NEW JERSEY INTELLECTUAL PROPERTY LAW ASSOCIATION

PATENT LITIGATION SEMINAR

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Inequitable Conduct after *Therasense v. Becton Dickinson*

Paul H. Berghoff
McDonnell Boehnen Hulbert & Berghoff LLP
Chicago
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Therasense

- En banc decision on May 25, 2011
- Authored by Chief Judge Rader
- Close decision

- Reshaped inequitable conduct

Therasense

- Accused infringer must prove that the patentee acted with a specific intent to deceive the PTO.
  - Proving that the applicant knew of a reference, should have known of its materiality and decided not to submit it to the PTO does **not** prove specific intent to deceive.

Therasense

- To meet the clear and convincing evidence standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence.
  - Indeed, the evidence must be sufficient to require a finding of deceitful intent in light of all the circumstances
  - When there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.

Therasense

- Patentee need not offer any good faith explanation unless the accused infringer first proves a threshold level of intent to deceive by clear and convincing evidence.
  - The absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.

Therasense

- But-for materiality is required to establish inequitable conduct
- When an applicant fails to disclose prior art to the PTO, the prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.

Therasense

- Courts apply the preponderance of the evidence standard in determining materiality
- And give claims their broadest reasonable construction
  - A withheld reference may be material even if it is not invalidating

Therasense

- New exception -- affirmative egregious conduct
- Based on Supreme Court cases dealing with deliberately planned and carefully executed schemes to defraud the PTO and the courts.
  - Bribery
  - Perjury
  - Manufacture and suppression of evidence

Therasense

- When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material
  - Egregious misconduct exception gives sufficient flexibility to capture extraordinary circumstances
  - This flexibility is appropriate "in the context of the way inequitable conduct has metastasized."

Stated Benefits of *Therasense*

- Reduce cost and complexity of adjudication
- Increase likelihood of settlement
- Reduce burden on the courts

- Reduce strain on PTO resources
- Reduce PTO backlog
- Improve patent quality

Effects of *Therasense*

- Pleadings
- Preliminary injunctions
- Summary judgment
- Trial
- Appeal

Pleadings

1. *Oracle v. Druglogic*, ND California
2. *Abaxis v. Cepheid*, ND California
3. *Pixion v. Citrix*, ND California
4. *W.L. Gore v. Medtronic*, ED Virginia
5. *Wyeth v. Sandoz*, D Delaware
6. *Alps South v. Ohio Willow Wood*, MD Florida
7. *Sipco v. Control4*, ND Georgia
8. *Recticel v. Automotive Components*, ED Michigan
9. *Jersey Asparagus Farms v. Rutgers University,* D New Jersey

Oracle v. Druglogic

- ND California -- MJ Spero
- Pleading dismissed with leave to amend
- Defendant did not allege any facts to support an inference that the information allegedly withheld from the PTO is not cumulative.
  - Did not properly plead the why and how ala *Exergen*
- Knowledge pleading inadequate
  - But court suggests that knowledge by inventors of the relevance of the withheld reference would be adequate to plead deceptive intent – close question

Abaxis v. Cepheid

- ND California – Judge Koh
- Pleading dismissed, no leave to amend
- Chain of inference is too tenuous to infer that the attorney knew that the withheld reference was but-for material
  - Even though reference was cited and discussed in a related patent application

Pixion v. Citrix

- ND California – Judge Illston
- Pleading dismissed, no leave to amend
- Patentee cited related applications but did not submit negative office actions
  - Disclosing applications points away from an intent to deceive.
  - Allegation of materiality alone does not create an inference of deceptive intent
- Citation of related applications means that an intent to deceive can never be the single most reasonable inference.
  - Leave to amend denied

W.L. Gore v. Medtronic

- ED Virginia – Judge Davis
- Pleading sustained
- Detailed why the uncited art was material and not cumulative
  - And how one could infer that the inventor and attorney were aware of the undisclosed patents and their potential materiality
- Because exclusion of material prior art could provide a patent applicant with the significant benefit of having the application granted, this is sufficient pleading upon which to base a reasonable inference of intent to deceive

Wyeth v. Sandoz

- D Delaware – MJ Burke
- Pleading sustained
- States that "single most reasonable inference" standard cited in *Therasense* did not tighten the pleading requirements of *Exergen*
- In order to adequately plead intent, only need to allege facts from which the Court could *reasonably infer* that the patent applicant made a deliberate decision to deceive the PTO.
  - It is at least plausible that the alleged misrepresentations traversed the line from mere argument to actionable falsehoods.

Alps South v. Ohio Willow Wood

- MD Florida – Judge Kovachevich
- Pleading dismissed
- Allegations of specific intent to deceive were inadequate
  - Based solely on but-for materiality of information
  - No allegation that inventor knew that any purported misrepresentations or omissions were but-for material

Sipco v. Control$_4$

- ND Georgia – Judge Carnes
- Pleading sustained
- Identified specific undisclosed prior art and its significance to patents in suit
- Allegations suggest a specific intent to deceive the PTO
  - Nothing more is required at the pleading stage

Recticel v. Automotive Components

- ED Michigan – Judge Cox
- Pleading dismissed with leave to amend
- Pleading did not sufficiently identify the what, where and how of the alleged material omission
  - General pleading that patentee knew or should have known of the undisclosed prior art is inadequate

Jersey Asparagus Farms v. Rutgers University

- D New Jersey – Judge Wolfson
- Antitrust and RICO case
- Pleading dismissed with leave to amend
- Failed to sufficiently allege scienter
  - No allegation that any of the inventors knew that the undisclosed prior uses constituted material prior art

Pleadings Scorecard

1.	*Oracle v. Druglogic*, ND California	Maybe
2.	*Abaxis v. Cepheid*, ND California	No
3.	*Pixion v. Citrix*, ND California	No
4.	*W.L. Gore v. Medtronic*, ED Virginia	Yes
5.	*Wyeth v. Sandoz*, D Delaware	Yes
6.	*Alps South v. Ohio Willow Wood*, MD Florida	No
7.	*Sipco v. Control4*, ND Georgia	Yes
8.	*Recticel v. Automotive Components*, ED Michigan	Maybe
9.	*Jersey Asparagus Farms v. Rutgers,* D New Jersey	Maybe

Pleadings

- Lessons learned
  - Patentee's perspective
  - Defendant's perspective

Preliminary Injunctions

1. *Apple v. Samsung*, ND California
2. *Generac Power v. Kohler*, ED Wisconsin
3. *Light Guard v. Spot Devices*, D Nevada

Apple v. Samsung

- ND California – Judge Koh
- Preliminary injunction denied for lack of irreparable harm
- Apple established a likelihood of success on merits
- Samsung's inequitable conduct argument insufficient since based on a "should have known" standard rejected in *Therasense*.

Generac v. Kohler

- ED Wisconsin -- Judge Randa
- Preliminary injunction denied
  - Undisclosed prior art raised substantial question of invalidity
- Inequitable conduct arguments lacked substantial merit
  - No showing that patent would not have issued
  - No showing of specific intent to deceive

Light Guard v. Spot Devices

- D Nevada – Judge Hicks
- Preliminary injunction denied
  - Undisclosed prior art raised substantial question of invalidity
- Defendant did not raise substantial question concerning inequitable conduct
  - Undisclosed prior art was material
  - But there was more than one reasonable inference concerning intent

PI Scorecard

1. *Apple v. Samsung*, ND California — No
2. *Generac Power v. Kohler*, ED Wisconsin — No
3. *Light Guard v. Spot Devices*, D Nevada — No

- Lessons learned?

