

Litigation Considerations for Local Generic Companies: Recent Developments, Local Patent Rules, and Discovery Issues

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Agenda: U.S. Considerations for Local Companies

- Recent Important Developments in U.S. Patent Law
- Local Patent Rules
- Strategies for Discovery and Privilege Issues

Agenda: U.S. Considerations for Local Companies

- **Recent Important Developments in U.S. Patent Law**
- Local Patent Rules
- Strategies for Managing Discovery and Privilege Issues

Claim Construction

Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., No. 13-854 (S. Ct.)

- Issue: Whether a district court’s factual finding in support of its construction of a patent claim term may be reviewed de novo, as required by Federal Circuit precedent, or only for clear error, as Federal Rule of Civil Procedure 52(a) requires
- Procedural history:
 - › The district court construed the term “molecular weight” in plaintiff Teva’s claims, which Sandoz argued were invalid for indefiniteness.
 - › In construing this term, the district court resolved conflicting expert testimony regarding interpretation of a figure, and how a person having ordinary skill in the art would understand the term “molecular weight.”
 - › The Federal Circuit reviewed de novo and reversed and remanded, finding that “molecular weight” was indefinite.

Proving Infringement: Claim Construction

Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., No. 13-854 (S. Ct.)

- Oral argument:
 - › Teva argued that Fed. R. Civ. P. 52(a) requires deferential review of factual findings, even when a question of law rests on these findings. Teva specifically argued that findings regarding the state of the art are factual and should receive deference on appeal.
 - › For the government, the Solicitor General drew a distinction between which claim construction determinations are factual findings entitled to deferential review, and which are legal conclusions subject to de novo review. The Solicitor General argued that factual findings include those based in part on extrinsic evidence outside the patent and its prosecution history, and that legal conclusions included determinations of how a person skilled in the art would interpret patent claims in light of such factual findings
 - › Sandoz argued that the Supreme Court's *Markman* decision requires that all factual determinations in claim construction are subsumed in the ultimate, legal determination of claim construction. As such, Sandoz argued that de novo review is appropriate.

Proving Infringement: Induced Infringement

Limelight Networks, Inc. v. Akamai Technologies, Inc., 134 S. Ct. 2111 (2014)

- Relevant Facts
 - › Patent-in-suit claimed a method of delivering electronic data using a content delivery network (CDN).
 - › Defendant Limelight Networks operated a CDN and carried out several of the steps claimed in the patent
 - › However, Limelight’s customers, and not Limelight itself, performed a step of the patent known as “tagging.”

- District Court (D. Mass.)
 - › Plaintiff Akamai Technologies brought patent infringement suit against Limelight. The case resulted in jury a verdict of direct infringement.
 - › Not long thereafter, the Federal Circuit decided *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (2008), holding that for direct infringement to exist when the defendant does not itself perform every step of a method claim, it must exercise “control or direction” over the steps performed by other parties.

Proving Infringement: Induced Infringement

Limelight Networks, Inc. v. Akamai Technologies, Inc., 134 S. Ct. 2111 (2014)

- District Court (D. Mass.) (cont.)
 - › Limelight moved for reconsideration of the district court's denial of its motion for judgment as a matter of law. The court granted Limelight's motion, and entered judgment for Limelight

- Federal Circuit (en banc)
 - › Reversed
 - › Held that sufficient evidence existed in support of induced infringement, even where under the circumstances, no one could be liable for direct infringement

Proving Infringement: Induced Infringement

Limelight Networks, Inc. v. Akamai Technologies, Inc., 134 S. Ct. 2111 (2014)

- U.S. Supreme Court
 - › Reversed and held that direct infringement is a prerequisite for a finding of induced infringement under § 271(b)
 - › The Court assumed “without deciding” that the *Muniauction* decision correctly held that a method claim is only directly infringed if performance of all its steps are “attributable to the same defendant, either because the defendant actually performed those steps or because he directed or controlled others who performed them”
 - › Accordingly, the Court reasoned that unless all the steps of a method claim are performed by the defendant or are attributable to the defendant under *Muniauction*, there can be no indirect infringement
 - › The Court acknowledged that *Muniauction*’s holding means that a would-be infringer can evade liability “by dividing performance of a method patent's steps with another whom the defendant neither directs nor controls,” but explained that this is not a sufficient reason to overrule *Muniauction*.

Proving Infringement: Induced Infringement

Limelight Networks, Inc. v. Akamai Technologies, Inc., 134 S. Ct. 2111 (2014)

- Impact of *Limelight* on patent infringement cases
 - › After the Supreme Court’s decision in *Limelight*, the law governing induced infringement of method claims is the same as it was under *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007) and *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed.Cir.2008).
 - › Accordingly, where a defendant does not practice all steps of a method claim, patent liability can only exist where the parties performing the additional steps have a relationship with the defendant that would traditionally give rise to vicarious liability, such as an agency relationship or contractual obligation
 - › Post *Limelight*, it will be easier for companies to engage in “divided infringement”
 - Fields where this impact is likely to be felt include business methods, software, medical diagnostics and treatment, and other areas where multiple actors are involved

Defenses: Indefiniteness

Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014)

- Relevant Facts:
 - › Patent-in-suit was directed to a heart-rate monitor to be used with exercise equipment
 - › Patent claimed that prior monitors were inaccurate due to presence of interfering electrical signals from users' muscles, which are filtered out by the patented invention
 - › Relevant claim comprised, among other elements “a ‘live’ electrode and a ‘common’ electrode ‘mounted . . . in spaced relationship with each other.’”

