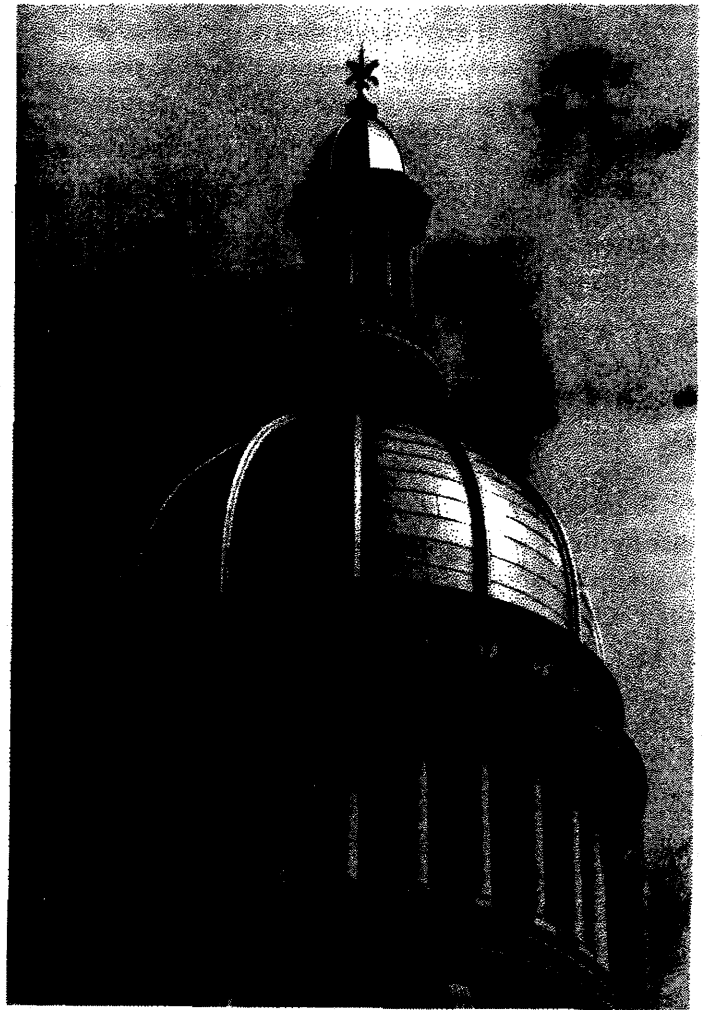


Litigation in New Jersey Under the New Local Patent Rules

by Jerome B. Simandle

Extensive collaboration between the bench and the bar led to the writing and adoption of the New Jersey Local Patent Rules, which took effect in the U.S. District Court on Jan. 1, 2009.¹ By 2007, the District of New Jersey had become one of the five busiest patent venues in the nation.² The need for a full assessment of our procedures for managing patent litigation became obvious during an in-court patent seminar held in May 2008. While the regular Local Civil Rules certainly applied to patent litigation, they failed to address the specialized needs of many patent cases, including procedures unknown in ordinary federal civil cases.



Chief Judge Garrett E. Brown Jr. appointed a robust committee of experienced patent practitioners from New Jersey and elsewhere, together with district judges and magistrate judges,³ with the mandate to examine the need for local patent rules and, if appropriate, to suggest such rules for consideration by the Board of Judges.

I served as chair of the Local Patent Rules Committee, a task as daunting, and ultimately as fulfilling, as any extra duty I'd taken on in 25 years on the bench. The committee quick-

ly got down to work, examining the practices in New Jersey and in at least eight other courts with local patent rules.⁴ Its members examined New Jersey's practices and sought to develop a more uniform approach, for district-wide application, in a format that would be even-handed, clear, concise, and consistent with the Federal Rules of Civil Procedure and the goal of Rule 1.⁵

The committee identified objectives for improving local practice, including controlling costs of discovery; drawing focus to principal matters in dispute at an earlier stage of litigation; avoiding prolix discovery motion practice; delineating disclo-

sure obligations in the various types of patent cases; discouraging 'rounds' of dispositive motions; considering use of a pattern protective order for discovery; enhancing, standardizing, and expediting the *Markman*⁶ hearing processes; providing for a trial judge tutorial in appropriate cases; and enhancing management of Hatch-Waxman Act⁷ cases, among others. The committee identified an overarching objective to preserve the discretion of the magistrate judges to manage cases under the resulting rules, while taking the legitimate needs of particular circumstances fully into account.

