Ethical Rules and Guidelines for the Filing and Defense of Hatch-Waxman and Other Life Sciences Litigation

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Applicable Ethical Rules

Rules of Professional Conduct

- ABA Model Rule of Professional Conduct 3.1
  - A lawyer shall not bring or defend a proceeding, or assert or controvert an issue therein, unless there is a basis in law and fact for doing so that is not frivolous, which includes a good faith argument for an extension, modification or reversal of existing law.
- New Jersey Disciplinary Rules of Professional Conduct 3.1
  - A lawyer shall not bring or defend a proceeding, nor assert or controvert an issue therein unless the lawyer knows or reasonably believes that there is a basis in law and fact for doing so that is not frivolous, which includes a good faith argument for an extension, modification, or reversal of existing law, or the establishment of new law.…
- New York Rule of Professional Conduct 3.1(a) follows Model Rule, but defines “frivolous” conduct

ABA Model Rule of Professional Conduct 3.3

(a) A lawyer shall not knowingly:

(1) make a false statement of fact or law to a tribunal or fail to correct a false statement of material fact or law previously made to the tribunal by the lawyer;

- Reflected in NY Rule 3.3, NJ Rule 3.3, and USPTO Rule of Professional Conduct § 11.303

Federal Rule of Civil Procedure 11(b)

Representations to the Court. By presenting to the court a pleading, written motion, or other paper--whether by signing, filing, submitting, or later advocating it--an attorney or unrepresented party certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances:

1. it is not being presented for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation;

2. the **claims, defenses, and other legal contentions are warranted by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law or for establishing new law**;

3. the **factual contentions have evidentiary support** or, if specifically so identified, **will likely have evidentiary support after a reasonable opportunity for further investigation or discovery**; and

4. the denials of factual contentions are warranted on the evidence or, if specifically so identified, are reasonably based on belief or a lack of information.

USPTO Rules of Professional Responsibility

- Effective May 3, 2013
- Based on the ABA Model Rules of Professional Responsibility
  - Previously followed the ABA 1969 Canons of Ethics, adopted in 1985
- 37 C.F.R. §§ 11.101-901

USPTO Rules of Professional Responsibility

ABA Model Rules of Professional Conduct	USPTO Rules of Professional Conduct
Rule 3.1 Meritorious Claims And Contentions A lawyer shall not bring or defend a proceeding, or assert or controvert an issue therein, unless there is a basis in law and fact for doing so that is not frivolous, which includes a good faith argument for an extension, modification or reversal of existing law. ~~A lawyer for the defendant in a criminal proceeding, or the respondent in a proceeding that could result in incarceration, may nevertheless so defend the proceeding as to require that every element of the case be established.~~	**§ 11.301 Meritorious claims and contentions.** A practitioner shall not bring or defend a proceeding, or assert or controvert an issue therein, unless there is a basis in law and fact for doing so that is not frivolous, which includes a good-faith argument for an extension, modification or reversal of existing law.

Source: http:www.ipethicslaw.com

Confidentiality & Disclosure under USPTO Rules of Professional Conduct

- 11.1: “Fraud” or “fraudulent” means conduct involving a misrepresentation of a material fact made with intent to deceive or a state of mind so reckless as to be the equivalent of intent.
  - May also be established by a “purposeful omission” to state a material fact.
- 11.303(e): “Candor toward the tribunal,” has the same requirements as ABA Model Rules
- 11.106(a): A lawyer must maintain client confidentiality, except where disclosure is necessary to prevent the client from committing inequitable conduct before the PTO.
- 11.106(c): A lawyer must disclose to the PTO information necessary to comply with applicable duty of disclosure provisions.

Ethical Obligations for Pre-Suit Investigation

Rule 11: Pre-Suit Infringement Analysis Required

- "Rule 11(b) requires an attorney to **conduct a reasonable inquiry into the law and facts before filing a pleading** in a court and **to certify that the claims contained therein are not frivolous, legally unreasonable, without factual foundation, or asserted for an improper purpose**."
- "Rule 11(c) then permits a district court to impose sanctions on a party and its attorneys for violation of subdivision (b)."