Summary Judgment

1. *Schering v. Mylan,* D New Jersey
2. *Kathrein-Werke v. Radiacion,* ND Illinois
3. *Mformation v. RIM,* ND California
4. *Carl Zeiss v. Signet Armorlite,* SD California
5. *MeadWestvaco v. Rexam,* ED Virginia
6. *WesternGeco v. Ion Geophysical,* SD Texas
7. *Kimberly-Clark v. First Quality,* MD Pennsylvania
8. *Joy MM v. Cincinnati Mine,* WD Pennsylvania
9. Five *Seiko Epson* cases, D Oregon

Schering v. Mylan

- D New Jersey – Judge Linares
- Patentee's SJ motion denied
- Defendant put forth sufficient evidence to establish that patentee had knowledge of the materiality of the withheld prior art
  - Also, a deliberate decision to withhold that information could be reasonably inferred

Kathrein-Werke v. Radiacion

- ND Illinois -- Judge Guzman
- Patentee's SJ motion denied
- The record contains circumstantial evidence from which an intent to deceive may be reasonably inferred.
  - Because the evidence permits multiple reasonable inferences, there is a triable issue of fact
  - A reasonable fact finder could infer that patentee intended to deceive the PTO by withholding information.

Mformation v. RIM

- ND California – Judge Ware
- Patentee's SJ motion granted
- Evidence permits the reasonable inference that patentee did not consider the uncited references to be material
  - Defendants have not shown that the evidence "requires" a finding of deceitful intent, which means that intent to deceive cannot be found.

Carl Zeiss Vision v. Signet Armorlite

- SD California – Judge Sabraw
- Patentee's SJ motion granted
- Only evidence of intent was patentee's failure to disclose a reference.
  - This does not amount to clear and convincing evidence of a specific intent to deceive the PTO
  - There is more than one reasonable inference that may be drawn from the failure to disclose

MeadWestvaco v. Rexam

- ED Virginia – Judge Lee
- Patentees' SJ motion granted
- Court concluded that patentee did not withhold any prior art references
  - Uncited references were cumulative
  - Patentees' voluminous disclosures establish that they were attempting to be as transparent as possible in applying for patents

WesternGeco v. Ion Geophysical

- SD Texas – Judge Ellison
- Patentee's SJ motion granted
- Copies of the supposedly mischaracterized references were provided to the Examiner
  - Attorney argument cannot give rise to inequitable conduct
  - Could not be a but-for causation of the patent's issuance
  - No need to consider intent to deceive

Kimberly-Clark v. First Quality

- MD Pennsylvania – Judge Caldwell
- Patentee's SJ motion granted
- Evidence failed to show that the patent attorney recognized that the uncited patent was material or that he made a deliberate decision to withhold.
  - Patent attorney's prior contact with the uncited patent would not compel a reasonable finder of fact to infer an intent to deceive

Joy MM v. Cincinnati Mine

- WD Pennsylvania – Judge Lancaster
- Patentee's SJ motion granted
- No intent to deceive where the inventor and the patent attorney reviewed the piece of prior art and considered it no more relevant than references already cited.
  - Uncited reference lacked many claim limitations

Five *Seiko Epson* Cases

- D Oregon – Judge Brown
- Patentee's SJ motion of no inequitable conduct and no *Walker Process* fraud granted
- Even if a complete translation had been filed, it would have been cumulative
- No reasonable juror could find that the patentee had a specific intent to deceive.
  - Or that an intent to deceive was the single most reasonable inference

SJ Scorecard

1.	*Schering v. Mylan,* D New Jersey	Maybe
2.	*Kathrein-Werke v. Radiacion,* ND Illinois	Maybe
3.	*Mformation v. RIM,* ND California	No
4.	*Carl Zeiss v. Signet Armorlite,* SD California	No
5.	*MeadWestvaco v. Rexam,* ED Virginia	No
6.	*WesternGeco v. Ion Geophysical,* SD Texas	No
7.	*Kimberly-Clark v. First Quality,* MD Pennsylvania	No
8.	*Joy MM v. Cincinnati Mine,* WD Pennsylvania	No
9.	Five *Seiko Epson* cases, D Oregon	No

Summary Judgment

- Lessons learned
  - Patentee's perspective
  - Defendant's perspective

Trial

1. *Pfizer v. Teva*, ED Virginia
2. *Osram v. American Induction,* CD California
3. *Medtronic v. Nuvasive,* SD California
4. *Duhn Oil v. Cooper Cameron,* ED California
5. *Linear Technology v. Monolithic Power,* D Delaware
6. *Pozen v. Par,* ED Texas
7. *Metso v. Powerscreen*, ED New York
8. *Metris v. Faro,* D Massachusetts
9. *Apotex v. Cephalon,* ED Pennsylvania

Pfizer v Teva I

- ED Virginia – Judge Smith
- Twelve day bench trial – no inequitable conduct
- Teva failed to show any materiality of the nondisclosed reference
  - Patent Complaint in Canada
- No evidence of deceptive intent
  - No duty to disclose Canadian Complaint
  - Hardly the single most likely inference
- The Court refuses to read *Therasense* in any way other than as a bulwark against the waste of resources by both the judiciary and litigants as has occurred in this case.

Pfizer v. Teva II

- ED Virginia -- Judge Smith
- Pfizer awarded $378,285 in attorney fees
- Teva's inequitable conduct claim was objectively baseless after *Therasense*
  - No evidence exists that would allow any reasonable litigant to think that patentee had engaged in affirmative egregious misconduct
- Teva's argument of willful blindness was a smokescreen
  - Teva had no evidence of any intent to deceive

Osram v. American Induction

- CD California – Judge Real
- No inequitable conduct
- Found patentee's witnesses to be credible
- No clear and convincing evidence that the uncited art was material or that the inventors believed it to be

Medtronic v. Nuvasive

- SD California – Judge Anello
- No inequitable conduct
- Alleged misrepresentation concerning the state of the prior art
  - Inventors' testimony was credible
  - Inventors still believe statements about the prior art are accurate
- No evidence that change in priority date was made with an intent to deceive

Duhn Oil v. Cooper Cameron

- ED California – Judge Wanger
- No inequitable conduct
- Jury gave advisory verdict of no inequitable conduct
- Jury found inventorship was correct
  - Eliminated inequitable conduct claim based on wrong inventorship
- Inventor had a good faith basis to believe that the uncited publication was unrelated to the claims

Linear Technology v. Monolithic Power

- D Delaware – Judge Sleet
- No inequitable conduct
  - Jury trial in 2008
  - Bench trial on inequitable conduct in 2009
- Defendant relied on Rule 56 for materiality
  - Did not establish but-for materiality
- Jury's verdict of nonobviousness creates a strong presumption against but-for materiality

Pozen v. Par

- ED Texas – Judge Davis
- No inequitable conduct
- Testing data and representations about the data were accurate
  - Patentee's witnesses were credible

Metso Minerals v. Powerscreen

- ED New York – Judge Spatt
- No inequitable conduct
- Uncited prior art reference would have been cumulative
- Inventor understood the uncited reference to be different from the claimed invention

Metris v. Faro

- D Massachusetts – Judge Saris
- No inequitable conduct
- Judge originally found inequitable conduct for one of the patents in suit
  - Case remanded after *Therasense*
- Earlier findings of materiality "have been cast to dust."
  - Record does not provide enough support for the more searching analysis called for by *Therasense*
- No evidence of a specific intent to deceive

Apotex v. Cephalon

- ED Pennsylvania – Judge Goldberg
- Bench trial – found inequitable conduct
- The withheld references invalidated the patent in suit
  - Establishes materiality
- The complete concealment of another company's extensive involvement in the product definitively establishes the patentee's deception by clear and convincing evidence
  - The patentee has not offered any alternative explanation for these misrepresentations and omissions

Trial Scorecard

1.	*Pfizer v. Teva*, ED Virginia	NO!!
2.	*Osram v. American Induction,* CD California	No
3.	*Medtronic v. Nuvasive,* SD California	No
4.	*Duhn Oil v. Cooper Cameron,* ED California	No
5.	*Linear v. Monolithic Power,* D Delaware	No
6.	*Pozen v. Par,* ED Texas	No
7.	*Metso v. Powerscreen*, ED New York	No
8.	*Metris v. Faro,* D Massachusetts	No
9.	*Apotex v. Cephalon,* ED Pennsylvania	Yes