- District Court (S.D.N.Y.)
 - › Plaintiff Biosig sued Nautilus for infringement
 - › The district court granted Nautilus's motion for summary judgment of invalidity, finding that “in a spaced relationship with each other” was indefinite under 35 U.S.C. § 112

Defenses: Indefiniteness

Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014)

- Federal Circuit
 - › Reversed and remanded, finding that the term “in spaced relationship with each other” was “amenable to construction” and was not “insolubly ambiguous”
- Supreme Court
 - › Granted Nautilus’s petition for certiorari and reversed and remanded
 - › Held that the Federal Circuit’s “amenable to construction” / “insolubly ambiguous” standard “lack[s] the precision” required by § 112 and were not “probative of the essential” definiteness inquiry
 - › Provided that the appropriate § 112 test requires “that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.”

Defenses: Indefiniteness

Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014)

- Application of *Nautilus* in the Federal Circuit:
 - *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014) (affirming holding that claim was invalid for indefiniteness)
 - The key claim language at issue was “unobtrusive manner,” a term of degree. The Court did “not understand the Supreme Court to have implied in *Nautilus* . . . that terms of degree are inherently indefinite.”
 - Nevertheless, a claim “must provide objective boundaries for those of skill in the art,” and the Court held that the “unobtrusive manner” phrase was “highly subjective” on its face, and was not supported by adequate guidance in the written description
 - The Court acknowledged that a claim may satisfy the definiteness requirement through examples, but it refused to adopt a single “e.g.” phrase from the written description to serve as the exclusive definition for “unobtrusive manner”

Defenses: Indefiniteness

Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014)

- Likely effects of *Nautilus* on patent litigation:
 - › Appears to be easier to argue invalidity based on indefiniteness.
 - After *Nautilus*, plausibly construing the terms is not enough to defeat indefiniteness challenge if the “scope of the invention” would not be clear to a person having skill in the art
 - › May increase the role of expert testimony
 - Person having skill in the art is central to the *Nautilus* standard
 - › The *Nautilus* court did not opine on whether factual issues are subject to clear and convincing standard
 - Ruling in *Sandoz* regarding claim construction deference may also play into this

Defenses: ODP

Gilead Sciences Inc. v. Natco Pharma Ltd., 753 F.3d 1208 (2014)

- Background:
 - › In 1995, the Uruguay Round Agreements Act (“URAA”) transformed the General Agreement on Tariffs and Trade into the World Trade Organization.
 - › As part of the URAA, the term for a U.S. patent was changed from seventeen years from the patent issue date to twenty years from the earliest effective filing date
- Relevant Facts:
 - › The two relevant patents (U.S. Patent Nos. 5,763,483 and 5,952,375), were directed to antiviral compounds and methods for their use.
 - › The patents list the same inventors and the written descriptions disclose similar content, but they did not claim priority to a common patent application and they had different expiration dates.
 - › While the ’483 patent issued first, under the URAA, the ’375 patent’s expiration date was 22 months before the ’483 patent’s expiration date.
 - › After the ’483 patent issued, Gilead filed a terminal disclaimer in the application that led to the ’375 patent, disclaiming any portion of the ’375 patent term that extended beyond the expiration date of the ’483 patent

Defenses: ODP

Gilead Sciences Inc. v. Natco Pharma Ltd., 753 F.3d 1208 (2014)

- District Court (D.N.J.)
 - › Plaintiff Gilead sued Natco for infringement after Natco filed a request with the FDA for approval to market a generic version of one of Gilead's drugs allegedly covered by the '483 patent
 - › Natco argued the '483 patent was invalid for obviousness-type double patenting over the '375 patent
 - › Gilead responded that as the '483 patent issued first, the '375 patent could not serve as a double patenting reference
 - › Held that the '375 patent could not serve as a double patenting reference against the '483 patent

Defenses: ODP

Gilead Sciences Inc. v. Natco Pharma Ltd., 753 F.3d 1208 (2014)

- Federal Circuit
 - › Natco appealed, and the Federal Circuit vacated and remanded
 - › The Court held that a patent that issues after, but expires before, another patent can qualify as a double patenting reference for that other patent
 - › The Court reasoned that the double patenting doctrine “has always been implemented to effectively uphold” the principle that “when a patent expires, the public is free to use” the claimed invention and any obvious or patentably indistinct modifications thereof, and that this weighed in favor of considering patents expiring before the patent in suit to be valid double-patenting references

Defenses: ODP

Gilead Sciences Inc. v. Natco Pharma Ltd., 753 F.3d 1208 (2014)

- Interpretation of *Gilead* in subsequent cases
 - › *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1373 (Fed. Cir. 2014), the Federal Circuit reaffirmed its holding in *Gilead*, noting that obviousness-type double patenting is “designed to prevent an inventor from securing a second, later expiring patent for the same invention.”

- Impact of *Gilead* on patent litigation:
 - › When an asserted patent is from one of multiple related patent families, the defendant will want investigate whether any patents in the other family expire before the asserted patent. This may give rise to an obviousness-type double patenting defense, even if the other patent was issued after the asserted patent.

Defenses: Obviousness

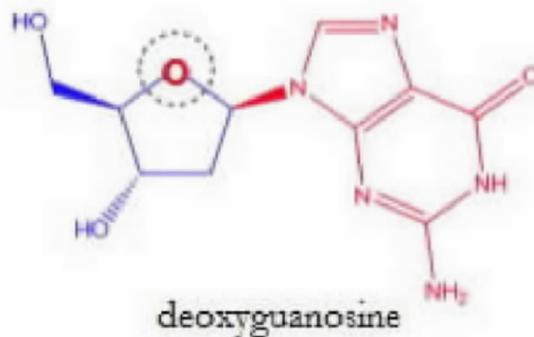
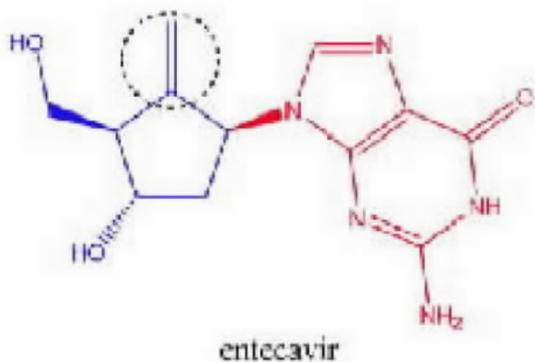
Bristol-Myers Squibb Co. v. Teva Pharmaceuticals, Inc., 752 F.3d 967 (2014)