Q–Pharma, Inc. v. Andrew Jergens Co., 360 F.3d 1295, 1300 (Fed. Cir. 2004) (emphasis added)

Rule 11: Requirements for Pre-Suit Infringement Analysis

"In the context of patent infringement actions, **we have interpreted Rule 11 to require, at a minimum, that an attorney interpret the asserted patent claims and compare the accused device with those claims before filing a claim alleging infringement**."

Q–Pharma, Inc. v. Andrew Jergens Co.,
360 F.3d 1295, 1300 (Fed. Cir. 2004) (emphasis added)

Rule 11: Analysis Must Be Reasonable

- Under Federal Circuit law, plaintiff must show its pre-suit infringement analysis was **reasonable.**

- "Once a litigant moves based upon non-frivolous allegations for a Rule 11 sanction, **the burden of proof shifts to the non-movant** to **show it made a reasonable pre-suit inquiry** into its claim."

Digeo, Inc. v. Audible, Inc.,
505 F.3d 1362, 1368 (Fed. Cir. 2007)

Rule 11: Reasonableness an Objective Inquiry

- Reasonable pre-suit investigation is a strictly objective inquiry; Rule 11 does not require a showing of bad faith.

- Instead, plaintiff must show it performed some **claim interpretation** and **compared** the accused device/product with the patent claims under *Q-Pharma*.

Pre-Suit Infringement Analysis: Claim Construction

- No Rule 11 sanctions where claim interpretations "comport with the plain meaning of the claim language and do not appear to be inconsistent with the patent's written description and prosecution history," and where pre-filing infringement analysis was supported by information from patentee's advertising and label.
- "Q–Pharma's claim interpretation, while broad, followed the standard canons of claim construction and was reasonably supported by the intrinsic record."

Q-Pharma, Inc. v. Andrew Jergens Co., 360 F.3d 1295, 1301 (Fed. Cir. 2004)

Pre-Suit Infringement Analysis: Claim Construction

- Where pre-suit claim construction violates basic cannons of claim construction, it may be found frivolous and Rule 11 sanctions may be imposed.
- This may include:
  - Adding words to actual claim language without support from the specification
  - Altering otherwise unambiguous claim language

See, e.g., Source Vagabond Sys. Ltd. v. Hydrapak, 753 F.3d 1291, 1299-1301 (Fed. Cir. 2014)

Pre-Suit Infringement Analysis: Claim Construction

- A **claim-by-claim chart is not required** for a reasonable pre-suit infringement analysis.

- Rather, "an infringement analysis can simply consist of a good faith, informed **comparison of the claims of a patent against the accused subject matter**."

Q-Pharma, 360 F.3d at 1302 (emphasis added)

Pre-Suit Infringement Analysis: Comparison of Claims and Accused Product

- Comparison of claims and accused product does not require reverse engineering or obtaining a sample.

- However, whether obtaining a sample is reasonable depends on the surrounding circumstances such as **whether it could be obtained easily and cheaply.**

See Graceway Pharms., LLC v. Perrigo Co., 2010 WL 2521026, at *4 (D.N.J. June 10, 2010)

Pre-Suit Infringement Analysis: Comparison of Claims and Accused Product

- Conclusory statement that an attorney "analyzed the sample to ascertain whether or not it infringes …" is not enough for a reasonable pre-suit infringement analysis.

Source Vagabond Sys. Ltd. v. Hydrapak, 753 F.3d 1291, 1302 (Fed. Cir. 2014)

- Pre-suit analysis showing neither infringement nor non-infringement is reasonable, where plaintiff chose to engage in discovery for more information.

Hoffmann-La Roche Inc. v. Invamed Inc., 213 F.3d 1359, 1363 (Fed. Cir. 2000)

Pre-Suit Infringement Analysis: Comparison of Claims and Accused Product

- Litigant filed an infringement suit, stating that they could not definitively determine with any analytical technique if the generic drug infringed the asserted patent.
- Litigant's pre-filing inquiry was reasonable because:
  1. Generic manufacturer "**refused to disclose manufacturing processes** because of a confidentiality agreement it had with the manufacturer," even where there was no evidence generic company had sought manufacturer's authorization to disclose; and
  2. Branded manufacturer **could not reverse-engineer sample** of generic drug to determine infringement.