Trial

- Lessons learned
  - Patentee's perspective
  - Defendant's perspective

Appeal

- Three Federal Circuit cases

1. *Cordis v. Boston Scientific*
2. *Powell v. Home Depot*
3. *American Calcar v. American Honda*

Cordis v. Boston Scientific

- Federal Circuit
  - Judge Gajarsa (Mayer and Bryson)
- No inequitable conduct affirmed
- "Y" reference from EPO Search Report
  - cited in later related application
- No clear error in judge's finding that evidence does not unequivocally demonstrate a specific intent to deceive.
  - Appears to be a case where a threshold level of intent to deceive was proved, but then rebutted by an explanation of good faith

Powell v. Home Depot

- Federal Circuit
  - Judge Prost (Linn and Dyk)
- No inequitable conduct affirmed
- Petition to Make Special
  - Supporting facts changed
- No but-for materiality and not the type of unequivocal act that would rise to the level of affirmative egregious misconduct

American Calcar v. American Honda

- Federal Circuit
  - Judge Lourie (Bryson and Gajarsa)
- Inequitable conduct holding vacated
- Undisclosed prior art was material because jury found anticipation
  - Judge never found that the inventors knew of the materiality of the prior art and made a deliberate decision to withhold it.
  - Remanded

Appeal Scorecard

1. *Cordis v. Boston Scientific* — No
2. *Powell v. Home Depot* — No
3. *American Calcar v. American Honda* — Maybe

Lessons learned?

Supposed Benefits of *Therasense*

- Reduce cost and complexity of adjudication
- Increase likelihood of settlement
- Reduce burden on the courts

- The future ??

Thank you

The Divide on Joint Infringement: The Federal Circuit's *En Banc* Review of *Akamai* and *McKesson*

14 March 2012

Presented by
Kara F. Stoll

What is “Joint Infringement”?

- Claims that involve steps performed by more than one actor
- These claims are infringed by “joint infringement:”

Where a claim is infringed

only by aggregating the conduct

of more than one actor

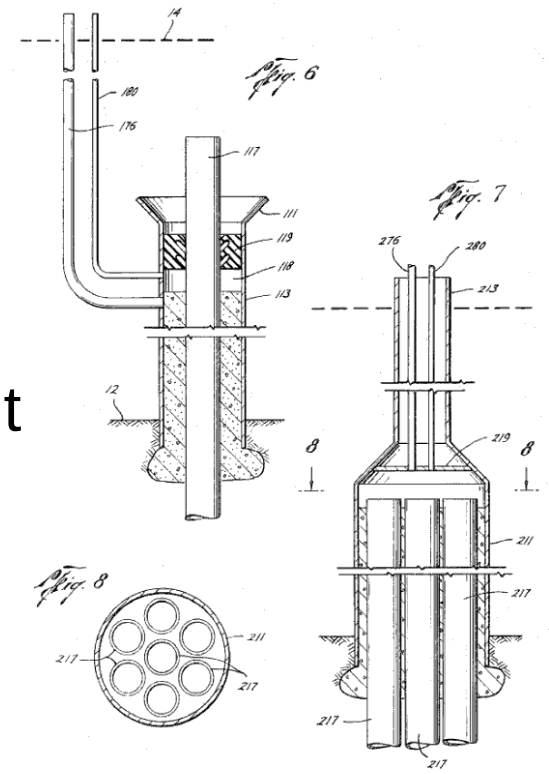
- Joint infringement can arise in various fields of technology, including computers, software, e-commerce, communication networks, chemistry, and biotechnology

Early Joint Infringement Cases

- *Peerless Equipment Co. v. W.H. Miner, Inc.* (7th Cir. 1937)
  - Patent was for process of making train gears
  - Defendant sold nearly-complete gears, knowing customers would perform the final claimed step of "flattening the crown"
  - Although two separate parties performed the claimed steps, Seventh Circuit found infringement

Early Joint Infringement Cases

- *Shields v. Halliburton, Co.* (W.D. La. 1980)
  - Shields performed all elements of the claim but one, which Brown & Root employees performed
  - "When infringement results from the participation and combined action of several parties, they are all **joint infringers** and jointly liable for patent infringement"



Early Joint Infringement Cases

- *E. I. du Pont de Nemours v. Monsanto* (D. Del. 1995)

  - Monsanto made a copolymer according to one step of claim for making stain-resistant fibers. The copolymer was sold to another company (CaMac), which made the fibers. Court found *no* infringement by Monsanto.
  - "Although DuPont's theory of **joint infringement** is *interesting*, the Court declines to find that Monsanto is liable as a direct infringer under § 271(a) in connection with its conduct in practicing step (a) of the claimed process and selling the resulting copolymer to CaMac"
  - *But* Court said that CaMac is a direct infringer, since it instructed and paid Monsanto to practice step (a)

Early Joint Infringement Cases

- *Faroudja Labs., Inc. v. Dwin Elecs., Inc.* (N.D. Cal.1999)
  - Claim to “improving image quality in television systems by converting motion picture film images to television signals and multiplying the resulting television signal scan lines”
  - “The connection between transfer companies who convert films and users of who improve the resulting images is too remote to constitute direct infringement. In the absence of direct infringement, there can be no inducement infringement or contributory infringement.”

The Federal Circuit Steps In

"Surprisingly, although the Federal Circuit acquired virtually exclusive jurisdiction over appeals in patent infringement suits in October 1982 and issued over 2000 precedential opinions in its first 25 years, it did not rule squarely on the question of liability for 'divided infringement' or 'joint infringement' until 2007"

Chisum on Patents, § 16.02[6][a]

The Federal Circuit Steps In

- *BMC Resources, Inc. v. Paymentech, L.P. (2007)*
  - Three different parties collectively performed the steps of the asserted method claims directed to processing debit transactions without a PIN
  - Federal Circuit established the "**control or direction**" test. The party in "control" is liable for the infringement.
  - "A party cannot avoid infringement…simply by contracting out steps of a patented process to another entity"
  - "[C]oncerns over a party avoiding infringement by arms-length cooperation can usually be offset by proper claim drafting"

The Federal Circuit Steps In

- *Muniauction, Inc. v. Thomson Corp. (2008)*
  - Patent for auctioning municipal bonds using online system and web browsers. Required combined bidders and auctioneers.

  - Federal Circuit affirmed the **"control or direction**" test for joint infringement. *But* found *no* infringement by Thomson.
  - Every step must be attributable to the "controlling party" or the "mastermind" of the infringement
  - "That Thomson controls access to its system and instructs bidders on its use is *not* sufficient to incur liability for direct infringement"

The Federal Circuit Steps In

- *Golden Hour Data v. EMSCharts, Inc. (2010)*
  - Two software companies formed strategic partnership to enable their products to work together, thus collectively performing all elements of the asserted claims. They also collaborated to sell the two products as a unit.
  - Federal Circuit affirmed non-infringement due to lack of "**control or direction**"
  - Judge Newman dissents:
    - "The court now holds that such a relationship avoids all liability for infringement, even when the defendants collaborate to practice every limitation in the claims"
    - No immunity because of separate corporate status

The Future of Joint Infringement

- *Akamai Technologies, Inc., v. Limelight Networks, Inc.*, 09-1372, -1380, -1416, -1417 (Fed. Cir.)
- *McKesson Technologies, Inc., v. Epic Systems, Corp.*, 10-1291 (Fed. Cir.)