- Relevant Facts:
 - › Plaintiff Bristol-Myers Squibb (BMS) owned a patent containing a claim directed to a particular nucleoside analog, entecavir
 - › Nucleoside analogs are manmade compounds designed to mimic the activity of natural nucleosides, the building blocks of DNA and RNA.
 - › Nucleoside analogs are modified slightly from natural nucleosides to interfere with the replication of viral DNA so they can serve as possible antiviral compounds
 - › The relevant claim covers a nucleoside analog, entecavir, that is structurally identical to the corresponding natural nucleoside, deoxyguanosine, except that entecavir has a carbon-carbon double bond where deoxyguanosine has an oxygen atom
 - › Defendant Teva filed an abbreviated new drug application for a generic version of entecavir, which is an effective treatment for Hepatitis B

Defenses: Obviousness

Bristol-Myers Squibb Co. v. Teva Pharmaceuticals, Inc., 752 F.3d 967 (2014)

- District Court (D. Del.)
 - › Plaintiff Bristol-Myers Squibb (BMS) sued Teva for patent infringement
 - › Following a four-day bench trial, the district court found the entecavir claim to be invalid as obvious
 - › Obviousness was based on the existence of a nucleoside analog in the prior art, 2'-CDG, that, like entecavir, is identical to deoxyguanosine except that prior art analog has a carbon atom where deoxyguanosine has an oxygen atom
 - › A prior art reference disclosed that replacing 2'-CDG's carbon atom with a carbon-carbon double bond led to significantly superior antiviral capabilities



Defenses: Obviousness

Bristol-Myers Squibb Co. v. Teva Pharmaceuticals, Inc., 752 F.3d 967 (2014)

- Federal Circuit (panel decision)
 - › BMS appealed, and the Federal Circuit affirmed after de novo review.
 - › The Federal Circuit agreed that Teva provided strong evidence of obviousness, and that the district court's factual determinations were based on the prior art and expert testimony.
 - › The Court disregarded BMS's evidence that 2'-CDG would not have been an obvious lead compound (a compound in the prior art that would be a natural choice for further development efforts), because 2'-CDG was shown to be toxic in the 1990's, subsequent to the time of invention.
 - › The Court held that "unexpected results do not *per se* defeat, or prevent, the finding that a modification to a lead compound will yield expected, beneficial properties."
 - › The Federal Circuit held that in assessing unexpected properties, "differences in degree' of a known and expected property are not as persuasive in rebutting obviousness as differences in 'kind'—i.e., a new property dissimilar to the known property."

Defenses: Inequitable Conduct

Apotex Inc. v. UCB, Inc., 763 F.3d 1354 (2014)

- Relevant Facts:
 - › Apotex's founder and chairman was the sole inventor of the asserted patent, and he authored the application
 - › The asserted patent was directed to a process for making monexipril tablets, an angiotensin-converting enzyme (“ACE”) inhibitor used to treat hypertension
 - › The two accused products made by UCB were both prior art to the asserted patent
 - › During prosecution, the patent received three obviousness rejections, each based in part on one of UCB’s patents for the accused device, in combination with other pieces of prior art.
 - › At the inventor’s direction, counsel for Apotex submitted an expert declaration, following which the claims were approved with the incorporation of an additional limitation

Defenses: Inequitable Conduct

Apotex Inc. v. UCB, Inc., 763 F.3d 1354 (2014)

- District Court (S.D. Fla.)
 - › The court found that the inventor was aware of and involved in all decisions in the prosecution of the patent application
 - › The court also ruled that the inventor made several misrepresentations to the PTO regarding the prior art, including UCB's patent, and also withheld relevant prior art
 - › The court concluded that the inventor gave the expert misleading and incomplete information to form the basis of his declaration
 - › The district court determined that the omissions and misrepresentations were material, and that in the alternative, a finding of but-for materiality was not necessary because of the inventor's egregious misconduct.
 - › The court also found specific intent to mislead the PTO.
 - › Held that the asserted patent was unenforceable due to the inventor's inequitable conduct before the PTO

Defenses: Inequitable Conduct

Apotex Inc. v. UCB, Inc., 763 F.3d 1354 (2014)

- Federal Circuit
 - › Apotex appealed, and the Federal Circuit affirmed, finding that clear and convincing evidence demonstrates that the inventor engaged in material misconduct before the PTO
 - The Court noted that the inventor was actively involved in the prosecution, wrote the written description that omitted prior art known to him, and presented an expert opinion that was based on selective and misrepresentative evidence designed to engineer a favorable opinion
 - › The Federal Circuit also found that the inventor made affirmative misrepresentations of material facts to the PTO. As a result, the Court held that the inventor's conduct was "but-for material" to the issuance of the patent and that the inventor had specific intent to deceive
 - › Presentation of the false expert testimony was "particularly significant and inexcusable"

Agenda: U.S. Considerations for Local Companies

- Recent Important Developments in U.S. Patent Law
- **Local Patent Rules**
- Strategies for Managing Discovery and Privilege Issues

What's the Purpose of Having Local Patent Rules?

- Local Patent Rules do not supersede the Federal Rules of Civil Procedure, but supplement them.
- Local Patent Rules seek to have parties' positions fixed as early as possible to prevent "shifting sands" litigation by requiring early disclosure of asserted claims and contentions.

How Many Jurisdictions Have Adopted Local Patent Rules?

- Out of the 94 District Courts in the United States, including territories, 30 District Courts have adopted Local Patent Rules.
- In some District Courts, such as the District of Delaware, judges have individual procedures or standing orders or form scheduling orders that apply to patent cases.

