
Leveraging Opinions of Counsel Focused on Non-Infringement, Protecting IP Rights and Containing Patent Liability Risk

THURSDAY, AUGUST 20, 2015

Today’s faculty features:

Patrick J. Coyne, Partner, Finnegan Henderson Farabow Garrett & Dunner, Washington, D.C.

Thomas L. Irving, Partner, Finnegan Henderson Farabow Garrett & Dunner, Washington, D.C.

Barbara R. Rudolph, Ph.D., Partner, Finnegan Henderson Farabow Garrett & Dunner, Washington, D.C.

The audio portion of the conference may be accessed via the telephone or by using your computer’s speakers. Please refer to the instructions emailed to registrants for additional information. If you have any questions, please contact Customer Service at 1-800-926-7926 ext. 10.
**Tips for Optimal Quality**

**Sound Quality**
If you are listening via your computer speakers, please note that the quality of your sound will vary depending on the speed and quality of your internet connection.

If the sound quality is not satisfactory, you may listen via the phone: dial 1-866-819-0113 and enter your PIN when prompted. Otherwise, please send us a chat or e-mail sound@straffordpub.com immediately so we can address the problem.

If you dialed in and have any difficulties during the call, press *0 for assistance.

**Viewing Quality**
To maximize your screen, press the F11 key on your keyboard. To exit full screen, press the F11 key again.
Continuing Education Credits

In order for us to process your continuing education credit, you must confirm your participation in this webinar by completing and submitting the Attendance Affirmation/Evaluation after the webinar.

A link to the Attendance Affirmation/Evaluation will be in the thank you email that you will receive immediately following the program.

For additional information about CLE credit processing call us at 1-800-926-7926 ext. 35.
a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

b) Whoever actively induces infringement of a patent shall be liable as an infringer.

c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented [invention] constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.
Section § 271(b)


- **Holding:** “[W]e now hold that induced infringement under §271(b) requires knowledge that the induced acts constitute patent infringement. . . . [W]e agree that deliberate indifference to a known risk that a patent exists is not the appropriate standard under §271(b). We nevertheless affirm the judgment of the Court of Appeals because the evidence in this case was plainly sufficient to support a finding of Pentalpha’s knowledge under the doctrine of willful blindness.”
Induced Infringement

- **Global-Tech (con’t)**
  - District court: Judgment for SEB. Jury found Global-Tech/Pentalpha induced infringement
  - Federal Circuit: Affirmed. Active inducement of infringement under 271(b) necessarily requires that infringer knew of the patent, but knowledge element is satisfied if defendant “deliberately disregarded a known risk”
• **Global-Tech (con’t)**

- Supreme Court: Affirmed on other grounds

• Induced infringement under 271(b) requires knowledge that induced acts constitute patent infringement.

• Rejected “deliberate disregard of a known risk” standard as too broad; would impose liability for conduct only negligent or reckless.

• Knowledge established not only through proof of actual knowledge, but also through proof of “willful blindness” (doctrine from criminal law).
Induced Infringement

• **Global-Tech (con’t)**

  - Supreme Court:

    • Elements of “willful blindness:

      (1) defendant must subjectively believe that there is a high probability that a fact exists;

      (2) defendant must take deliberate actions to avoid learning of that fact
• Facts in Akamai
  - Claimed method consists of placing some content elements on a set of replicated servers and modifying the content to instruct web browsers to retrieve that content from those servers.
  - Limelight’s accused process places some content elements on its servers, and then instructs its customers on the steps needed to modify.

• District court, 614 F.Supp.2d 90 (D.Mass 2009)
  - Jury finding of patent infringement and award of $45.5 million in damages
  - JMOL of noninfringement
    • “Under Muniauction, this is insufficient to establish the requisite direction or control by Limelight of its customers necessary to find it liable for direct infringement.”
Akamai Techs. v. Limelight Networks
692 F.3d 1301 (Fed. Cir. 2012)(en banc)

- On rehearing *en banc*: 6-5 decision that a defendant may be held liable for inducing patent infringement under 35 U.S.C. § 271(b) even though no one entity committed direct infringement under § 271(a).