Akamai Technologies, Inc., v. Limelight Networks (Panel Decision Dec 2010)

- Limelight performed all steps of method claims except one. But Limelight's contract obligated customers to perform this step if they wanted to use Limelight's service.
- Jury found Limelight "**controls or directs**" the customer in performing the step Limelight does not perform
- Federal Circuit held that Limelight did not infringe because its customers were not agents of Limelight or contractually obligated to perform the steps
- "[A]s a matter of Federal Circuit law . . . there can only be joint infringement when there is an ***agency relationship*** between the parties . . . ***or*** when one party is ***contractually obligated*** to the other to perform the steps"

McKesson Technologies v. Epic Systems Corp. (Panel Decision April 2011)

- Epic develops the MyChart software for communication between patients and doctors
- All claim steps are performed, *but* some performed by patients and some performed by doctors
- Federal Circuit: "In this case, *nothing* indicates that MyChart users are performing any of the claimed method steps **as agents** for the MyChart providers"
- Judge Newman dissents again:
  - "[A granted patent that cannot be enforced under any theory of infringement] is a cynical, and expensive delusion to encourage innovators to develop new interactive procedure, only to find that the courts will not recognize the patent because the participants are independent entities"

Questions for *En Banc* Rehearing

- *Akamai* order (April 2011)
  - If separate entities each perform separate steps of a method claim, under what circumstances would that claim be directly infringed and to what extent would each of the parties be liable?
- *McKesson* order (May 2011)
  - If separate entities each perform separate steps of a method claim, under what circumstances, if any, would either entity or any third party be liable for inducing infringement or for contributory infringement? *See Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565 (Fed. Cir. 1983)*
  - Does the nature of the relationship between the relevant actors—e.g., service provider/user; doctor/patient—affect the question of direct or indirect infringement liability?

Amicus Briefs

- A total 21 amicus briefs have been filed in *Akamai*:
  - Favoring reversal (but neither party): 6
    - PhRMA; BIO; AIPLA
  - Favoring Akamai's position: 3
  - Favoring Limelight's position: 12
- A total of 10 amicus briefs have been filed in *McKesson*:
  - Favoring reversal (but neither party): 3
  - Favoring McKesson's position: 2
  - Favoring Epic's position: 5

Answer: Direct Infringement

- *Akamai/McKesson:*
  - An actor is liable for direct infringement if it:
    - Performs some method steps while directing or controlling another's performance of the remaining steps;
    - Acts in concert with another to perform all of the steps;

      or

    - Knowingly combines its actions with those of another to practice an entire patented method

Answer: Direct Infringement

- *Limelight/Epic:*
  - For direct infringement liability, there must be a basis to attribute or impute the acts of a third party to the defendant
  - Requires an ***agency relationship*** between the parties. . . ***or*** when one party is **contractually obligated** to the other to perform the steps

Answer: Indirect Infringement

- *McKesson*:
  - A third party is also liable for induced or contributory infringement if multiple actors together performed an entire patented method and the third party induced or contributed to that performance
  - Induced infringement is possible without anyone being found liable for direct infringement
- *Epic*:
  - No liability for indirect infringement without underlying direct infringement. *Fromson* does not hold otherwise.

Policy Considerations: Bright-Line Rule

- Advantages:
  - Reduces complication
  - Patent owner bears burden of drafting claims
  - Leaves no room for varying interpretations
  - Will not allow unsuspecting and unrelated parties to be aggregated into an infringement allegation
- Disadvantages:
  - Overly simplistic
  - Eliminates patent protection for some multiple-participant inventions
  - Makes method claims unfairly vulnerable to loopholes in the law

Policy Considerations: Fact-Based Standard

- Advantages:
  - Allows for more careful and flexible consideration
  - Consistent with Supreme Court rejection of rigid rules
- Disadvantages:
  - Open to interpretation and varying results
  - Some argue that this standard would encourage NPEs to sue large corporations only tangentially related to these inventions (e.g., wireless service providers)

Oral Argument in *Akamai* and *McKesson*

- **Judge Dyk**: “Can you give me an example of a situation that you’re concerned about that couldn’t be solved by claim drafting?”
- **Judge Prost:** “Are you suggesting that just knowledge [of the performance of all claim steps] is sufficient?”
- **Judge Linn:** “What are the implications, if any, of the rule you would like us to adopt for apparatus claims?”

Oral Argument in *Akamai* and *McKesson*

- **Judge Reyna:** “But the statute says ‘whoever.’ And it doesn’t say ‘whoever alone forms an invention.’ And doesn’t that include plural?”
- **Judge Newman:** “This situation . . . on the face of it just reeks of, let’s say, inequity”
- **Judge Bryson:** “I’m having trouble getting a handle on the third [proposed test] – knowingly combining”

Oral Argument in *McKesson*

- **Judge Moore:** "But counsel, the Supreme Court in *Aro Manufacturing* [held that] '[t]here can be no contributory infringement in the absence of a direct infringement under 271(a)'"

Joint Infringement: Prosecution Strategies

- Claims*:*
  - If possible, draft multiple claim sets, each with a different focus in terms of infringing activity by a single actor or multiple actors; also include different claim types
- Continuations/divisionals:
  - File continuations/divisionals to maintain pendency, especially for key inventions
  - Reformulate claims based on changes in law

Joint Infringement: Litigation Strategies

- Patentee*:*
  - Analyze claim elements during pre-suit investigation and identify relevant parties for infringement
  - Consider scope of discovery and evidentiary burdens to satisfy “control or direction” test
  - Correct claims through reissue w/in two years or seek additional claims through continuation/divisional application
- Defendant:
  - Analyze claims for defenses and design-around options
  - Examine relationships and/or contracts with third parties

Akamai and *McKesson:* Anticipated Timeline

- When will the opinion be published?

Current estimate:

May 2012 or later

Questions?

Thank You.

Kara F. Stoll
Finnegan, Henderson,
Farabow, Garrett & Dunner, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
Tel 1 202 408 4119
Fax 1 202 408 4400
kara.stoll@finnegan.com

Speaker Information

Kara Stoll has extensive experience in appellate practice, patent litigation, and client counseling. She has drafted numerous briefs and argued in appeals to the U.S. Court of Appeals for the Federal Circuit.

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The Written Description Requirement After *Ariad*

William G. McElwain

WILMERHALE

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Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co., 598 F.3d 1366 (2010)

Questions presented and *en banc* answers:

a. Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?

YES!

Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.

b. If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?

- It applies to both original and amended claims.
- "the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant invention." *Id.* at 1351.

Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.

"A few broad principles hold true across all cases." *Id.* at 1352.

- Examples or actual reduction to practice not required.
- Conversely, actual but undescribed "possession" not enough.
- Not a "super-enablement standard" for chemical and biotechnology cases."
- The requirement "ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish the function." *Id.*

Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.

- "A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Id.* at 1353.
- The purpose of the requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the filed of art as described in the patent specification." *Id.*

Not a Hunting License

"A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Centocor Ortho Biotech, Inc. v. Abbott Laboratories, 636 F.3d. 1341 (Fed. Cir. 2011)

- Claim covers fully human antibodies binding to human protein called TNFα
- Specification disclosed:
  - Specific embodiment of murine antibodies to TNFα
  - Specific embodiment of chimeric antibodies to TNFα
  - Amino acid sequence to TNFα
  - "a few sentences sprinkled throughout the '775 patent that mention human antibodies or human variable regions." *Id.* at 1350.

Centocor Ortho Biotech, Inc. v. Abbott Laboratories

- Unrebutted testimony from Abbott's expert
  - Disclosure of mouse variable region not useful in making human antibodies.
  - Reference in patent specification to article describing making human antibodies was limited to low affinity antibodies to red blood cells.
- "At the time the 1994 CIP applications were filed it was entirely possible that no fully-human antibody existed that satisfied the claims." *Id.* at 1351.
- EDTX jury awards $1.67 billion in damages, JMOL denied.