What Are the Major Areas Covered by Local Patent Rules?

- Patent Disclosures – Both sides will disclose their respective theories of infringement and invalidity with specificity and produce documents or things that support their theories early in the litigation.
- Claim Construction – What do the words in the claims mean?

Comparison of Local Patent Rules in Four District Courts

- District of New Jersey
- Northern District of California
- Eastern District of Texas
- Southern District of New York



Patent Disclosures

Disclosure of Asserted Claims and Infringement Contentions

- District of New Jersey
 - › Must be served no later than 14 days **after** the Initial Scheduling Conference, and contain the following:
 - Each claim alleged to be infringed, including applicable statutory subsections of 35 U.S.C. § 271;
 - The identification of the “Accused Instrumentality” that infringes each claim;
 - Other than design patents, a chart identifying specifically where each limitation of each asserted claim is found within each “Accused Instrumentality”, including for limitations governed by 35 U.S.C. §112(f), the identity of the structure(s), act(s), or material(s) in the “Accused Instrumentality” that performs the claimed function;
 - On claims alleged to be indirectly infringed, the identification of the direct infringement and the act(s) of indirect infringement

Disclosure of Asserted Claims and Infringement Contentions

- District of New Jersey (continued)
 - › Other than design patents, whether each limitation of each asserted claim is alleged to be literally present or present under the Doctrine of Equivalents in the Accused Instrumentality;
 - › Priority date over earlier application;
 - › Identification of patentee's own product that practices the claimed invention upon which patentee wishes to rely;
 - › The basis of any alleged willful infringement; and
 - › Documents and things relied upon in support of infringement contentions including contracts, documents regarding conception/reduction to practice, file histories, ownership documents, etc.

Disclosure of Asserted Claims and Infringement Contentions

- Northern District of California
 - › Same as the District of New Jersey, but no design patent carve out.

- Eastern District of Texas
 - › Must be served no later than 10 days **before** the Initial Case Management Conference, and include the same information as the District of New Jersey, except there is no design patent carve out, no identification of 35 U.S.C. §271 subsections, no indirect infringement identification, and no identification of the basis for willful infringement.

Disclosure of Asserted Claims and Infringement Contentions

- Southern District of New York
 - › Must be served no later than 45 days **after** the Initial Scheduling Conference.
 - › Must identify each claim allegedly infringed, and each product or process alleged to infringe each identified claim.

Non-Infringement Contentions and Responses

- District of New Jersey
 - › Must be served no later than 45 days after service upon it of the Disclosure of Asserted Claims and Non-Infringement Contentions, and
 - Must contain the written bases for Non-Infringement Contentions and Responses;
 - Must follow the order of the infringement claims chart;
 - Must note agreement or disagreement with the allegations;
 - Must include any additional or different claims at issue; and
 - Must include documents or things relied on in defense of the infringement contentions.

Non-Infringement Contentions and Responses

- Northern District of California
 - › None

- Eastern District of Texas
 - › None

- Southern District of New York
 - › None

Invalidity Contentions

- District of New Jersey
 - › Must be served no later than 45 days after serve of the Disclosure of Asserted Claims and Infringement Contentions, and include:
 - The identity of prior art that anticipates each asserted claim or renders each claim obvious, if obviousness is alleged, an explanation of why the prior art renders the asserted claim obvious;
 - Other than design patents, a chart identifying where specifically in each alleged prior art each limitation of each asserted claim is found, including for limitations governed by 35 U.S.C. §112(f), the identity of the structure(s), act(s), or material(s) in each item of prior art that performs the claimed function;

Invalidity Contentions

- District of New Jersey
 - › Must be served no later than 45 days after serve of the Disclosure of Asserted Claims and Infringement Contentions, and include:
 - Any grounds of invalidity based on 35 U.S.C. § 101, indefiniteness under 35 U.S.C. § 112(b) or enablement or written description under 35 U.S.C. § 112(a) of any asserted claims; and
 - Documents and things relied on, including prior art, with English translations if necessary.

Invalidity Contentions and Accompanying Document Production

- Northern District of California
 - › Similar to District of New Jersey, but no design patent carve out.
- Eastern District of Texas
 - › Similar to District of New Jersey, but no design patent carve out.
- Southern District of New York
 - › Must be served no later than 45 days after service of the Disclosure of Asserted Claims and Infringement Contentions and identify each item of prior art that allegedly anticipates or renders obvious each asserted claim, and any other grounds of invalidity, including any under 35 U.S.C. § 101 or § 112, or unenforceability of any of the asserted claims.

Responses to Invalidity Contentions

- District of New Jersey
 - › Not later than 14 days after service of the Invalidity Contentions, the party defending the validity of the patent must serve its Responses to Invalidity Contentions, and:
 - Must include for each item of asserted prior art, the identification of each limitation of each asserted claim that the party believes is absent from the prior art, except for design patents, where the party shall supply an explanation why the prior art does not anticipate the claim;
 - Must include an explanation of why the prior art does not render the asserted claim obvious, if obviousness is alleged;

Responses to Invalidity Contentions

- District of New Jersey
 - › Not later than 14 days after service of the Invalidity Contentions, the party defending the validity of the patent must serve its Responses to Invalidity Contentions, and:
 - Must follow the order of the invalidity contentions chart;
 - Must note agreement or disagreement with each allegation and the written basis thereof; and
 - Must include documents or things relied on in response to defendant's invalidity contentions.

Responses to Invalidity Contentions

- Northern District of California
 - > None

- Eastern District of Texas
 - > None

- Southern District of New York
 - > None

Requirements in Patent Cases for Declaratory Judgment of Invalidity

- District of New Jersey
 - › The Disclosure of Asserted Claims and Infringement Contentions and accompanying document production will be made **ONLY** if the declaratory defendant asserts patent infringement.
 - › If no claim of patent infringement or 14 days after the Initial Scheduling Conference, whichever is later, the declaratory plaintiff must serve its Invalidity Contentions and accompanying documents.
 - › Responses to the Invalidity Contentions must be served 14 days after service of the Invalidity Contentions.
 - › This rule is inapplicable if a claim for declaratory judgment is made in response to a complaint for infringement as to the same patents.