Through some ambitious subcommittees, the group reached out to practitioners in some of the other local patent rule districts, surveyed our own district and magistrate judges about patent management practices and preferences, examined the feasibility of pattern orders for e-discovery and confidentiality, analyzed the needs of Hatch-Waxman Act cases, reached out to other New Jersey practitioners for advice upon these efforts, and plumbed the Federal Judicial Center's forthcoming draft monograph on the management of patent litigation in federal courts.⁸

Through much candid discussion, the proposed new rules took shape. The committee's consensus focused upon the Northern District of California's Patent Local Rules, the third iteration of which took effect in early 2008, the product of a similarly active advisory committee. While the Northern District of California's rules provided an initial framework for organizing our rules, about half the content of the New Jersey proposal was new or substantially revised from versions in Northern California and elsewhere. Examining, debating, and rewriting five drafts expressed the effort to evolve a coherent set of rules that would be a suitable template for the vast majority of patent cases (all but the very simplest and the most complicated). The drafters tried to clearly articulate the

expectations placed on the practitioners and the judicial officers.

The committee also drafted "Explanatory Notes to Proposed Local Patent Rules," to explain its intentions behind the proposals.⁹ The notes emphasized the special role played by New Jersey's magistrate judges in case management and other pre-trial activities, wishing to preserve judicial flexibility while "providing guidance in the management of patent cases as well as providing to the parties some predictability in the format of the process."¹⁰

The committee also encouraged adoption of a discovery confidentiality order early in the case, consistent with Third Circuit authority. The committee recognized that Hatch-Waxman Act case management presents concerns different from the conventional patent cases in some respects. The members were divided on one aspect of Hatch-Waxman case management, namely the sequencing of disclosure of the parties' contentions, and presented optional proposals for consideration of the court, discussed below.

At its September 2008 meeting, the Board of Judges considered the proposed new rules and published them for public notice and comment.¹¹ Over an extended comment period, the court received thoughtful and constructive comments, which it considered, leading to several additional changes and adoption of the Local Patent Rules on Dec. 11, 2008.¹²

Some Notable Provisions of the New Rules

Like the Northern District of California and several other courts borrowing its structure, our Local Patent Rules are divided into four overall parts: scope of rules, general provisions, patent disclosures, and claim construction proceedings.

Interaction With Other Rules

The relationships between the Local Patent Rules, the Local Civil Rules, and Federal Rules of Civil Procedure are

addressed in L. Pat. R. 1.2 & 2.3. These new rules take pains to cross-reference the aspects of other rules that are augmented, such as the requirements for the discovery plan required in civil cases by Fed. R. Civ. P. 26(f) and L. Civ. R. 26.1(b)(2), by adding patent-specific topics.¹³ Even before the initial scheduling conference is convened, the parties to a patent case are required to discuss and address whether the obligations or deadlines of the Local Patent Rules are suitable for the circumstances of the particular case,¹⁴ the scope and timing of any claim construction discovery including experts,¹⁵ and the format of the claim construction hearing (such as whether live testimony will be needed).¹⁶

Flexibility and Discretion

The rules emphasize the flexibility of the template for patent case management, reminding litigants that the obligations or deadlines may be modified by the court *sua sponte* or upon a showing of good cause.¹⁷ Significantly, the rule places the duty upon counsel to meet and confer for the purpose of reaching agreement, if possible, upon any request for modification of obligations or deadlines, before the request can even be submitted.¹⁸ This rule recognizes the value of meet-and-confer requirements, and it appeals to the professionalism of patent counsel to subdue the impulse for involving the judicial officer in case management disputes that can often be resolved by counsel.