Centocor Ortho Biotech, Inc. v. Abbott Laboratories

- Federal Circuit Reverses.
  - "Thus, while the patent broadly claims a class of antibodies that contain human variable regions, the specification does not describe a single antibody that satisfies the claim limitations. See *Eli Lilly*, 119 F.3d at 1566–69. It does not disclose any relevant identifying characteristics for such fully-human antibodies or even a single human variable region. See *id*. Nor does it disclose any relationship between the human TNF- α protein, the known mouse variable region that satisfies the critical claim limitations, and potential human variable regions that will satisfy the claim limitations." *Id.* at 1350-51.

Centocor Ortho Biotech, Inc. v. Abbott Laboratories

PTO Guidelines

- "a functional claim reciting "an isolated antibody capable of binding to [protein] X" is adequately described where the specification fully characterizes protein X—even if there are no working or detailed prophetic examples of actual antibodies that bind to protein X. *See also* Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004).
- "Depending on the state of the art, this rea-soning might not apply to obtaining hu-man antibodies to a human protein for several reasons." *Id.* fn. 4.

Boston Scientific Corporation v. Johnson & Johnson, 647 F.3d 1353 (Fed. Cir. 2011)

- "a sufficient description of a genus requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad*, 598 F.3d at 1350.
- Patent claimed genus of macrocyclic lactone analogs of rapamaycin for drug-eluting stents.
- Summary judgment of invalidity for failure to comply with written description defense affirmed.

Boston Scientific Corporation v. Johnson & Johnson

- "no analogs are disclosed in the specification. While a small number of such analogs were known in the prior art, the claims cover tens of thousands of possible macrocyclic lactone analogs. With no guidance at all in the specification as to how to properly identify or choose the claimed analogs, and in light of the unpredictability and nascent state of using drug-eluting stents to treat restenosis, we agree with the district court " *Id.* at 1365.

Billups-Rothenberg, Inc. v. Associated Regional and University Pathologists, Inc., 642. F.3d 1031 (Fed. Cir. 2011)

- Method of diagnosis involving detecting a mutation somewhere in a 300 base pair segment of a DNA sequence.
- *"Ariad* also explained that "[f]unctional claim language can meet the written description requirement when the art has established a correlation between structure and function."
- But, the "[p]atentee's general location disclosure is too imprecise to constitute structural features necessary to meet the written description requirement." *Id.* at 1037.

Scope Of The Inventor's Contribution

"The purpose of the requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the filed of art as described in the patent specification."

Eli Lilly and Company v. Teva Pharmaceuticals USA, Inc., 619 F.3d 1329 (Fed. Cir. 2010).

- Claim covered drug formulation having particular particle size.
- Patent disclosed particle size only of bulk raloxifene.
- “Lilly's own expert conceded that “[o]ne reading the [Particle Size Patent] in 1996 would not know whether the particle size was being increased or decreased [or remain the same] in the formulation.” *Id.* at 1345.
- Claims invalid under written description requirement

Crown Packaging Technology, Inc. v. Ball Metal Beverage Container Corporation, 635 F.3d 1373 (Fed. Cir. 2011)

- Patent for saving metal in manufacture of metal cans.
- Two techniques: "increasing the slope of the chuck wall" and limiting the width of the reinforcing bead."
- Claims drawn only to "chuck wall" feature.
- "the critical question is whether the specification, including the original claim language, demonstrates that the applicants had possession of an embodiment that improved metal usage by increasing the slope of the chuck wall without also limiting the width of the reinforcing bead." *Id.* at 1382.

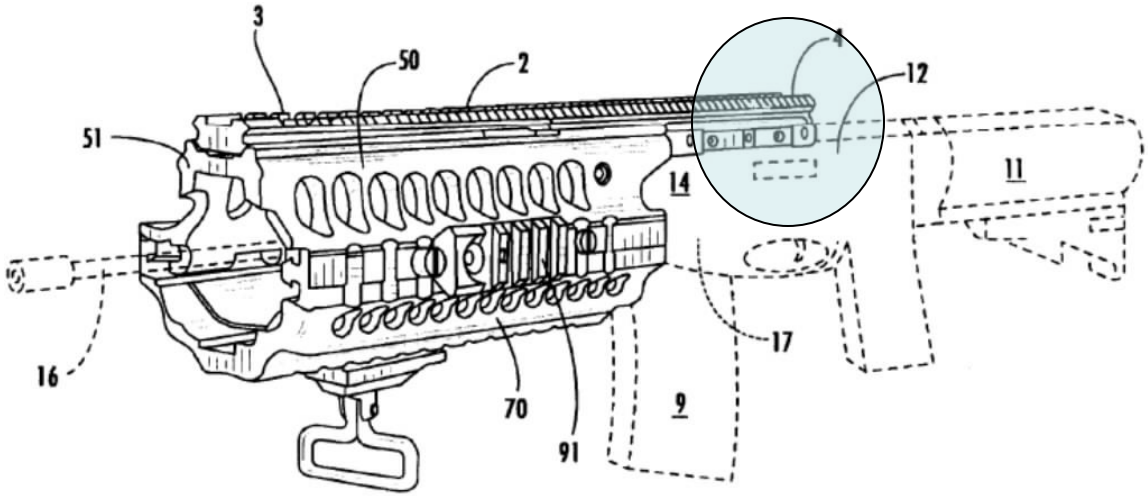
Crown Packaging Technology, Inc. v. Ball Metal Beverage Container Corporation

- District court erred in finding invalidity based on written description requirement.
- The patent "nowhere suggests that saving metal by increasing the slope of a can end's chuck wall necessarily requires that there be no driving contact with the interior of the reinforcing bead. The problems the patents address are related, but they are still separate, and solving one does not necessarily require solving the other." *Id.* at 1382.

Hynix Semiconductor, Inc., 645 F.3d 1336 (Fed. Cir. 2011)

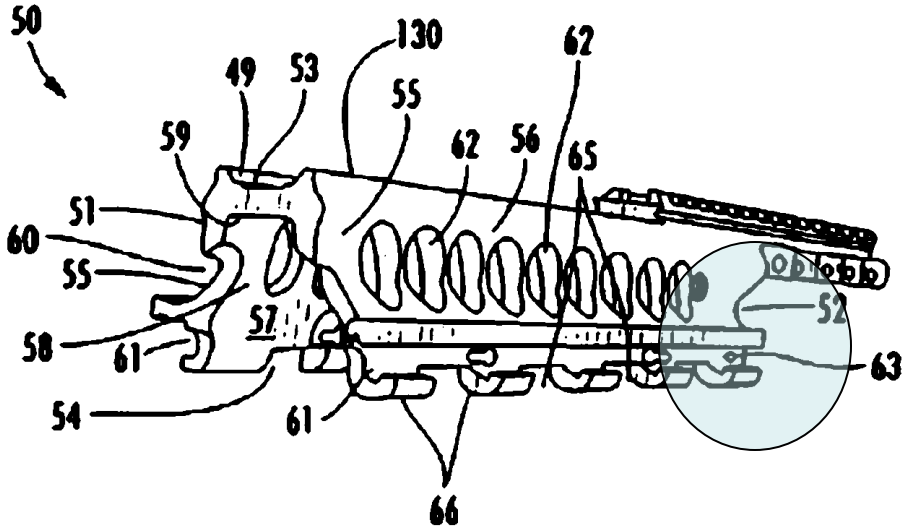
- Defendant argued that deletion of "narrow multiplexed bus limitations" was unsupported by written description.
- "there is no categorical rule that a species cannot suffice to claim the genus." *Id.* at 1352.
- "Hynix has not argued that the disclosure of the multiplexed bus was not representative of the genus of buses that encompasses both the narrow multiplexed bus and the non-multiplexed bus." *Id.*
- Jury verdict of no written description sustained.