Requirements in Patent Cases for Declaratory Judgment of Invalidity

- Northern District of California
 - › Similar to the District of New Jersey, except that if there is no claim of infringement, service of invalidity contentions and accompanying documents shall be made no later than 14 days after service of the answer or 14 days after the Initial Case Management Conference, whichever is later.

Requirements in Patent Cases for Declaratory Judgment of Invalidity

- Eastern District of Texas
 - Similar to Northern District of California, except that if no claim of infringement, service of invalidity contentions and accompanying documents shall be made no later than 10 days after service of the answer or 10 days after the Initial Case Management Conference, whichever is later.
 - 10 days after service of the Invalidity Contentions, the parties are to meet and confer to determine the date on which the plaintiff will file its Final Invalidity Contentions, which shall be no later than 50 days after service by the court of its claim construction ruling.

Requirements in Patent Cases for Declaratory Judgment of Invalidation

- Southern District of New York
 - › If no claim of patent infringement, invalidity contentions must be served no later than 45 days after the Initial Scheduling Conference, unless a different date is set in the court's scheduling order.

Amendments

- District of New Jersey
 - › Amendments to contentions (**and all other disclosures**) are permitted only by court order upon a timely application and with good cause shown.
 - › **Diligence** is paramount for the party seeking amendment.
 - › **Good cause**, absent undue prejudice to non-moving party, includes, but is not limited to:
 - a claim construction by the court different from that proposed by the party seeking amendment;
 - recent discovery of material prior art despite earlier diligent search; and
 - recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contentions.

Amendments

- District of New Jersey
 - › **Good cause**, absent undue prejudice to non-moving party, includes, but is not limited to:
 - disclosure of an infringement contention by a Hatch-Waxman Act party asserting infringement that requires response by the adverse party because it was not previously presented or reasonably anticipated; and
 - consent by the parties in interest to the amendment and a showing that it will not lead to an enlargement of time or impact other scheduled deadlines.
 - › The general duty under the Federal Rules to supplement discovery responses does not excuse the need for leave of court to amend contentions.

Amendments

- Northern District of California
 - › Amendments are permitted only by order of the court upon a timely application and with good cause shown.
 - › **Good cause**, absent undue prejudice to non-moving party, includes:
 - a claim construction by the court different from that proposed by the party seeking amendment;
 - recent discovery of material prior art despite earlier diligent search; and
 - recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contentions.
 - › The general duty under the Federal Rules to supplement discovery responses does not excuse the need for leave of court to amend contentions.

Amendments

- Eastern District of Texas
 - › Amendments are allowed **WITHOUT** leave of court if:
 - Not later than 30 days after service by the court of its claim construction ruling, a party claiming patent infringement believes in good faith that the court's ruling so requires.
 - Not later than 50 days after service of the court's claim construction ruling, parties opposing a claim of patent infringement may serve amended invalidity contentions **IF** a party claiming patent infringement has served amended infringement contentions, **OR** the party opposing a claim of patent infringement believes in good faith that the court's ruling so requires.
 - › Any amendment or supplementation that does not fall under the above circumstances may **ONLY** be made by order of the court upon a showing of **good cause**.

Amendments

- Eastern District of Texas
- Southern District of New York
 - › SDNY applies Fed. R. Civ. P. 26(e)'s duty to supplement to infringement and invalidity contentions.

Advice of Counsel

- District of New Jersey
 - › Not later than 30 days after entry of the court's claim construction order (or other date set by the Court), any party relying on advice of counsel must produce any written advice and documents related thereto for which claims of privilege have been waived, a written summary of any oral advice for which claims of privilege have been waived, and a privilege log.
 - › A party that fails to comply with the above will not be permitted to rely on advice of counsel absent a stipulation of all parties or order of the court.

Advice of Counsel

- Northern District of California
 - › Same as District of New Jersey except that the production must be made no later than 50 days after service by the court of its claim construction ruling.

Advice of Counsel

- Eastern District of Texas
 - › By a date set by the court (Docket Control Order), a party relying on opinion of counsel **as a defense to a claim of patent infringement** shall produce the opinion(s) and related documents for which claims of privilege have been waived, and a privilege log.
 - › A party opposing a claim of patent infringement who does not comply with the above will not be permitted to rely on the defense of opinion of counsel absent a stipulation of all parties or court order upon a showing of **good cause**.

Advice of Counsel

- Southern District of New York
 - › Not later than 30 days after entry of the court's claims construction order, a party relying on an opinion of counsel as part of a defense to a claim of willful infringement or inducement of infringement, or that a case is exceptional, must produce the opinion(s) and related documents for which claims of privilege have been waived.

Modified Disclosure Procedures for Cases Filed Under Hatch-Waxman

- These local rules “invert” the standard disclosure exchange used in ordinary patent cases by having Hatch-Waxman defendants make their disclosures first, often without knowing which claims the plaintiff will assert.
 - › District of Idaho
 - › District of Maryland
 - › District of New Jersey
 - › Northern District of Ohio
 - › Western District of Tennessee
 - › Eastern District of Texas

Order of Service of Contentions in Modified Procedures for Hatch-Waxman

- District of Idaho
 - › Defendant must produce ANDA before or at initial conference.
 - › Defendant goes first with service of Invalidity and Non-Infringement Contentions and accompanying documents. (14 days after initial conference)

THEN

- › Plaintiff serves its Disclosure of Asserted Claims and Infringement Contentions and accompanying documents. (42 days after defendant's contentions)

Order of Service of Contentions in Modified Procedures for Hatch-Waxman

- District of Maryland
 - › Defendant goes first with service of Invalidity and Non-Infringement Contentions and accompanying documents, and must produce ANDA (30 days after scheduling order)
 - THEN**
 - › Plaintiff serves its Disclosure of Infringement Contentions and accompanying documents. (60 days after scheduling order)

Order of Service of Contentions in Modified Procedures for Hatch-Waxman

- District of New Jersey
 - › Defendant must produce the complete ANDA with its answer or motion.
 - › Each ANDA applicant must notify FDA of any motion for injunctive relief within 3 business days of same and must produce copies of any correspondence with FDA within 7 days of same
 - › Plaintiff goes first with service of its Disclosure of Asserted Claims . (7 days after initial conference)

THEN

- › Defendant serves its Invalidity Contentions and Non-Infringement Contentions and accompanying documents. (14 days after initial conference)...