Hoffmann-La Roche Inc. v. Invamed Inc., 213 F.3d 1359, 1363 (Fed. Cir. 2000)

No Pre-Suit Obligation to Investigate Infringement of ANDA Filer

"[Plaintiff] and its attorneys had ***no pre-filing obligation to investigate*** whether [defendant's] methylphenidate drug actually infringed Celgene's patents. Because there is no dispute that [defendant] submitted an ANDA … and because [defendant] states that, prior to filing suit, [plaintiff] had received the Notice Letter … this Court concludes that [plaintiff's] prefiling infringement investigation was *reasonable under the circumstances*."

Celgene Corp. v. KV Pharm. Co.,
2008 WL 2856469, at *3 (D.N.J. July 22, 2008) (emphasis added)

No Pre-Suit Obligation to Investigate Infringement of ANDA Filer

"[Defendant] fails to persuade this Court that the holding of *Q–Pharma*, requiring a pre-filing infringement analysis, applies to a Hatch–Waxman ANDA case.…The pre-filing requirements stated in *Q–Pharma* make sense only in the context of a typical patent infringement case, and not in the context of a Hatch–Waxman ANDA case."

Celgene Corp. v. KV Pharm. Co.,
2008 WL 2856469, at *2 (D.N.J. July 22, 2008)

No Pre-Suit Obligation to Investigate Infringement of ANDA Filer

- "The Federal Circuit held that Q–Pharma, as plaintiff, was obligated under Rule 11 to make a sufficient pre-filing infringement analysis to determine whether the accused product infringed."

- "Here, in contrast the act of infringement alleged in the complaint is the filing of an ANDA—not the manufacture or sale of the product. *Because the Act has made the act of submitting an ANDA itself an act of infringement, in a Hatch–Waxman ANDA case, the attorney can conduct a reasonable and competent inquiry into the act of infringement by investigating whether a relevant ANDA has been filed."*

Celgene Corp. v. KV Pharm. Co.,
2008 WL 2856469, at *3 (D.N.J. July 22, 2008)

No Pre-Suit Obligation to Investigate Infringement of ANDA Filer

- "Celgene and its attorneys had no pre-filing obligation to investigate whether KV's methylphenidate drug actually infringed Celgene's patents." *Id*. at *3.
- To hold otherwise would "put pharmaceutical patent owners in an untenable position" *Id*. at *4.
  - It would require patent owners to perform infringement analysis on "possibly nonexistent product."
  - Patent owner has only 45 days to make what is likely to be a "highly technical infringement analysis," and decide whether to sue. *Id*.

No Pre-Suit Obligation to Investigate Infringement of ANDA Filer

- "Mylan gave Astra an objectively reasonable basis to sue: Mylan provided Astra notice of its Paragraph IV certification. This is an act of infringement under 35 U.S.C. § 271(e)(2)(A)."

- "The Court agrees with Astra[Zeneca] that *a reasonable plaintiff in a Hatch–Waxman case would be expected to know few details* about the accused product at the outset of litigation and plaintiff's counsel may reasonably rely on discovery to learn the material details."

AstraZeneca AB v. Mylan Labs., Inc. (In re Omeprazole Patent Litig.), 2010 U.S. Dist. LEXIS 50049 (S.D.N.Y. May 19, 2010)

No Rule 11 Violation Where Defendants Rebuffed Plaintiff's Efforts to View ANDA

- "Plaintiffs made several attempts to obtain access to the ANDA…. Defendants rebuffed these efforts, and did not respond to plaintiffs' final request to receive the entire ANDA …. [A]s was found in *Hoffmann–La Roche*, plaintiffs did not run afoul of Rule 11 in bringing this infringement action."

- "[T]he Federal Circuit has rejected the notion that Rule 11 prohibits a patentee from bringing an infringement action based upon the submission of an ANDA where the patentee 'is unable to obtain and set forth in [its] complaint facts showing infringement.'"

In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 693 F. Supp. 2d 409, 416 (D. Del. 2010)

Pre-Suit Analysis Hypothetical 1

- Innovator product is tablet dosage form
- Pharmaceutical formulation claim
  - A tablet dosage form comprising compound X and a binder, disintegrant, and lubricant.
- Notice letter with Offer of Confidential Access
  - Generic product is a tablet, but does not contain a binder
  - Does not identify any of the excipients in the generic product
- Can innovator file suit in accordance with Ethical Rules and Rule 11?
  - Must/should innovator accept OCA?