- Not necessary that all steps of claimed method be performed by single entity to find induced infringement under § 271(b)

- Abolished “single-entity rule” for § 271(b), but left rule intact for finding joint infringement under § 271(a)

- Overruled *BMC Resources*, which held that for party to be liable for induced infringement, some other single entity must be liable for direct infringement
Akamai Techs. v. Limelight Networks
692 F.3d 1301 (Fed. Cir. 2012)

- Divided Infringement
  - Claim with steps A, B, C
  - Easy if single entity performs all three steps

- What if first actor induced second actor to perform steps A, B, C? 2nd actor directly infringes, 1st actor induces infringement

- Issue was whether a defendant who performed some of the steps of a claimed method and induces another to perform other steps
Rationale

- § 271(b): “Whoever actively induces infringement of a patent shall be liable as an infringer.”
- “Infringement” in § 271(b) refers to acts necessary to infringe patent, whether performed by single entity or not

What type of relationship is required?

- Induced infringement does not require induced party be agent of the inducer or be acting under inducer’s direction or control
- Sufficient that inducer causes, urges, encourages, or aids direct infringer to carry out infringing conduct
Akamai Techs. v. Limelight Networks  
692 F.3d 1301 (Fed. Cir. 2012)(en banc)

- Legislative history of § 271 supported interpreting induced infringement as not requiring that single entity must perform all claimed steps.

- Comments by Judge Giles S. Rich in Congressional hearings—§ 271 was intended to reach cases of divided infringement, even when no single entity would be liable for direct infringement.

- Principles of criminal and tort laws support holding.

- Avoids bizarre result where a party could avoid liability for inducement by performing one step itself.
Akamai Techs. v. Limelight Networks
692 F.3d 1301 (Fed. Cir. 2012)(en banc)

- Judge Newman (dissenting)
  - Majority should abolish single-entity rule for direct infringement under § 271(a)
  - Solution would be to apportion remedies
- Judge Linn, joined by Judges Dyk, Prost, and O’Malley (dissenting)
  - Advocated for single-entity rule
  - Majority’s decision contravenes statute and Supreme Court precedent that there can be no contributory infringement without direct infringement
  - Vicarious liability is proper test for establishing direct infringement liability in multi-actor context
  - Without direct infringement, the patentee has not suffered compensable harm
Induced Infringement

- **Limelight Networks Inc. v. Akamai Techs. Inc.**, 134 S.Ct. 2111 (U.S. June 2, 2014)

  Supreme Court: Unanimous reversal of Federal Circuit *en banc* decision that a defendant may be held liable for inducing patent infringement under 35 U.S.C. § 271(b) even though no one entity committed direct infringement under § 271(a).

  - “The Federal Circuit's analysis fundamentally misunderstands what it means to infringe a method patent.”

  - A defendant may not be liable for infringing a patent under §271(b) when no one has directly infringed the patent under §271(a) or any other statutory provision.

  - Acknowledged that “a would-be infringer [could] evade liability by dividing performance of a method patent’s steps with another whom the defendant neither directs nor controls.” However, that was caused by “the Federal Circuit's interpretation of § 271(a) in Muniauction.”
Induced Infringement (con’t)

- **Limelight (con’t)**
  - *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008): when multiple parties perform infringing acts in separate steps, no one party infringes, so no liability under §271(a) unless “direction/control” by one.

- Supreme Court:
  - the Federal Circuit’s reasoning permits inducement liability when fewer than all of a claimed method’s steps have been performed.
  - Congress showed in § 271(f) that when it wanted a special rule to cover induced infringement without requiring direct infringement, it knew how to do so.

- On remand: Federal Circuit must determine whether §271(a) direct infringement can be found where all claim steps are performed by multiple parties but not by any single entity.

- Limelight's accused process: no single entity practiced all of the claim steps for § 271(a) direct infringement.
Akamai Technologies Inc. v. Limelight Networks Inc.,

786 F.3d 899 (Fed. Cir. 2015), on remand from Supreme Court

• Reaffirmed single-entity rule: 2-1 decision
  • Infringement of a method claim requires that a single actor perform every step of the claim.