Atlantic Reseach Marketing Systems, Inc. v. Troy, 659 F.3d 1345 (Fed Cir. 2011)



receiver sleeve

Atlantic Reseach Marketing Systems, Inc. v. Troy



yoke/barrel nut

Atlantic Reseach Marketing Systems, Inc. v. Troy

"Here, the '465 specification discloses an invention with two support points, one at the receiver sleeve and one at the yoke/barrel nut. See '465 patent col.10 ll.56–59. The '465 specification also appears to disclose an invention where the receiver sleeve provides complete support for the handguard accessory. See id. col.2 ll.30–36. But as the district court explained and as Atlantic Research admitted at oral argument, the specification does not disclose an invention where the yoke/barrel nut attachment point provides complete support for the handguard accessory." *Id.* at 1354.

Atlantic Research Marketing Systems, Inc. v. Troy

- "Atlantic Research sought a claim construction in district court that would cover a barrel nut-only design, perhaps to support its infringement arguments against the accused products (the accused products undisputedly attach to and receive support from only the barrel nut). Now, however, having lost on written description grounds, Atlantic Research argues for a construction that precludes the barrel nut-only attachment design." *Id.* at 1355.

Laryngeal Mask Company, Ltd. v. AMBU A/S, 618 F.3d 1367 (Fed. Cir. 2010)

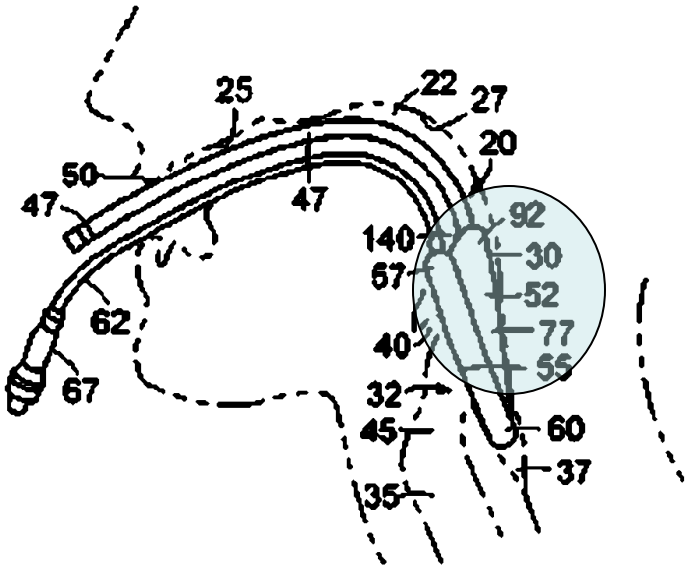


FIG. 2

Laryngeal Mask Company, Ltd. v. AMBU A/S

"Claim 1 requires "at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff." '100 patent, claim 1. The court construed this phrase according to its plain meaning and thus concluded that the phrase does not require that the "thicker and stiffer" cuff portion be connected to the backplate." *Id.* at 1373.

Laryngeal Mask Company, Ltd. v. AMBU A/S

- "LMA explains that the specification is silent as to whether the cuff reinforcement must be, or even should be, connected to the backplate. LMA further explains that the specification does not describe the invention in terms of the connection, extol any advantages of a connected cuff reinforcement, identify disadvantages of a disconnected cuff reinforcement, or identify a connection as a critical feature." *Id.* at 1373.
- Summary judgment reversed.

NEW JERSEY INTELLECTUAL PROPERTY LAW ASSOCIATION

PATENT LITIGATION SEMINAR

MARCH 14, 2012

LATHAM & WATKINS LLP

The Patentability of Personalized Diagnostic and Treatment Methods

The Statute

- Section 101 defines patent-eligible subject matter broadly to include “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”

- For 200 years the courts have struggled to apply this deceptively simple language.

The Tension: Invention versus Discovery

- The Patent Act often is described as covering "everything under the sun made by man."
- It is at the same time well established that the patent laws exclude "laws of nature, physical phenomena, and abstract ideas."
- All judicial attempts to enforce the boundary between these principles with bright line rules have failed, leaving a junk–pile of discarded tests.

The History: Difficult Line Drawing

- The Supreme Court has repeatedly re-focused the analysis on case-specific applications of general standards

  - Early days: the telegraph, telephony, and industrial processes
  - Special problems posed by computers
  - Special problems caused by business methods
  - Biotechnology and personalized medicine

Mayo Collaborative Services v. Prometheus Laboratories, Inc.

- The Problem: How to calibrate thiopurine dosages for auto-immune disorders accurately when the proper dosage varies individual by individual?
- The Solution: A method that uses specific metabolite measurements to better gauge the therapeutic range for each patient
- The Patents
- The Lawsuit

Mayo Collaborative Services v. Prometheus Laboratories, Inc.

- District Court's judgment
- Federal Circuit's holdings:
  - Transformation remains an "important clue" to patentability.
  - The use of natural laws does not make a process unpatentable.
  - A process is not patentable if it is purely abstract or essentially preempts natural laws.
  - A process may be patentable even if it ultimately produces only information (rather than something physical).

Issues Before the Supreme Court

- "How much" must be added to a natural principle (or abstract idea) for a process to be a patent-eligible (i.e., an *application* of a law of nature)?
- At what level of generality should courts view the natural principle (how much must be preempted to be problematic)?
- What is the continuing role (and weight) of the "machine-or-transformation test"?

Issues Before the Supreme Court

- Are methods that end by *merely* producing information patent-eligible or must they end with a physical product or step (e.g., perform a certain treatment)?

- In the Section 101 patent-eligibility analysis, should the courts "peek" at considerations from other statutory sections (e.g., utility per Section 101, novelty per Section 102, and non-obviousness per Section 103)?

- How much, if at all, should the Section 101 inquiry be rooted in the courts' own view of what "deserves" patent protection?

The Next Generation of Issues

- Inherent lack of novelty and the printed matter doctrine
- *Myriad*, and isolated DNA molecules
- Conflicting guidance from the Federal Circuit on the patentability of computer-aided processes

Strategies for Litigation Under the Biologics Price Competition and Innovation Act

Barbara A. Fiacco

March 14, 2012

FOLEY HOAG LLP

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Enactment in 2010

- Patient Protection and Affordable Health Care Act (PPAC Act) signed into law March 23, 2010
- Amends Public Health Services Act to create abbreviated approval pathway for biological products that are “biosimilar” or “interchangeable” with an FDA-approved biological product
  - Creates new section 351(k) of PHS Act
  - Amends 35 U.S.C. § 271

Applicability

- Applies to licensure of a “biological product”:
  - virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or
  - protein (except any chemically synthesized polypeptide) (NEW)
  - applicable to the prevention, treatment, or cure of a disease or condition of human beings.
- Application must show that biological product is “biosimilar to a “reference product”
- “Reference product” for purposes of BPCI is a single biological product licensed under PHS Act, i.e., under a BLA

Approval of Biosimilar

- Must be “highly similar” to the reference product
  - “No clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency of the product”
- Must be based upon data from a clinical study, subject to waiver by the Secretary
- Must have same condition of use in labeling as approved for reference product
- Must utilize same mechanism of action for use listed in labeling
- Must have same route of administration, dosage form, and strength as reference product

Data Exclusivity vs. Market Exclusivity

- Data exclusivity = period when innovator has exclusive right to rely on its clinical data to support FDA determination of safety and efficacy

- Because 351(k) pathway would permit approval of biologics based upon their similarity rather than identicality, the innovator's underlying patents may not cover the biosimilar

- Hatch-Waxman provides up to 14 years of patent protection for small molecule drugs through patent term extension, but patent protection alone will not assure adequate period of exclusivity for biologics

Data Exclusivity Period

- 351(k) applicant may not submit application for 4 years after reference product first licensed
- FDA may not approve application until 12 years after reference product first licensed
- No new exclusivity period for:
  - new indication
  - new route of administration
  - new dosing schedule
  - new dosing form delivery system
  - new delivery device or strength
  - structural modification to molecule that does not change safety, purity or potency