Pre-Suit Analysis Hypothetical 2

- Innovator product is X-dihydrate
- Claims
  - X-dihydrate and methods of treatment using an effective amount of X-dihydrate
- Notice letter with OCA
  - PIV Certification says ANDA product is not a dihydrate, but does not describe type of solvate
- Can innovator file suit in accordance with Ethical Rules and Rule 11?
  - Must/should innovator accept OCA?
  - Pre-suit testing?
  - Different analysis for method of treatment claims?

Rule 11: Requirements for Pre-Suit Invalidity Analysis

- Issued patents are presumed valid
- Ethical Rules and Rule 11 requires that "**the claims, defenses, and other legal contentions are warranted by existing law**…."
  - What ethical obligation exists to analyze prior art or other defenses asserted in PIV Notice Letter?
  - Is there an ethical obligation for innovator to analyze potential validity issues independent of those asserted in PIV Notice Letter?
  - *Post-Myriad,* is there an ethical obligation to investigate subject matter eligibility under Section 101 before asserting infringement?

Rule 11: Requirements for Pre-Suit Invalidity Analysis

- "[Plaintiff] argues that because patents are presumed valid and enforceable under 35 U.S.C. § 282, an attorney has a right to rely upon that presumption in pursuing an infringement claim. … True enough…"

- BUT "the presumption of validity is itself overcome when a patent is obtained through fraud. … [Litigant] had no objectively reasonable basis for bringing or maintaining this litigation."

See, e.g., *Intellect Wireless, Inc. v. Sharp Corp.*, 2015 WL 1539605, at *24 (N.D. Ill. Apr. 3, 2015)

Rule 11: Requirements for Pre-Suit Invalidity Analysis

- "[Defendant] contends that this case should be found exceptional or that Rule 11 sanctions are appropriate because [plaintiff] filed and maintained a suit asserting a patent that [plaintiff] knew was invalid. … **Although there may be factual circumstances in which, absent inequitable conduct, a patent infringement plaintiff knows its asserted patent is invalid, this action does not present such a case**."

See Brady Constr. Innovations v. Cal. Expanded Metal Co., 2007 U.S. Dist. LEXIS 98156 (C.D. Cal. Sept. 25, 2007) (emphasis added)

Section 101: USPTO Guidelines

Newest PTO guidelines provide examples of claim language the PTO deems ineligible under Section 101

Claim	Result
Antibiotic L	Ineligible
Purified Antibiotic L	Patentable subject matter
The Antibiotic L of claim 1, which is in a tetrahedral crystal form.	Patentable subject matter
The Antibiotic L of claim 1, which is expressed by recombinant yeast.	Patentable subject matter

Pre-Suit Analysis Hypothetical 3

- Scenario 1:
  - Patents claims (1) isolated DNA; (2) purified DNA; and (3) a pharmaceutical formulation of isolated or purified DNA.
- Scenario 2:
  - PIV Notice letter includes obviousness argument combining two references. You believe one reference anticipates your claims, but the Generic challenger has not raised this issue.
- Scenario 3:
  - Your company inherits a product that is challenged in a PIV. When reviewing the patent family, you learn that Provisional Applications were filed one year after the product was first marketed.

Certification Letters: Sanctions Against Generics

- Baseless certification letter containing scientific errors, among other findings of litigation misconduct found to support an award of fees and costs totaling **$16,800,000**.

- Paragraph IV obviousness certification of deemed "utterly frivolous":
  - Rule 30(b)(6) designee testified that no reason existed to choose compound 14 as the lead compound, and
  - Other expert testified compound 14 taught nothing related to pyridines at issue.

Takeda Chemical Indus., Ltd. v. Mylan Laboratories, Inc., 549 F. 3d 1381 (Fed. Cir. 2008)

Certification Letters: Sanctions Against Generics

- Federal circuit affirmed a district court's award of attorney's fees for baseless Paragraph IV certification and chemistry errors in pre-suit opinion.