• May be vicarious liability if:
  • agency relationship;
  • contract to perform some of the acts amounting to infringement;
  • joint enterprise.
Akamai Technologies Inc. v. Limelight Networks Inc.,

--F.3d___ (Fed. Cir. Aug. 13, 2015), rehearing en banc

• 10 judges; opinion per curiam

• Holding:
  • Substantial evidence supports jury verdict that Limelight directly infringed.
  
  • “Direct infringement under §271(a) occurs where all steps of a claimed method are performed by or attributable to a single entity.”

  • “[A]n entity [is] responsible for others’ performance of method steps...:
    • (1) where that entity directs or controls others’ performance, and
    • (2) where the actors form a joint enterprise.”
rehearing en banc (con’t)

• “To determine if a single entity directs or controls the acts of another, we continue to consider general principles of vicarious liability.”

• FN2: “We note that previous cases’ use of the term ‘vicarious liability’ is a misnomer...In the context of joint patent infringement, an alleged infringer is not liable for a third party’s commission of infringement - rather, an alleged infringer is responsible for method steps performed by a third party. Accordingly, we recognize that vicarious liability is not a perfect analog. Nevertheless, as both vicarious liability and joint patent infringement discern when the activities of one entity are attributable to another, we derive our direction or control standard from vicarious liability law. [citation to BMC]”
rehearing *en banc* (con’t)

- “on the facts of this case, ...liability under §271(a) can also be found when an alleged infringer conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance.”

- “In those instances, the third party’s actions are attributed to the alleged infringer such that the alleged infringer becomes the single actor chargeable with direct infringement. When a single actor directed or controlled the acts of one or more third parties is a question of fact, reviewable on appeal for substantial evidence, when tried to a jury.”

- “Section 271(a) is not limited solely to principal-agent relationships, contractual arrangements, and joint enterprise, as the vacated panel decision held. Rather, to determine direct infringement, we consider whether all method steps can be attributed to a single entity.”
rehearing en banc (con’t)

• “The jury verdict heard substantial evidence from which it could find that Limelight directs or controls its customers’ performance of each remaining method step, such that all steps of the method are attributable to Limelight.”

• “[S]ubstantial evidence indicates that Limelight conditions customers’ use of its content delivery network upon its customers’ performance of the tagging and serving method steps.”

• “Substantial evidence also supports finding that Limelight established the manner or timing of its customers’ performance.”

• “Therefore, Limelight is liable for direct infringement.”
Induced Infringement


- When determining induced infringement, accused infringer’s good-faith belief about patent invalidity could potentially negate finding of intent; such belief is evidence that should be considered.

- Jury instructions: intent requirement for induced infringement can be satisfied if defendant knew or should have known that its actions would induce actual infringement.

- Fed. Cir. held instructions erroneous based on *Global-Tech Appliances v. SEB S.A.* (standard knowledge or willful blindness).
“With respect to whether the induced acts constitute patent infringement, it is clear that the jury was permitted to find induced infringement based on mere negligence where knowledge is required. This erroneous instruction certainly could have changed the result. Facts sufficient to support a negligence finding are not necessarily sufficient to support a finding of knowledge. Accordingly, we vacate the jury's verdict on induced infringement and remand for a new trial.”

“no principled distinction between a good-faith belief of invalidity and a good-faith belief of non-infringement for the purpose of whether a defendant possessed the specific intent to induce infringement of a patent.... evidence of an accused inducer's good-faith belief of invalidity may negate the requisite intent for induced infringement. ...[Such] evidence that should be considered by the fact-finder in determining whether an accused party knew ‘that the induced acts constitute patent infringement.’”
Commil v. Cisco Sys. – Relevant Holdings

• Relevant holdings:

  • negligence or recklessness is not sufficient to satisfy knowledge requirement for a claim of induced patent infringement;

  • evidence of an accused inducer's good-faith belief of the invalidity of a patent may negate the requisite intent for induced patent infringement.
• NEWMAN, concurring-in-part, dissenting-in-part.