Approval as Interchangeable

Heightened Requirements:

- "Biosimilar" to reference product
- Expected to produce the same clinical result in any given patient
- No risk in switching between reference product and biosimilar

Benefits of Interchangeability:

- If conditions met, biosimilar may be substituted for reference product without intervention of prescribing physician
- First interchangeable biosimilar has some market exclusivity before FDA can approve second interchangeable product

Patent Enforcement Overview

- No Orange Book
  - Requires exchange of information to identify relevant patents
  - Raises issues of confidentiality and prosecution bar
- Timing of patent litigation relative to approval date
  - No automatic 30-month stay of approval for litigation
  - Two waves of pre-launch litigation
  - Complicated procedure to select patents for earliest litigation
  - Potential for at-risk biosimilar product launch
  - Implications of *eBay* for grant of injunctive relief
- Notification to third party patent owners and standing requirements
  - Practical issues raised by necessary participation of third party patent owners
  - Effect on rights of third party patent owners

Pre-Launch Biosimilars Litigation

1st Wave of Litigation

Within 20 days after FDA notice, (k) applicant must provide a copy of (k) application to RPS

FDA notice: (k) app. accepted for filing

If (k) applicant does not provide (k) application, RPS can bring DJ action on any patent

= 30 days

Who has access to 351(k) application?

- Prosecution bar provision

"(B) IN GENERAL. —

"(ii) RECIPIENTS OF INFORMATION. —The persons described in this clause are the following:

"(I) OUTSIDE COUNSEL. — One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the "outside counsel"), **provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.**

"(II) IN-HOUSE COUNSEL.—One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, **provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.**

Who has access to 351(k) application?

- Prosecution bar provision:

"(H) EFFECT OF VIOLATION. — The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

- Prosecution bar effects:
  - Constraints on in-house counsel's role/responsibilities
  - Constraints on outside counsel

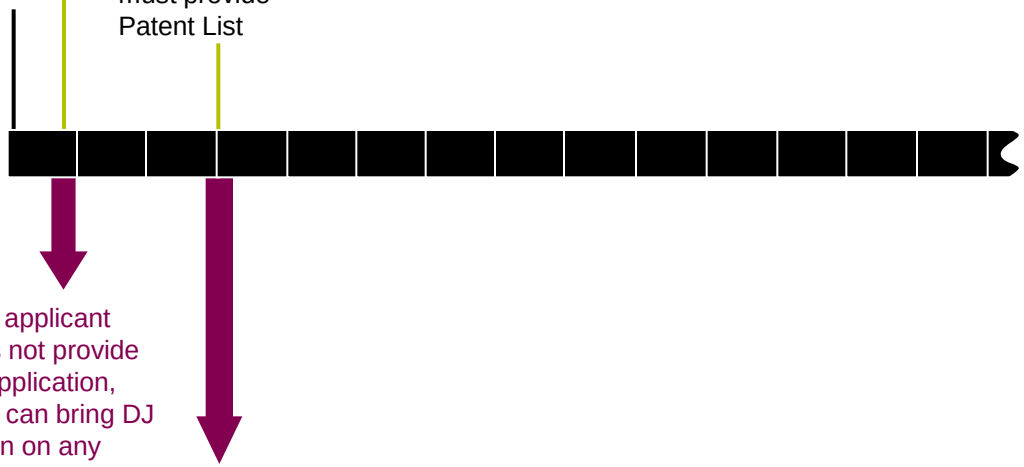
Pre-Launch Biosimilars Litigation

1st Wave of Litigation

Within 20 days after FDA notice, (k) applicant must provide a copy of (k) application to RPS

FDA notice: (k) app. accepted for filing

Within 60 days after receiving application, RPS must provide Patent List



If (k) applicant does not provide (k) application, RPS can bring DJ action on any patent

If patent is omitted from list RPS cannot sue for infringement of that patent

= 30 days

What should be on RPS's Patent List?

"(3) LIST AND DESCRIPTION OF PATENTS. –

"(A) LIST BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

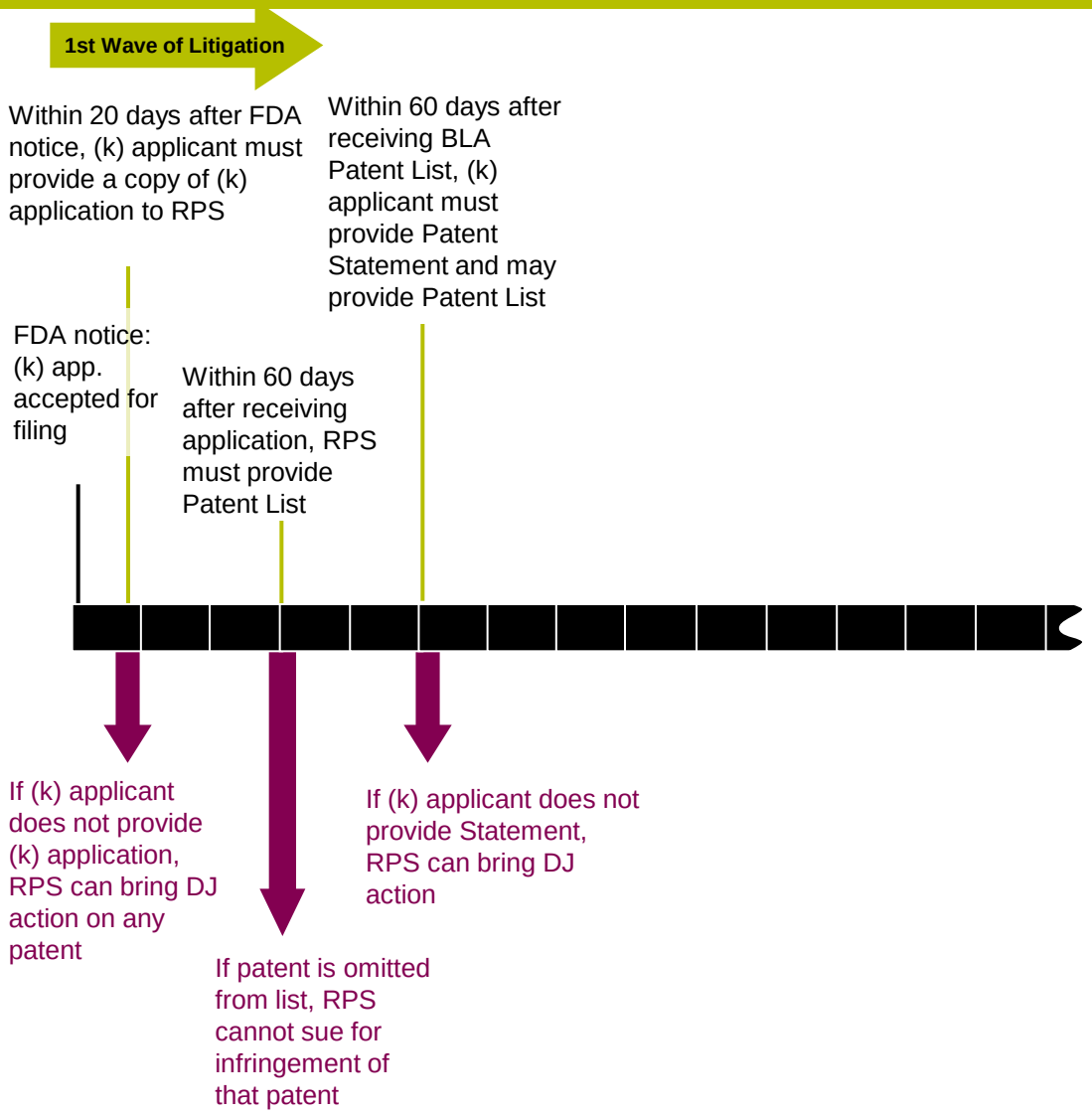
"(i) a list of patents for which **the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor**, **or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product**, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

"(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

What should be on RPS's Patent List?