Order of Service of Contentions in Modified Procedures for Hatch-Waxman

- District of New Jersey

...THEN

- ▶ Plaintiff serves its Infringement Contentions and accompanying documents, and its Responses to Invalidity Contentions. (45 days after defendant's contentions)

Order of Service of Contentions in Modified Procedures for Hatch-Waxman

- Northern District of Ohio
 - › Defendant must produce ANDA at or before the initial conference.
 - › Defendant goes first with service of its Invalidity Contentions and accompanying documents. (not less than 15 days after case management conference)
 - THEN**
 - › Defendant serves its Non-Infringement Contentions and accompanying documents. (not less than 30 days after case management conference)
 - THEN**
 - › Plaintiff serves Infringement Contentions and accompanying documents. (not less than 45 days after case management conference)

Order of Service of Contentions in Modified Procedures for Hatch-Waxman

- Western District of Tennessee
 - › Defendant must produce ANDA at or before initial conference.
 - › Defendant goes first with service of its Invalidity Contentions (14 days after initial conference) and Non-Infringement Contentions (30 days after initial conference), each with accompanying documents.

THEN

 - › Plaintiff serves its Infringement Contentions and accompanying documents. (45 days after defendant's disclosure of infringement contentions)

Order of Service of Contentions in Modified Procedures for Hatch-Waxman

- Eastern District of Texas
 - › Defendant must produce ANDA at or before initial conference.
 - › Same rules as DNJ regarding notifying FDA of injunction motion and producing FDA correspondence.
 - › Defendant goes first with service of its Invalidity Contentions and Non-Infringement Contentions and accompanying documents. (14 days after initial conference)

THEN

 - › Plaintiff serves its Disclosure of Asserted Claims and Infringement Contentions and accompanying documents. (45 days after non-infringement contentions)



Claim Construction

Exchange of Proposed Terms for Construction

- District of New Jersey
 - › Other than design patents, parties serve on each other a list of claim terms for construction, and identify any term governed by 35 U.S.C. § 112(f):
 - 14 days after service of the Responses to Invalidity Contentions, or
 - 45 days after service of the Non-Infringement Contentions and Responses where validity is not at issue, or
 - 14 days in all cases seeking a declaratory judgment not based on validity, after the defendant serves an answer that does not assert a claim for patent infringement.
 - › Parties then meet and confer to narrow the claims in dispute.

Exchange of Proposed Terms for Construction

- Northern District of California
 - › Parties serve on each other a list of claim terms for construction, and identify any term governed by 35 U.S.C. § 112(f):
 - 14 days after service of the Invalidity Contentions, or
 - 42 days after service of the Disclosure of Asserted Claims and Infringement Contentions where validity is not at issue, or
 - in all cases seeking a declaratory judgment not based on validity, 14 days after the defendant serves an answer that does not assert a claim for patent infringement.
 - › Parties then meet and confer to narrow the claims in dispute. The parties must also jointly identify the 10 terms likely most significant in resolving the parties' dispute, including terms whose construction may be case or claim dispositive.

Exchange of Proposed Terms for Construction

- Eastern District of Texas
 - › Parties simultaneously exchange a list of claim terms, phrases, or clauses for construction, and identify any term governed by 35 U.S.C. § 112(f):
 - 10 days after service of the Invalidity Contentions
 - › Parties then meet and confer to narrow the claims in dispute.

- Southern District of New York
 - › No initial exchange of proposed claim terms for construction by the court.

Exchange of Preliminary Claim Constructions and Extrinsic Evidence

- District of New Jersey
 - › 21 days after the exchange of proposed terms for construction, the parties exchange preliminary claim constructions, identify all extrinsic and intrinsic evidence that supports the party's proposed construction, and a description of all witness testimony, including expert testimony.
 - › 14 days after the exchange of preliminary claim constructions, the parties exchange an identification of intrinsic evidence and extrinsic evidence relied upon to oppose the other party's construction.
 - › Parties then have 30 days to meet and confer to narrow the issues and file a Joint Claim Construction and Prehearing Statement.
 - › Not applicable to design patents.

Exchange of Preliminary Claim Constructions and Extrinsic Evidence

- Northern District of California
 - › Similar to the District of New Jersey, except no exchange of an identification of intrinsic evidence and extrinsic evidence relied upon to oppose the other party's construction.

Exchange of Preliminary Claim Constructions and Extrinsic Evidence

- Eastern District of Texas
 - › 20 days after the exchange of Proposed Terms and Claim Elements for Construction, the parties exchange preliminary claim constructions, identify all extrinsic evidence that supports the party's proposed construction, and a description of witness testimony.
 - › Parties then meet and confer to narrow the issues and prepare a Joint Claim Construction and Prehearing Statement.

- Southern District of New York
 - › No exchange of preliminary claim constructions and extrinsic evidence.

Joint Claim Construction and Prehearing Statement

- District of New Jersey
 - › 30 days after the exchange of preliminary claim constructions, the parties shall file their Joint Claim Construction and Prehearing Statement, which identifies:
 - terms agreed upon;
 - disputed terms with proposed constructions and citations to extrinsic and intrinsic evidence;
 - those terms whose construction will be most significant for resolution of the case;
 - any term whose construction is claim or case dispositive or promote settlement, and reason for same;
 - anticipated length of hearing; and
 - identification of witnesses and summary of testimony.