Of course, even if there is counsel agreement to an enlargement of deadlines or a modification of some obligation, court approval is needed.¹⁹ The rule implicitly recognizes that such modifications are most easily achieved at the initial conference, when the 'game plan' for the patent case is being discussed and memorialized.²⁰

Tutorials for Judges

To intelligently decide patent issues, especially claim construction, a federal

judge must learn a lot about an invention or art that may be technical and complicated. The subject of tutorials for the judge is addressed, as the parties are required to address "[h]ow the parties intend to educate the Court on the patent(s) at issue."²¹

While the new rules do not prescribe a format for such an educational process, they require that careful thought be given at an early stage, thus addressing one of the main concerns of patent litigators.

Discovery Confidentiality

Judges and practitioners generally agreed that bickering about discovery confidentiality wastes time and money, and draws judges into disputes that ought to be routinely handled among counsel. When pretrial disclosures and discovery are delayed several months for arguments about the details of discovery confidentiality, the overall case cannot progress, and such issues become unworthy surrogates for the important disputes. So the court adopted L. Pat. R. 2.2, "Confidentiality," addressing this problem by several means where entry of a discovery confidentiality order may be appropriate.

First, the rule encourages counsel to meet and confer about the need for a discovery confidentiality order and a schedule for submitting the certifications supporting such an order as generally required in all civil cases by L. Civ. R. 5.3(b)(2).²²

Second, the rule gives an incentive to counsel to arrive at a stipulated discovery confidentiality order within 30 days of the initial scheduling conference (supported by a sufficient certification under L. Civ. R. 5.3(b)(2)), or, failing this, a party must move for a confidentiality order within the 30-day period.²³

Third, in deciding a motion for a discovery confidentiality order, the court may enter an appropriate order, as usual, or may, if appropriate, enter the

district court's approved discovery confidentiality order, in whole or in part, as set forth in Appendix S to the Local Civil Rules.²⁴ Perhaps the most innovative feature of the new confidentiality rule in patent cases lies in its directive that the absence of a confidentiality order will not be permitted to delay discovery, providing simply:

Discovery cannot be withheld on the basis of confidentiality absent Court order. Pending entry of a discovery confidentiality order, discovery and disclosures deemed confidential by a party shall be produced to an adverse party for outside counsel's Attorney's Eyes Only, solely for purpose of the pending case and shall not be disclosed to the client or any other person.

Thus, the parties must exchange disclosures and discovery of non-privileged materials whether or not a party deems the material to be confidential. In the absence of a discovery confidentiality order, the material deemed 'confidential' by a party shall be produced to the adverse counsel for outside (*i.e.*, non-corporate) counsel's eyes only, but may not be further disclosed by the outside counsel, while the issues of the confidentiality dispute are sorted out and a discovery confidentiality order entered. Some may regard this as a bold stroke. The committee in preparing these mechanisms, and the court in adopting them, hoped to create incentives for stipulation of discovery confidentiality orders to accelerate and streamline the discovery process without ultimately sacrificing the protection of confidential information.

Timing of Expert Reports

The new rules recognize that most patent cases will require claim construction; that often claim construction should take place before experts on matters of infringement, enforceability and

damages can reach final opinions; and that it may be premature to require service of experts' reports on issues other than claim construction until the *Markman*²⁵ issues have been decided. L. Pat. R. 2.4(b) gives such flexibility in scheduling of expert discovery, while claim construction experts' discovery is governed by L. Pat. R. 4.1, *et seq.*

Disclosures of Assorted Claims, Infringement Contentions, Invalidity Contentions, and Related Document Production

The court adopted, in L. Pat. R. 3.1-3.5, rules specifying the content and timing of disclosures in patent cases where infringement and validity are issues, as well as in cases where only a declaratory judgment of invalidity is sought. These requirements are in addition to the normal initial and pretrial disclosures required by Rule 26(a) of the Federal Rules of Civil Procedure.

The pattern for L. Civ. R. 3.1-3.5 was generally derived from the Northern District of California, with several additions. The date of the initial scheduling conference starts the clock for such disclosures, generally within 14 days for the party claiming infringement and 45 days thereafter for the party claiming a patent is invalid. These deadlines approach rapidly and early, requiring a party to have done much of its homework before ever staking out its cause of action in patent litigation in New Jersey.