  • “The court holds that if the inducer of infringement believes in good faith that the patent is invalid, there can be no liability for induced infringement, although the patent is held valid. ...This change in the law of induced infringement is inappropriate.”

  • “A good-faith belief of patent invalidity may be raised as a defense to willfulness of the infringement, but it is not a defense to the fact of infringement. .... No rule eliminates infringement of a valid patent, whether the infringement is direct or indirect.”

  • “If one intentionally interferes with the interests of others, he is often subject to liability notwithstanding the invasion was made under an erroneous belief as to some legal matter that would have justified the conduct.” Id. (quoting Keeton on Law of Torts 110 (5th ed. 1984)).

  • “whether there is infringement in fact does not depend on the belief of the accused infringer that it might succeed in invalidating the patent.”
Dissent from denial of petition for rehearing en banc (REYNA, Rader, Newman, Lourie, Wallach)

• “By holding that a good faith belief in the invalidity of a patent may negate the requisite intent for induced infringement, the two-judge Commil majority created a new noninfringement defense to induced infringement that is premised on the accused infringer’s belief of invalidity.”

• “the majority holding ...wrongly rearranges the legal foundation that underpins the enforceability of valid patents and the finding of liability for infringement.”

• “under the majority’s holding, an accused inducer that is deriving a benefit by knowingly and intentionally inducing an unsuspecting third party to directly infringe patent rights can itself escape liability based on a belief that the patent is invalid while the unsuspecting third party cannot.”

• “the Commil majority nevertheless imputes questions of invalidity into induced infringement under the guise of “intent.”

• “The new rule is a powerful tool in patent litigation in that it establishes an escape hatch from liability of infringement that is not now in the statute. This has a compromising effect on the only axiom that we should all observe, and that is issued patents are presumed valid.”

Commil v. Cisco Sys. – Federal Circuit Dissent from Denial of Rehearing En Banc
Petition for Certiorari Granted

- **Commil USA, LLC v. Cisco Systems, Inc.**, 135 S.Ct. 752 (U.S. Dec. 5, 2014)

  - Petition for Certiorari granted as to this question:

    1. Whether the Federal Circuit erred in holding that a defendant's belief that a patent is invalid is a defense to induced infringement under 35 U.S.C. § 271(b).
Commil v. Cisco Sys. – Supreme Court


- Supreme Court:
  - Vacated and remanded.
    - Direct infringement is a strict-liability offense (no knowledge requirement), but induced infringement and contributory infringement require “knowledge of the patent in suit and knowledge of patent infringement.”

- A reasonable belief of noninfringement is a defense to claims of inducement, but a good faith belief that a patent is invalid is not a defense to a charge of induced or contributory infringement.

- “invalidity is not a defense to infringement, it is a defense to liability. And because of that fact, a belief as to invalidity cannot negate the scienter required for induced infringement.”
Supreme Court (con’t):

- Also, reaffirmed *Global-Tech v. SEB* that a defendant can only be liable for inducing or contributing to infringement if the defendant has knowledge that a third party’s acts constitute infringement; knowledge of a patent alone is insufficient.

- Accused inducers have other options: file a declaratory judgment action, file IPR petition, file ex parte reexamination request, raise affirmative defense of invalidity.

- “district courts have the authority and responsibility to ensure frivolous cases are dissuaded. ...These safeguards, combined with the avenues that accused inducers have to obtain rulings on the validity of patents, militate in favor of maintaining the separation expressed throughout the Patent Act between infringement and validity. This dichotomy means that belief in invalidity is no defense to a claim of induced infringement.”
Suprema, Inc. v. ITC

--F.3d- (Federal Circuit Aug. 10, 2015)

• 6-4 decision

• ITC has the authority to prevent the importation of products that could induce infringement of U.S. patents after they are imported, even if they don’t infringe at the time they enter the country.