- Obviousness certification deemed baseless:
  - District court characterized Danbury's case for obviousness as largely hindsight, speculation, and argument without an adequate foundation
  - Certification was accompanied with two affidavits which were incomplete and later contradicted by trial testimony

Yamanouchi Pharm. Co. v. Danbury Pharma., Inc., 231 F.3d 1339, 1347 (Fed. Cir. 2000)

Ethical Obligations Under New Discovery Rules

Ethical Obligations Under New Discovery Rules

- On April 29, 2015, Chief Justice John Roberts announced that the U.S. Supreme Court had adopted a package of amendments of Federal Rules of Civil Procedure.
- Amendments will take effect on December 1, 2015.
- Questions:
  - How will these rules impact your ethical obligations when responding to discovery requests?
  - How, if at all, will your discovery practices change?

“New” Rule 26(b)(1)

Current Rule	Proposed Amendment
…Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense [-including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter….-]	…Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense ***and proportional to the needs of the case***, *considering the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit*….

“New” Rule 26(b)(1)

Current Rule	Proposed Amendment
[…For good cause, the court may order discovery **of any matter relevant** to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence….]	*…Information within the scope of discovery need not be admissible in evidence to be discoverable.*

“New” Rule 34(b)(2)(B)

Current Rule	Proposed Amendment
For each item or category, the response must either state that inspection and related activities will be permitted as requested, or state [an objection] to the request, including the reasons	For each item or category, the response must either state that inspection and related activities will be permitted as requested, or ***state with specificity the grounds for objecting to the request, including the reasons***. **The responding party may state that it will produce copies of documents or of electronically stored information instead of permitting inspection. The production must then be completed no later than the time for inspection specified in the request or another reasonable time specified in the response.**

“New” Rule 34(b)(2)(C)

Current Rule	Proposed Amendment
An objection to part of a request must specify the part and permit inspection of the rest.	***An objection must state whether any responsive materials are being withheld on the basis of that objection.*** An objection to part of a request must specify the part and permit inspection of the rest.

"New" Rule 37(e)(1)

Current Rule	Proposed Amendment
Absent exceptional circumstances, a court may not impose sanctions under these rules on a party for failing to provide electronically stored information lost as a result of the routine, good-faith operation of an electronic information system.	If a party failed to preserve electronically stored information that should have been preserved in the anticipation or conduct of litigation, the court may: **1. Order measures no greater than necessary to cure the loss** of information, including permitting additional discovery; requiring the party to produce information that would otherwise not be reasonably accessible; and ordering the party to pay the reasonable expenses caused by the loss, including attorney's fees. 2. Upon a finding of prejudice to another party from loss of the information, order **measures no greater than necessary to cure the prejudice.** **3. Only upon a finding that the party acted with the intent to deprive** another party of the information's use in the litigation: a. presume that the lost information was unfavorable to the party; b. instruct the jury that it may or must presume the information was unfavorable to the party; or c. dismiss the action or enter a default judgment.

New Rules Hypothetical

- NDA for X drug approved on January 1, 2012
- Innovator document retention policy permits non-retention of emails after 1 year
- ANDA filed on January 1, 2016; Notice letter received shortly thereafter
- Innovator promptly puts “Litigation Hold” in place, including emails
- Is innovator at risk of having violated your ethical obligations for “new” Rule 37(e)(1)?
  - When does obligation to put “Litigation Hold” in place attach?
  - Different for innovator and generic?

Duty to Preserve Documents Under Rule 37

Denying in part and granting in part litigant's motion for discovery sanctions under Rule 37:

- *Denied* – No spoliation where litigant, who followed regular document destruction procedures, consented to production of an email's omitted attachment for purposes of inspection. The email concerned the production and manufacture of verapamil, a compound not at issue in the case.
- *Granted* – Duty to impose a litigation hold does not arise when the decision is made to create a generic drug. But where litigant practices "systematic document destruction," an adverse inference can be drawn that the destroyed documents were relevant to claims and defenses in the case.

Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., 2010 WL 2652412, at *6 (D.N.J. July 1, 2010)

Backup Materials

Sanctions for Litigation Misconduct

Typical Types of Litigation Misconduct

- Extensive improper confidentiality markings, including legal arguments, table of contents, statement of issues and summary of arguments
- Systematic document destruction, as opposed to regular document destruction practices
- Failure to produce documents by improper privilege or assertion other gamesmanship (e.g., avoiding court order by claiming order did not specify manner in which documents should be provided)

Sanctions for Extensive Confidentiality Markings

- "The briefs submitted by Defendant–Appellant contain extensive confidentiality markings, including portions of the Table of Contents, Statement of the Issues, Summary of the Argument, and Argument sections. A number of the portions marked confidential appear to consist of legal arguments."