Disclosures in Hatch-Waxman Act Cases

The Local Patent Rules Committee, as noted above, presented two options for the court's consideration regarding disclosures in Hatch-Waxman Act cases.²⁶ The first option would require the generic defendant to disclose its abbreviated new drug application (ANDA) application to the plaintiff, but would otherwise require the patentee plaintiff to go first in making its disclosure of asserted claims and contentions under

L. Pat. R. 3.1 & 3.2, with the generic defendant not having to make its disclosure of invalidity contentions until 45 days later, under L. Pat. R. 3.3 & 3.4.

The second option, likewise, would require the generic defendant to disclose its ANDA application at or before the initial scheduling conference and to go first in disclosing its "invalidity contentions" and "non-infringement contentions" for any patents of the plaintiff referred to in the defendant's paragraph IV certification,²⁷ to which the patentee plaintiff has 45 days to serve its "disclosure of asserted claims and infringement contentions" and related documents.

The court chose the second option, adopting L. Pat. R. 3.6 for Hatch-Waxman Act cases. New Jersey's extensive experience in Hatch-Waxman litigation over the years led the judges to the conclusion that the generic defendant, having developed a proposed new generic drug and having filed an ANDA with the Food and Drug Administration with full knowledge of the plaintiff patentee's drug product and patent(s), is in the better position to stake out its contentions of non-infringement and invalidity at the outset of the case.

The plaintiff patentee has typically not seen the generic defendant's ANDA before litigation (although the ANDA may be exchanged under a confidentiality agreement in some instances before litigation), nor does it usually receive a sample of the generic product, and it has not been uncommon for generic defendants to resist production of the underlying ANDA and product even after litigation has ensued. The patentee plaintiff has received the paragraph IV certification before filing suit—indeed, this is required.²⁸ The view prevailed that these paragraph IV certifications are often too sketchy to inform the patentee of the basis for the contentions of non-infringement and invalidity. The paragraph IV certification must disclose a colorable basis for asserting non-

infringement or invalidity of the patent, but it need not disclose all bases for invalidity or non-infringement.

Thus, while the patentee is indeed the plaintiff, as required by statute, and the patentee must plead its causes of action for infringement or for a declaration of validity, the adopted rule looks to the generic defendant to concretize the "lines of battle" because it is generally in the better position to do so. The generic defendant will not be operating in the dark—it will have received the plaintiff's complaint stating the plaintiff's cause(s) of action with the specificity required by Rule 8(a)(2), Fed. R. Civ. P. and *Bell Atlantic Corp. v. Twombly*,²⁹ which may, in appropriate cases, be aided by a more definite statement under Rule 12(e), Fed. R. Civ. P.

The court also provided at least two means of potential relief for a Hatch-Waxman Act defendant that finds itself unable to satisfy its L. Pat. R. 3.6 disclosure obligations. First, as with most procedures under the Local Patent Rules, the defendant can (after meeting and conferring with the plaintiff) propose a modification of the L. Pat. R. 3.6 obligations or deadlines in the discovery plan submitted before the initial scheduling conference, such as by showing something unusual or atypical about its circumstances.³⁰ Second, if the defendant demonstrates that the plaintiff has disclosed an asserted claim and infringement contention that was not previously presented or reasonably anticipated, the judge may permit the defendant to amend its contentions.³¹

Amendments to Contentions

The new rules likewise seek to induce greater attention to the formulation of the parties' contentions in all patent litigation. Patent counsel and judges complained of too many instances of 'cat-and-mouse,' where incomplete or even diversionary contentions were served to buy time or to flush out the adversary's

position. Hence, L. Pat. R. 3.7 makes it more difficult to amend infringement or invalidity contentions, since such an amendment requires a timely application and showing of good cause. The rule contains a non-exhaustive list of examples supporting good cause to amend.

Advice of Counsel

Some patent cases involve reliance upon advice of counsel as part of a patent-related claim or defense. The practitioners and judges observed that the litigation of advice-of-counsel issues too early in a patent case can be distracting, unproductive, and often ultimately unnecessary. Such issues will now ordinarily be deferred until 30 days after entry of the court's claim construction order, at which time new L. Pat. R. 3.8(a)-(c) triggers disclosure obligations for the party claiming such reliance on advice of counsel. Thus, the pursuit of this issue may only become germane after claim construction is completed, and, if so, the uniform disclosure requirements of L. Pat. R. 3.8(a)-(c) will hopefully tee up the issue for disposition.