Joint Claim Construction and Prehearing Statement

- Northern District of California
 - › 60 days after service of Invalidity Contentions, the parties shall file their Joint Claim Construction and Prehearing Statement, which identifies:
 - terms agreed upon;
 - disputed terms with proposed constructions and citations to extrinsic and intrinsic evidence;
 - up to 10 terms whose construction will be most significant to the resolution of the case, and from the 10, those terms whose construction is claim or case dispositive, if no agreement on the 10 most significant, the parties are to identify those on which they agree upon, and evenly divide to remainder;
 - anticipated length of hearing; and
 - identification of witnesses and summary of testimony.

Joint Claim Construction and Prehearing Statement

- Eastern District of Texas
 - › 60 days after service of Invalidity Contentions, the parties shall file their Joint Claim Construction and Prehearing Statement, which identifies:
 - terms agreed upon;
 - disputed terms with proposed constructions and citations to extrinsic and intrinsic evidence;
 - anticipated length of hearing;
 - witnesses and summary of expert opinion with sufficient detail to allow for a meaningful deposition;
 - any other appropriate issue to be addressed at the prehearing conference prior to the claim construction hearing, and proposed date for the conference.

Joint Claim Construction and Prehearing Statement

- Southern District of New York
 - › On a date set by the court, the parties shall file their Joint Disputed Claim Terms Chart, which lists disputed terms with each party's proposed constructions with cross-references to infringement and invalidity contentions.

Completion of Claim Construction Discovery

- District of New Jersey
 - › 30 days after filing of the Joint Claim Construction and Prehearing Statement, except for expert depositions.
 - › Does not apply to design patents.
- Northern District of California
 - › 30 days after filing of the Joint Claim Construction and Prehearing Statement, including expert depositions.
- Eastern District of Texas
 - › 30 days after filing of the Joint Claim Construction and Prehearing Statement, including expert depositions.
- Southern District of New York
 - › No specified date.

Claim Construction Submissions

- District of New Jersey
 - › 45 days after filing of the Joint Claim Construction and Prehearing Statement, opening briefs, supporting evidence, and supporting certifications or declarations must be filed and served.
 - › Discovery from experts who submitted a supporting certification or declaration must be completed within 30 days after filing of opening submissions.
 - › Responding briefs, supporting evidence, and responsive expert certifications or declarations are due 60 days after opening submissions are filed.
 - › With respect to design patents, opening submissions are due 45 days after service of Non-Infringement Contentions and Responses and/or Responses to Invalidity Contentions. Responsive submissions are due 30 days after.

Claim Construction Submissions

- Northern District of California
 - › 45 days after filing of the Joint Claim Construction and Prehearing Statement, the party claiming patent infringement or the party asserting invalidity if there is no infringement issue in the case, must file and serve an opening brief and supporting evidence.
 - › Responding brief and supporting evidence are due 14 days after.
 - › Reply brief and evidence rebutting the supporting evidence contained in the opposing party's response are due 7 days after.

Claim Construction Submissions

- Eastern District of Texas
 - › 45 days after filing of the Joint Claim Construction and Prehearing Statement, the party claiming patent infringement shall file and serve an opening brief and supporting evidence.
 - › Responding brief and supporting evidence are to be filed and served by the opposing party 14 days after.
 - › Reply brief and evidence rebutting supporting evidence are due 7 days after.
 - › Claim chart outlining disputed terms and proposed constructions is due 10 days after.

Claim Construction Submissions

- Southern District of New York
 - › 30 days after filing of the Joint Disputed Claim Terms Chart, the party asserting infringement or the party asserting invalidity if there is no infringement issue in the case, must file and serve an opening brief and supporting evidence and testimony.
 - › Responding brief and supporting evidence and testimony are due 30 days after.
 - › Reply brief rebutting the opposing party's response is due 7 days after.

Claim Construction Hearing Date

- District of New Jersey
 - › Two weeks after responding briefs are submitted, the parties are to meet and confer and propose a schedule for the claim construction hearing, to the extent the parties or the court believe it's necessary.

- Northern District of California
 - › Two weeks after the reply brief is submitted, the court will conduct a claim construction hearing, to the extent the parties or the court believe it's necessary.
 - › Failure to make a good faith effort to narrow the disputed terms or otherwise meet and confer as required, may expose counsel to sanctions.

Claim Construction Hearing Date

- Eastern District of Texas
 - › Subject to the court's convenience, two weeks after the reply brief is submitted, the court will conduct a claim construction hearing, to the extent the parties or the court believe it's necessary.

- Southern District of New York
 - › Silent on a hearing date.

Agenda: U.S. Considerations for Local Companies

- Recent Important Developments in U.S. Patent Law
- Local Patent Rules
- **Strategies for Managing Discovery and Privilege Issues**

Strategies for Managing Discovery and Privilege Issues

- **What You Write Down Each Day Matters**
 - › Patent infringement claims concerning API or ANDA products often concern:
 1. patented compounds present as trace impurities, or used as intermediates;
 2. crystal polymorphs, solvates or hydrates present as trace impurities, or used as intermediates;
 3. methods of manufacture;
 4. levels of purity;
 5. levels of stability (including modification of pH, method of formulating API, inclusion of stabilizers, etc.); or
 6. particle size.

Strategies for Managing Discovery and Privilege Issues

- This means that the outcome of the litigation can turn on the results of routine laboratory analyses, especially in the developmental stages of a new API or formulation.
- Litigations have been lost because of documents containing comment about what a chemist or formulator thought a patent said, or what the example of a patent produced, in a way that ended up being contrary to their employer's legal defense.
- In short: Even very routine analyses and records can be important to a litigation. Comments about patents, including what a patent says or how to repeat an example, can be very harmful and should be avoided whenever possible.