• Reversed a precedential 2013 ruling holding that § 337 of the Tariff Act covers only products that directly infringe U.S. patents at the time of importation.
Issues Specific to Pharma Patents
Introduction

ANDA or B2 Application

Para I Certification

Para II Certification

Para III Certification

Paragraph IV Certification

Section viii “carve out”

Hatch-Waxman Infringement
35 USC 271(e)(2)

Induced Infringement
35 USC 271(b)
Two Variables in Method-of-Use Cases

1. FDA Approved Use

2. Patented Use
35 U.S.C. § 271(e)(2) It shall be an act of infringement to submit an application under section 505(j) of the [FDA Act] or described in section 505(b)(2) of that Act for a drug claimed in a patent or the use of which is claimed in a patent. . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use or sale of a drug . . . claimed in a patent before the expiration of such patent.

Requirement 1: an application

Requirement 2: a patent claiming a use of the drug
Amarin manufactures a triglyceride-lowering drug, Vascepa®.

FDA approved Vascepa® for one use, but doctors prescribe for another.

FDA threatened to bring a misbranding action against Amarain if it promotes Vascepa® for an off-label use.

District court: granted preliminary relief.
  • Amarin may engage in truthful and non-misleading speech promoting the off-label use of Vascepa® - will not be basis of a prosecution for misbranding.
**AstraZeneca v. Apotex (2012)**

<table>
<thead>
<tr>
<th><strong>Drug</strong></th>
<th>Crestor® (rosuvastatin)</th>
</tr>
</thead>
</table>
| **Use Sought in ANDA** ("Approved Use") | 1. Treatment of HoFH  
2. Treatment of hypertriglyceridemia |
| **Asserted Method Patent(s)** | 1. Treatment of HeFH  
2. Prevention of elevated C-reactive protein |
| **Key Fact**      | Undisputed that AZ did not have patents on HoFH or hypertriglyceridemia |
| **Problem for Patentee** | ANDA use not patented |
| **Outcome**       | Failure to state claim under 271(e)(2) |

AZ v. Apotex, 669 F.3d 1370 (Fed. Cir. 2012)
AstraZeneca v. Apotex

• **Issue:** “In Warner-Lambert, we construed the term ‘the use’ as used in § 271(e)(2)(A) to mean ‘the use listed in the ANDA’ based on our evaluation of the statutory language, its context within the Act, and the legislative history behind its enactment...”

• **Holding:** “Because Appellees have submitted ANDAs seeking approval to market rosuvastatin calcium for uses that are not subject to AstraZeneca’s ’618 and ’152 method of use patents, AstraZeneca does not state a claim for infringement of these patents under § 271(e)(2).”

AZ v. Apotex,
669 F.3d 1370 (Fed. Cir. 2012)
## Recap

### Accused use must be “approved use” and patented use

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug</strong></td>
<td>Neurontin® (gabapentin)</td>
<td>Alphagan® (brimonidine)</td>
<td>Crestor® (rosuvastatin)</td>
</tr>
<tr>
<td><strong>Use Sought in ANDA (“Approved Use”)</strong></td>
<td>Treatment of partial seizures. in adults with epilepsy</td>
<td>Prevention of post-operative interocular pressure (IOP) in patients</td>
<td>1. Treatment of HoFH 2. Treatment of hypertriglyceridemia</td>
</tr>
<tr>
<td><strong>Key Fact</strong></td>
<td>Undisputed that patented neurodegenerative method was “off-label” (unapproved) use</td>
<td>Undisputed that patented nerve protection method was “off-label”</td>
<td>Undisputed that AZ did not have patents on HoFH or hypertriglyceridemia</td>
</tr>
<tr>
<td><strong>Problem for Patentee</strong></td>
<td>Patented use not FDA approved</td>
<td>Patented use not FDA approved</td>
<td>ANDA use not patented</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td>SJ noninfringement</td>
<td>SJ noninfringement</td>
<td>Failure to state claim under 271(e)(2)</td>
</tr>
</tbody>
</table>
Bayer Schering Pharma v. Lupin Ltd. (Yasmin®)
Facts