Claim Construction Proceedings

Like most other courts having local patent rules, New Jersey has now put into practice uniform procedures for claim construction in L. Pat. R. 4.1 through 4.6. New Jersey decided not to follow those courts that limit the number of claim terms a party contends should be construed by the court.³² Instead, no limit is placed and counsel are directed to meet and confer for the purposes of voluntarily limiting the terms in dispute.³³

The remaining provisions of Part 4 deal with the exchange of preliminary claim constructions and extrinsic evidence;³⁴ preparation of the joint claim construction and prehearing statement,³⁵ including for each anticipated expert a summary of his or her testimony including each opinion to be offered

related to claim construction;³⁶ the completion of discovery including expert depositions within 30 days after filing of the joint claim construction and pre-hearing statement;³⁷ and opening *Markman* submissions and the responding briefs and evidence to be used at the hearing.³⁸ Counsel then confer and propose to the court a schedule for the claim construction hearing,³⁹ which is meant to assist the district judge in the prompt scheduling and determination of the *Markman* issues.

Monitoring the New Local Patent Rules

Chief Judge Brown has asked the Local Patent Rules Committee members to monitor the workings of this new set of rules as actual experience is gathered. The committee will be reconvening after 12-18 months of operation to attempt to gauge the success of these rules in actual practice, and to propose any modifications that seem warranted. This is further proof, if any is needed, of the high professional esteem in which the district court holds its patent bar. I look forward to meeting again to revisit these patent case management processes, to roll up the sleeves, and to continue the dialog. ☛

Endnotes

1. District of New Jersey Local Patent Rules (L. Pat. R.) appear at Local Civil Rule 9.3, U.S. District Court for the District of New Jersey, effective Jan. 1, 2009. These local rules appear at the court's website: www.njd.uscourts.gov/rules.
2. The judicial branch does not keep separate figures for patent case filings. In the combined statistical category for copyright, patent, trademark for the most recent available year, only four districts have more intellectual property filings than the District of New Jersey's 420 cases, namely, C.D. Cal. (1,564), S.D.N.Y. (768), N.D. Cal. (529), and N.D. Ill.

(427), while E.D. Tex. is also close (408). Administrative Office of the U.S. Courts, Judicial Business of the United States Courts, Table C-3 at 152-156 (Sept. 30, 2007).

3. The Local Patent Rules Committee members include 10 attorneys (Arnold B. Calmann, Thomas Curtin, Marc Friedman, Dennis F. Gleason, Mary Sue Henifin, William L. Mentlik, George F. Pappas, Matthew D. Powers, Donald Robinson, and Robert G. Shepherd), a law professor (Peter Mennell of Berkeley), and 11 judges (Stanley R. Chesler, Mary L. Cooper, Joseph A. Greenaway, Faith S. Hochberg, Jose L. Linares, William Martini, Peter G. Sheridan, Tonianne J. Bongiovanni, Joel Schneider, Patty Shwartz, and Jerome B. Simandle, chair), and the court's legal coordinator (John T. O'Brien).
4. The committee compared and contrasted the local patent rules of N.D. Cal., S.D. Cal., N.D. Tex., E.D. Tex., D. Minn., W.D. Pa., N.D. Ga., and D. Mass.
5. Rule 1, Fed. R. Civ. P. provides, *inter alia*, that the civil rules "should be construed and administered to secure the just, speedy, and inexpensive determination of every action and proceeding."
6. In *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996), the federal circuit determined the construction of the meaning of terms in a patent claim is a function to be performed by judges, not juries, before a trial. A non-jury hearing for the determination of disputed issues of claim construction is thus called a *Markman* hearing.
7. The Hatch-Waxman Act, 21 U.S.C. § 355, provides a special procedure for litigation in the area of pharmaceutical patents, with a purpose of speeding the availability of non-infringing low-cost generic drugs.