Strategies for Managing Discovery and Privilege Issues

■ What Documents Do the “Bad Guys” Get?

- Short answer: Everything, if it concerns the U.S. API or U.S. product.
- If you’ve worked on a U.S. product, you can expect that you will have to give the “bad guys” the following:
 - All of your e-mails concerning the product;
 - All of your personal notes concerning the product;
 - All of your memos, reports and spreadsheets concerning the product, including drafts;
 - All of your notebooks concerning the product; and
 - Possibly deposition testimony, where the bad guys’ lawyer will interview you about the things you’ve written in your documents.

Strategies for Managing Discovery and Privilege Issues

- **Generating and Maintaining Business Records: “Do’s and Don’ts”**
 - › USE THE PHONE whenever you can.
 - E-mails are convenient but leave a record.
 - Text messages are increasingly becoming subject to discovery.
 - › STATE ONLY THE FACTS about your review or work on patents.
 - When examining a patent to learn from it, avoid written comments about what a patent says or claims. If you comment in writing about the meaning of a word in a claim, for example, your company may end up being stuck with that meaning in later litigation, even if it’s wrong.

Strategies for Managing Discovery and Privilege Issues

- **Generating and Maintaining Business Records: “Do’s and Don’ts”**
 - AVOID COMMENTING ON WHETHER PROCESSES, PRODUCTS OR INGREDIENTS ARE COVERED BY, OR DISCLOSED IN, A PATENT.
 - Such judgments are best left to trained patent lawyers, and such speculation can be very harmful to your company.
 - When repeating an example of a patent, report just the facts. Do not comment on those facts, for example by saying the example “doesn’t work,” unless absolutely necessary.
 - Project meeting minutes and development reports are usually the most interesting documents to the bad guys. Ask yourself whether the minutes or report you’re drafting contain any information, for example discussions of patents or infringement, that you wouldn’t want ending up in the bad guys’ hands.

Strategies for Managing Discovery and Privilege Issues

■ Use Common Document Storage

- › Rely on common document storage wherever possible. If a report is kept on a central server, resist the urge to keep a separate copy on your computer or in your file cabinet. Avoid multiple drafts; maintain only one version of a document. The fewer records you keep, the fewer you will need to collect and produce for litigation.
- › Private notes and files are discoverable, even the ones you keep at home. Maintain such private records about U.S. products only when necessary.

Strategies for Managing Discovery and Privilege Issues

- **Use common document storage.**
 - › Avoid any written comments about U.S. litigation unless it is your job to make such comments. Do not assume that communications between employees at your company are “privileged” because they are about a U.S. litigation.
 - › Read and understand your company’s document policies. Apply them to your daily work. It can mean the difference between being able to launch the product you’re working on or not.

Strategies for Managing Discovery and Privilege Issues

- **Best Practices for Making U.S. Fact Discovery Easier and More Successful**
 - › **Give each product a separate product or project code. Have a separate code for U.S. versions of products and include that code on as many records as possible.** When it comes time to collect documents for the U.S. litigation, the code will make it very easy to separate documents concerning the U.S. product from those concerning other products.
 - › **Keep the records for U.S. products separate from the records for non-U.S. products.** For example, if API is to be manufactured by one process for the U.S., and by a different process for ex-U.S., keeping the notebooks, manufacturing records and other documents for the U.S. API separate will avoid confusion about what to collect for litigation.

Strategies for Managing Discovery and Privilege Issues

- **Best Practices for Making U.S. Fact Discovery Easier and More Successful**

- **Briefing the members of a development team on likely infringement/invalidity issues early will help them avoid creating documents that can cause trouble later.** Involving U.S. patent litigation counsel in this effort, e.g., to help identify likely key issues, can help.
- **Litigation hold memo:** Send company-wide the day the decision is made to file an ANDA or DMF. Many companies have document retention policies that require all documents for U.S. products to be kept from the date the project is begun until the litigation ends, or a decision is made not to file an ANDA/DMF.
- **Designate a member of the Intellectual Property Cell to act as the expert on U.S. discovery issues and document retention/collection/destruction.**

Strategies for Managing Discovery and Privilege Issues

■ Best Practices for Making U.S. Fact Discovery Easier and More Successful

- › In generating a document, ask yourself whether it contains any information, for example discussions of patents or infringement, that you wouldn't want ending up in your opponents' hands.
- › Do not procrastinate when responding to instructions to collect documents for a litigation. U.S. courts can and will punish your company for producing documents in an untimely manner.
- › If you must write about U.S. litigation, work with the U.S. lawyers to make sure that the resulting work product will be privileged, i.e., immune from production to the bad guys. Such work product should be appropriately labeled, either with the phrase **“CONFIDENTIAL ATTORNEY-CLIENT PRIVILEGED COMMUNICATION”** or **“CONFIDENTIAL WORK PRODUCT REQUESTED BY ATTORNEY.”**

Strategies for Managing Discovery and Privilege Issues

- **The most successful generic drug companies in U.S. litigation are very good about their documents. They:**
 - › Generate as few documents as possible;
 - › Are savvy about what they say in writing, and assume that every document they create may end up being collected for a litigation;
 - › Train their employees regularly and thoroughly on the company's document policies;
 - › Organize their records, including e-mails, in a way that makes collection easier, less expensive and less disruptive;
 - › Designate certain key individuals to handle depositions, so that the company's litigation witnesses are experienced and credible; and
 - › Have e-mail and document management systems that have sophisticated search capabilities, to aid in document collection.

Strategies for Managing Discovery and Privilege Issues

- **Good practices make for better results**
 - › Taking the time to create uniform and consistent document and ESI policies will assist in the long run by making the U.S. discovery process easier and less expensive.
 - › Good document and ESI practices also assist in avoiding the creation of harmful documents.

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Questions?