- Yasmin® (drospirenone)
- Oral contraceptive
- FDA Approved 2001
- Other known activities
Bayer Schering Pharma v. Lupin Ltd. (Yasmin®)

- U.S. Pat. No. 5,569,652
- “Simultaneous effect”
  - gestagenic (contraceptive)
  - antiandrogenic (anti-acne)
  - antialdosterone (anti-water retention)

1. A method of simultaneously achieving, during pre-menopause or menopause a gestagenic effect, antiandrogenic effect, and an antialdosterone effect in a female patient in need thereof comprising administering an amount of dihydrospirorenone to said female patient, wherein said amount of dihydrospirorenone is effective to simultaneously achieve a gestagenic effect, antiandrogenic effect and antialdosterone effect in said patient.
Uncontested Facts

1. “Bayer does not enjoy patent protection for the drug Yasmin or for the use of the drug for contraception alone.”

2. “The '652 patent claims a method of use consisting of simultaneously achieving [the three effects].”

3. “The only proposed “indication for use” in the NDA application filed by Bayer's predecessor was for oral contraception.”

4. “The Indications and Usage section of the defendants' ANDAs . . . did not refer to the other effects claimed in the '652 patent.”
Four Pieces of Bayer’s Case

1. 21 C.F.R. § 314.53: requires the submission not only of patents that claim “indications,” but also patents that claim “other conditions of use.”

2. Declaration of Dr. Shulman
   - obstetrician-gynecologist with experience in the clinical use of contraceptives
   - doctors prescribe Yasmin as an oral contraceptive with the intent to produce all three effects as “clearly stated and on-label.”

3. Declaration of Dr. Allen, a former FDA official
   - oversaw the approval of the Yasmin NDA while at FDA
   - those effects were confirmed in Yasmin and are “‘pertinent’ to human use of the drug.”

4. FDA's approval of certain promotional materials
   - highlighted anti-aldosterone and anti-androgenic properties of Yasmin
Bayer Schering Pharma v. Lupin Ltd. (Yasmin®)

**Holding**

While that passage states that Yasmin exhibits antimineralocorticoid activity and has the potential for antiandrogenic activity based on animal studies, neither that passage nor anything else on the label provides any safety or efficacy information associated with the possible use of Yasmin in treating patients who are in need of those effects. Thus, while the label mentions potential antimineralocorticoid and anti-androgenic activity, it does not do so in any way that recommends or suggests to physicians that the drug is safe and effective for administration to patients for the purposes of inducing these effects.

the point is not simply that the method of use was not described in the Indications and Usage section that shows lack of FDA approval; the point is that the label, taken in its entirety, fails to recommend or suggest to a physician that Yasmin is safe and effective for inducing the claimed combination of effects in patients in need thereof.
The infringement question is whether sale or use of the generic equivalent of the Yasmin® product, in accordance with the representations in the ANDA with respect to FDA approval for the generic equivalent of Yasmin®, infringes the ’652 patent.

The panel majority is incorrect in its statement that the safety and efficacy of the anti-androgenic and anti-mineralocorticoid effects were never reviewed by the FDA. The portion of the FDA label in which a product’s properties are described is irrelevant to whether the patent is infringed by sale or use of the product.

The evidence before the district court, presented in response to this motion, supported the statement in Bayer’s complaint that a “significant proportion of drospirenone and ethinylestradiol prescriptions are written with the intent of producing three pharmacological effects – gestagenic, anti-aldosterone, and anti-androgenic.” Even were these threshold facts disputed – and they were not – it is improper for a court to make contrary findings under Rule 12(c).
Comparing Approved Use to Claim May Require Claim Construction First


  - When determining whether the drug is approved for the uses claimed, a motion of summary judgment of noninfringement premature when a claim construction issue exists.

