F. Supp. 2d 433 (D.N.J. 2000).

Comer, D., et al. (Aug. 1992). Advisory Commission on Patent Law Reform. Report to the Secretary of Commerce 99.
Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank (1999). 527 U.S. 627, 651 n.3 (1999) (J. Stevens dissenting).
Generic Drug Entry Prior to Patent Expiration: An FTC Study, Federal Trade Commission, July 2002, p. 22, available at http://purl.access.gpo.gov/GPO/LPS21619.
Glaxo Wellcome v. Geneva Pharm., 45 U.S.P.Q.2d 1702 (D.N.J.), aff'd, 110 F.3d 1562 (Fed. Cir. 1997).
H.R. Rep. No. 98-857, pt. 1 (1984).
Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, 332 F.3d 896 (6th Cir. 2003) (ruling a settlement agreement between a brand name drug maker and a generic ANDA filer was per se illegal under the Sherman Act).
Moore, K. (2000). Judges, juries, and patent cases—an empirical peek inside the black box. *Michigan Law Review* 99. pp. 365, 386.
Mossinghoff, G. (1999). Overview of the Hatch-Waxman Act and its impact on the drug development process. *Food and Drug Law Journal* 54:187.
Pub. L. No. 98-417, 1984 Stat. 1538 [codified in various sections of Titles 15, 21, 28, and 35 of the United States Code (U.S.C.)].
Roche Prod. Inc. v. Bolar Pharm. Co., (1984). 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856.
SmithKline Beecham v. Watson Pharms., (2000) 211 F.3d 21 (2d Cir.) (ruling that it is not copyright infringement for a generic drug maker to use labeling nearly identical to the brand name product), *cert. denied*, 531 U.S. 872.
Upjohn v. Mova Pharm., 31 F. Supp. 2d 211 (D.P.R. 1998), *aff'd in part, rev'd in part*, 225 F.3d 1306 (Fed. Cit. 2000).
21 U.S.C. § 355(j) (2004a).
21 U.S.C. § 355(j)(2)(A)(iv) (2004b).
21 U.S.C. § 355(j)(2)(A)(vii) (2004c).
21 U.S.C. § 355(j)(2)(A)(vii) (2004d).
21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2004e).
21 U.S.C. § 355(j)(5)(B)(iv) (2004f).
21 U.S.C. § 355(j)(5)(B)(iii) (2004g).
35 U.S.C. § 271(e)(1) (2004).
35 U.S.C. § 282.