- "We have specifically held that marking legal arguments as confidential is subject to sanction, because '[n]o good faith reading of our rule could support [a party's] marking of its legal arguments as confidential.'"

Gilead Sciences, Inc. v. Sigmapharm Labs., LLC,
584 F. App'x 929, 930 (Fed. Cir. 2014)

Forcing Litigant to Inspect Full ANDA Record, Rather than Produce Ordered Documents, is Sanctionable

Finding that the magistrate judge did not err in imposing discovery sanctions for the following conduct:

1. Defendants were aware that plaintiffs sought testing records for a certain period and failed to disclose them despite a court order to do so; and

2. Defendants' failure to produce previously produced documents in an unredacted form warranted sanctions in light of an order to produce such documents.

- Defendants sought “to obfuscate the issues” by contending that the magistrate judge's order did not specify the manner of production and therefore their offer to allow counsel for the plaintiffs to inspect the complete ANDA records in California sufficed.

Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 2014 WL 257394, at *4 (D. Mass. Jan. 22, 2014)

Adverse Inference Sanctions for Discovery Abuses

- Imposing an adverse inference sanction on plaintiff for various discovery abuses:
  - Improperly asserting privilege to withhold documents, despite Court Order
  - Precluding testimony of an inventor and an attorney
- "Only this [adverse] inference … is sufficient to remedy the array of issues [] and to place [defendant] in a position as near as possible to that which it would occupy in the absence of misconduct."
- "Merely striking the declarations and precluding testimony treats the most recent issues as isolated and remediable—when they are yet another step in a long pattern of litigation choices that have caused delay, inefficient use of resources, and diversion from the merits."

Regeneron Pharms., Inc. v. Merus BV,
1-14-cv-01650 (S.D.N.Y. August 6, 2015, Order) (Forrest, J.)

No Negative Inference Assumption of Bad-Faith for Filing Lawsuit Merely by Invoking Privilege

- Declining to draw "negative inference" assumption of bad-faith motive for filing lawsuit where defendant invoked attorney-client privilege regarding the information it had before filing the lawsuit.
- The court explained that, "no such negative inference can arise from the assertion of the privilege and, even if it did, such a negative inference cannot substitute for the requisite clear and affirmative evidence of bad faith."

In re Terazosin Hydrochloride Antitrust Litig., 335 F. Supp. 2d 1336, 1365 (S.D. Fla. 2004)

No Negative Inference From Failure to Present Evidence of One's Own Product

- Declining to draw a negative inference about Bayer's "failure to present evidence about [Bayer's 30 mg drug tablets]" in an earlier ANDA proceeding, because evidence about its own tablets "would have been, at best, only tangentially relevant to an ANDA infringement analysis."
- Bayer's tablets, while not in existence in first case, were still not relevant in second patent infringement case based on ANDA filing.

Bayer AG. v. Biovail Corp., 279 F.3d 1340, 1349 (Fed. Cir. 2002)

No Sanctions for Seeking "New Formulation"

- Denying discovery sanctions for discovery regarding a "new formulation." Litigant was entitled to seek information regarding the new formulation because that formulation was a component of the product-in-suit.

Ben Venue Labs., Inc. v. Novartis Pharm. Corp.,
146 F. Supp. 2d 572, 584 (D.N.J. 2001)

“Bad” Lawyering & “Sloppy” Argument is not Necessarily Misconduct

- In *Gaymar Indus., Inc. v. Cincinnati Sub-Zero Prods.*, *Inc*., the Federal Circuit remanded district court’s denial of Sub-Zero's motion for attorneys' fees based on alleged “misconduct” by Sub-Zero itself.
- Sub-Zero made several overstatements that the district court took issue with:
  - E.g., telling the judge that Sub-Zero needed to identify an expert in the technology, then later asserting that it had maintained "from the outset" that no technological expert was needed
- “The examples cited by the district court — whether considered in isolation or in the aggregate — amount to sloppy argument, at worst. … While such sloppiness on the part of litigants is unfortunately all too common, it does not amount to misrepresentation or misconduct.”