Stated simply, under paragraph IV of the Hatch-Waxman Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a generic drug company files an abbreviated new drug application (ANDA) with the FDA and delivers a letter to the patentee providing the generic company's contentions that its proposed generic drug does not infringe the patent, or that the patent is invalid, or both. The ANDA contains the information specified in 21 U.S.C. § 355(j)(2)(A)(i)-(viii). Under Hatch-Waxman and related FDA regulations, the generic company's paragraph IV letter need only disclose information sufficient to support a meritorious non-infringement, invalidity, or unenforceability case, *see* 21 C.F.R. 314.52(c)(6), with the degree of specificity varying widely in practice, according to practitioners. The patentee may then commence suit against the generic defendant to challenge the generic defendant's assertions of non-infringement and/or invalidity, thus triggering an automatic moratorium of the FDA's processing of the ANDA until the patent issues are determined, up to three years. The generic company's filing of its ANDA with the FDA constitutes an artificial act of infringement, 35 U.S.C. § 271(e)(2)(A), that gives rise to subject matter jurisdiction; once litigation is launched, the patentee plaintiff has the burden of pleading and proving infringement.

8. Peter S. Menell, *et al.*, Patent Case Management Judicial Guide, a forthcoming publication of the Federal Judicial Center (2009), available at [www.fjc.gov/public/pdf.nsf/lookup/pag=tgudr9.pdf/\\$file/patgudr9.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/pag=tgudr9.pdf/$file/patgudr9.pdf).
9. *See* L. Pat. R. Explanatory Notes.
10. *See* L. Pat. R. Explanatory Notes.
11. Local rules are promulgated under the procedure of Rule 83(a)(1), Fed.

- R. Civ. P., which includes giving public notice and an opportunity for comment, and which requires consistency with federal statutes and rules adopted under 28 U.S.C. §§ 2072 (including the federal civil, criminal, and evidence rules) and 2075 (bankruptcy rules).
12. The new Local Patent Rules govern cases filed, transferred, or removed to the district court on or after Jan. 1, 2009, while for actions pending prior to that date, the rules require the judge to confer with the parties and to apply the rules "as the Court deems practicable." L. Pat. R. 1.4.
13. See L. Pat. R. 2.1(a).
14. See L. Pat. R. 2.1(a)(1).
15. See L. Pat. R. 2.1(a)(2).
16. See L. Pat. R. 2.1(a)(3).
17. See L. Pat. R. 1.3.
18. *Id.*
19. *Id.*
20. *Id.*
21. L. Pat. R. 2.1(a)(4).
22. See L. Pat. R. 2.1(a)(5).
23. See L. Pat. R. 2.2.
24. The enactment of the pattern or template discovery confidentiality order in Appendix S of the Local Civil Rules also became effective Jan. 1, 2009. The Appendix S discovery confidentiality order was the product of a year's work of the District Court's Lawyers Advisory Committee whose chair, Thomas Curtin, was also a member of the Local Patent Rules Committee. The purpose of Appendix S is to publish a suitable, balanced confidentiality order with broad applicability to all civil cases. The Appendix S order is available to the judge and counsel in any patent or other civil case. It has already received general acceptance by adoption, in whole or in part, in a wide array of cases this year, according to the magistrate judges, saving many hours of litigation effort and conflict.
25. See n. 7, *supra*.
26. See brief description of Hatch-Waxman Act litigation involving new generic prescription drug products in n. 8, *supra*.
27. *Id.*
28. *Id.*
29. 550 U.S. 544 (2007).
30. See L. Pat. R. 2.1(a)(1).
31. See L. Pat. R. 3.7(d).
32. See, e.g., N. D. Cal. Pat. L. R. 4-1(b) (2008) (requiring the parties to "jointly identify the 10 terms likely to be most significant to resolving the parties' dispute, including those terms for which construction may be case or claim dispositive").
33. L. Pat. R. 4.1(b).
34. L. Pat. R. 4.2.
35. L. Pat. R. 4.3.
36. L. Pat. R. 4.3(e).
37. L. Pat. R. 4.4.
38. L. Pat. R. 4.5.
39. L. Pat. R. 4.6.

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