  - Bayer “did not depend on a court's construction of a term in the patent. In this case, however, the dispute directly relates to the construction of a key term in the relevant patent claims. That dispute is about whether the undisputed FDA-approved use for EXJADE® (captured in the “Indications and Usage” section of the drug's label)—“the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older”—is claimed by the patented method of “treating diseases which cause an excess of metal in a human or animal body or are caused by an excess of metal in a human or animal body.”
Hatch–Waxman Infringement

- ANDA or B2 Application
  - Para I Certification
  - Para II Certification
  - Para III Certification
  - Paragraph IV Certification
  - Section viii “carve out”
    - Induced Infringement
      - 35 USC 271(b)
Facts

- Pulmicort Respules® (budesonide)
- anti-inflammatory corticosteroid for asthma
- FDA Approved 2000

• **Label:**
  - once or twice daily
  - titrate downward

• **Patents?**

Does the label induce infringement???

Apotex ANDA

• Section viii
• Twice-daily only
• BUT proposed Label still contained “titrate down” language

District Court Proceedings

• AZ arguments
  - DJ action under 271(b)
  - request for preliminary injunction

• Apotex arguments
  - invalidity §§ 102, 103
  - FDA required Apotex to include the downward-titration statements in the label
  - downward-titration statements do not instruct users to take the generic drug “once daily”
    • FDA had previously issued a letter agreeing that the downward-titration language did not “teach” once-daily usage

FDA Letter to Apotex:

Titration to the lowest effective dose may involve, for example, a twice-daily regimen, *once-daily dosing*, or even alternate day dosing.... The labeling does not state the lowest effective dose is 0.25 mg once daily. As such, contrary to your assertion, the downward titration statement does not “teach” once-daily dosing.

.... and need not be carved out as protected by the 6,598,603 and 6,899,099 patents.

**District Court Holding**

- Patents valid and enforceable
- “Downward-titration” would lead users to infringe
- FDA Letter “explicitly stated (and therefore put Apotex on notice) that downward titration may involve once-daily dosing.”
- Apotex could have formally appealed the FDA's denial of Apotex's proposed labeling amendments
- Preliminary injunction warranted
Federal Circuit

- “Apotex's reliance on the FDA's statements that the downward-titration language does not ‘teach’ once-daily dosing and is not protected by the '603 and '099 patents is misplaced. . . the FDA is not the arbiter of patent infringement issues.”

- “[T]he district court did not abuse its discretion by granting the preliminary injunction . . .”
  - “(1) Defendants will induce infringement of the ’603 Patent; but (2) that Patent is invalid as obvious and anticipated by the prior art; and (3) Defendants will not infringe the ’834 Patent. Accordingly, the Court enters judgment against AstraZeneca and in favor of Defendants.”

  - kit claims are invalid
  - the Court's Order dismissing the method claims with prejudice “effectively represents a final judgment of non-infringement in favor of all of the defendants”

• Appeal and cross-appeal filed: June 2013
Example 1

- **Indicated Use:** Drug X for treating disease A
- **Patented Use:** A method for causing pharmacologic effect.
- **Expert:** Drug X treats disease A via pharmacologic effect.
Example 2

- Indicated Use: Drug X for treating disease A
- Patented Use: A method for treating class of diseases.
- Expert: Disease A is member of patented class.
Unanswered Questions

Label Construction Example

- What evidence determines the scope of the approved use?
  - Under *Bayer*, “the label, taken in its entirety, [must] recommend or suggest to a physician that [the drug] is safe and effective for inducing the claimed [effect].”
Drafting and Prosecution Tips for Pharma Patents

- Coordinate patent, regulatory and clinical personnel early.

- Maintain consistency between claims and likely or actual label language.

- Maintain the coordination referenced above throughout the U.S. patent prosecution and label negotiation with FDA.
• Consider drafting claims so that one party infringes claims (e.g., one party performs all recited steps).

• Consider obtaining a noninfringement opinion to show good-faith belief of noninfringement.
  
  - Opinion of counsel concluding that the patent in question is invalid will not be relevant to induced infringement allegation.

• Consider explicitly pleading indirect infringement and knowledge of the patent prior to the complaint.
Thank You!

Contact Information:

tom.irving@finnegan.com
barbara.rudolph@finnegan.com
patrick.coyne@finnegan.com