“Bad” Lawyering & “Sloppy” Argument is not Necessarily Misconduct

“In view of the serious consequences of a finding of misconduct, it is important that the district court be particularly careful not to characterize bad lawyering as misconduct.”

Gaymar Indus., Inc. v. Cincinnati Sub-Zero Prods., Inc., 2015 WL 3893711 (Fed. Cir. June 25, 2015)

Exceptional Case Under 35 U.S.C. § 285

The *Octane Fitness* Standard for "Exceptional Case" Under 35 U.S.C. § 285

- An "exceptional case" is "simply one that stands out from others with respect to the substantive strength of a party's litigating position … or the unreasonable manner in which the case was litigated."

- District courts may determine whether a case is "exceptional" "in the case-by-case exercise of their discretion, considering the totality of the circumstances."

Octane Fitness, LLC v. ICON Health & Fitness, Inc.,
134 S. Ct. 1749, 1756 (2014)

Attorneys' Fees Appropriate When Evidence Shows Clear Intent to Defraud

Granting award of attorney's fees under 35 U.S.C. § 285 because:

1. Evidence showed that plaintiff's principal conspired to defraud Univ. of South Florida and Imperial College in London of ownership rights in the invention;

2. Evidence also demonstrated that inventors intentionally hid the discovery of the claimed invention from USF to avoid its claiming rights in the invention; and

3. AIA's conduct was "objectively unreasonable," because the conspiracy, plot and deception were "beyond common decency." The award of fees is also motivated by deterrence, because "litigants must be discouraged from bringing an infringement action based upon a patent they know … they do not rightfully own, especially where they defrauded the PTO and the rightful owner of the patent."

Alzheimer's Inst. of Am., Inc. v. Avid Radiopharmaceuticals, 2015 WL 1422337, at *1 (E.D. Pa. Mar. 30, 2015)

Attorneys' Fees for Entirety of Action Appropriate for Fraud on the PTO and Untimely Assertion of Additional Claims

Granting motion for attorneys' fees, costs, and expenses "for defending the entirety of [the] action" because:

1. Plaintiff, "an apparent shell corporation, seems to have been formed with the sole intent to create jurisdiction;"

2. Plaintiff "further prolonged the reexamination process … by refusing to present the USPTO with additional [dispositive] prior art;

3. Plaintiff sought to "reopen the underlying litigation" by attempting to engage in discovery about the asserted patents which were previously held invalid by the USPTO; and

4. Plaintiff "violated clear, important canons of professionalism in proffering clearly privileged information" in support of its argument to minimize liability for attorneys' fees.

Large Audience Display Sys., LLC v. Tennman Productions, LLC,
11-cv-3398 (C.D. Cal. Aug. 18, 2015) (Real, J.)

Attorneys' Fees Not Appropriate for Continuing to Litigate Plausible Claims Through Summary Judgment

Declining to award attorney's fees under 35 U.S.C. § 285:

1. Declined to draw the inference that litigant lacked an objective basis to file suit for infringement, even when litigant received FDA approval to market a generic version of the drug, because it was "plausible at the outset that [defendant] used the claimed methods"; and

2. Found that plaintiff acted reasonably in litigating the claims because "it knew that [defendant's] overseas manufacturer employed a process" featured "prominently" in the claimed methods.

3. Plaintiff's failure to amend complaint was not of consequence because plaintiff notified defendant it would not assert claims.

Momenta Pharm., Inc. v. Teva Pharm. USA, Inc.,
60 F. Supp. 3d 261, 262 (D. Mass. 2014)

Attorneys' Fees Not Appropriate Where Defendant Failed to Demonstrate Plaintiff's Objective Bad Faith

Denying motion for attorney's fees because:

1. Plaintiff had a subjective good faith basis "as well as an objective basis" for viewing any alleged "sales/purchases" of [drug] as non-invalidating sales because they were made for the purposes of experimentation, and such evidence "negates the assertion of invalidity"; and

2. Defendant's reliance on meeting minutes document as evidence of knowledge of subjective intent to deceive the PTO was insufficient to prove plaintiff committed inequitable conduct.

Gilead Sciences, Inc. v. Sigmapharm Labs.,
2014 WL 1293309, at *1 (D.N.J. Mar. 31, 2014) *aff'd*,
586 F. App'x 585 (Fed. Cir. 2014)

Questions?