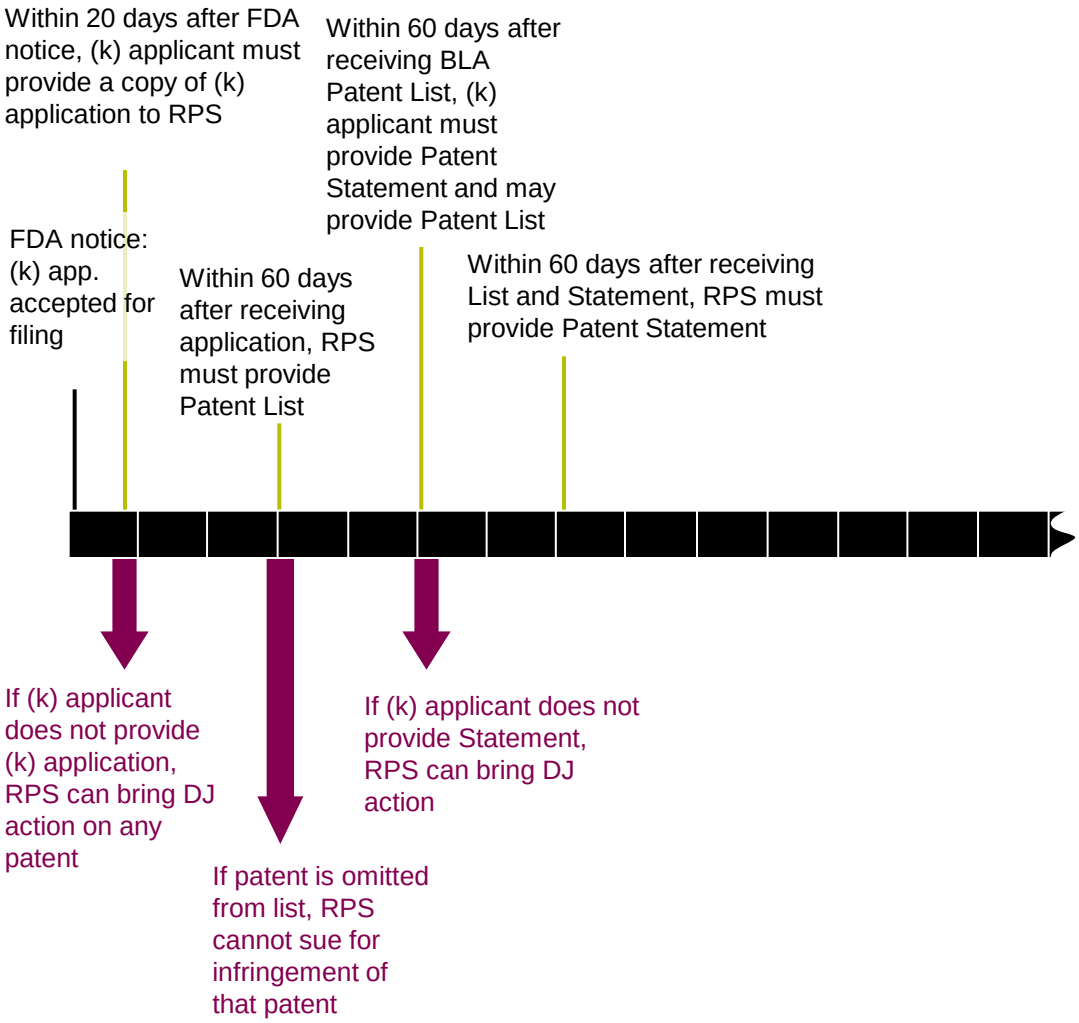
- What patents are relevant in addition to those covering the reference product?
- When should this analysis begin?
- Who should do the analysis?
- Which patents should be asserted?
  - Strategic choices
  - Contractual requirements

Pre-Launch Biosimilars Litigation

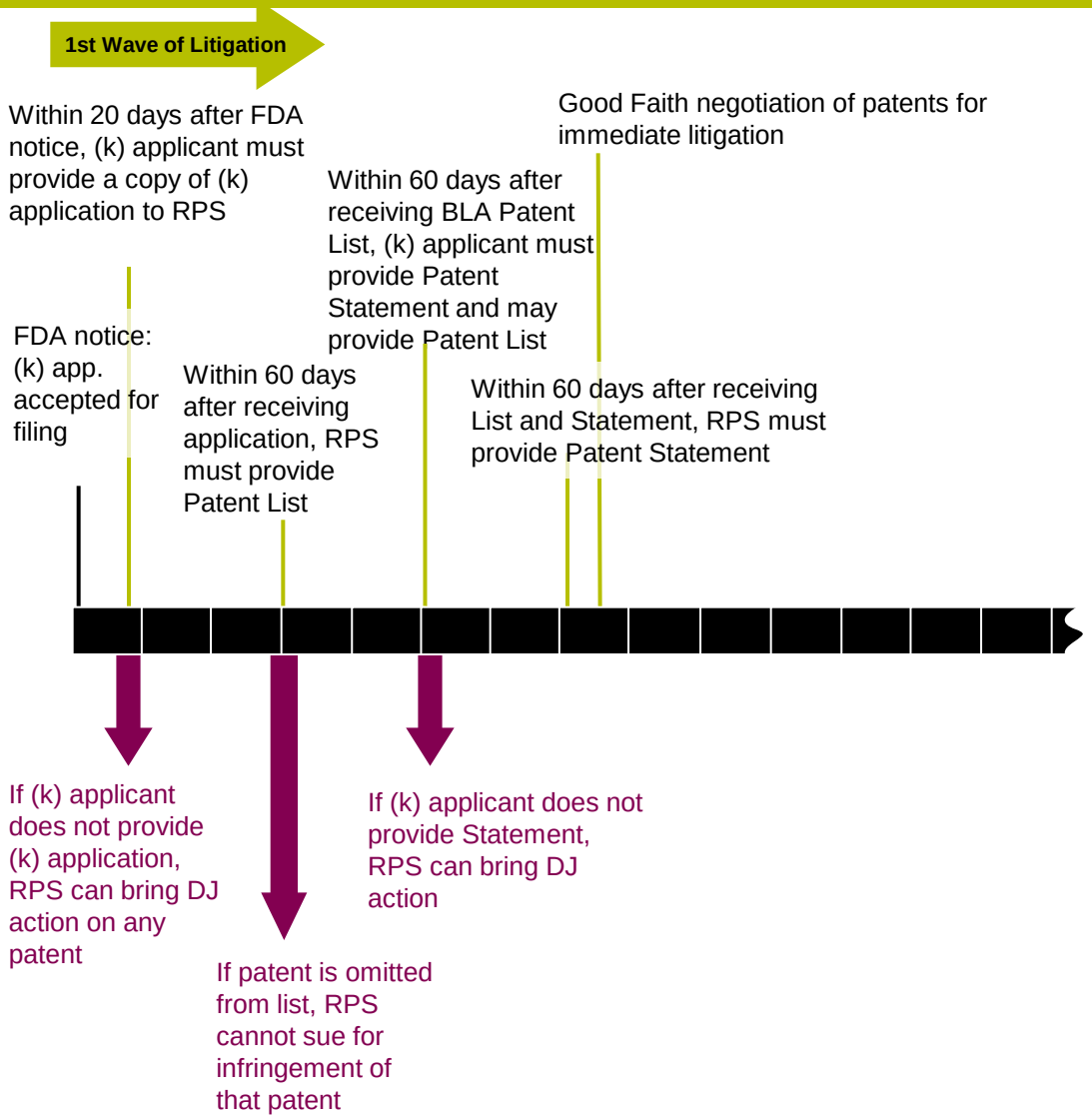


Pre-Launch Biosimilars Litigation

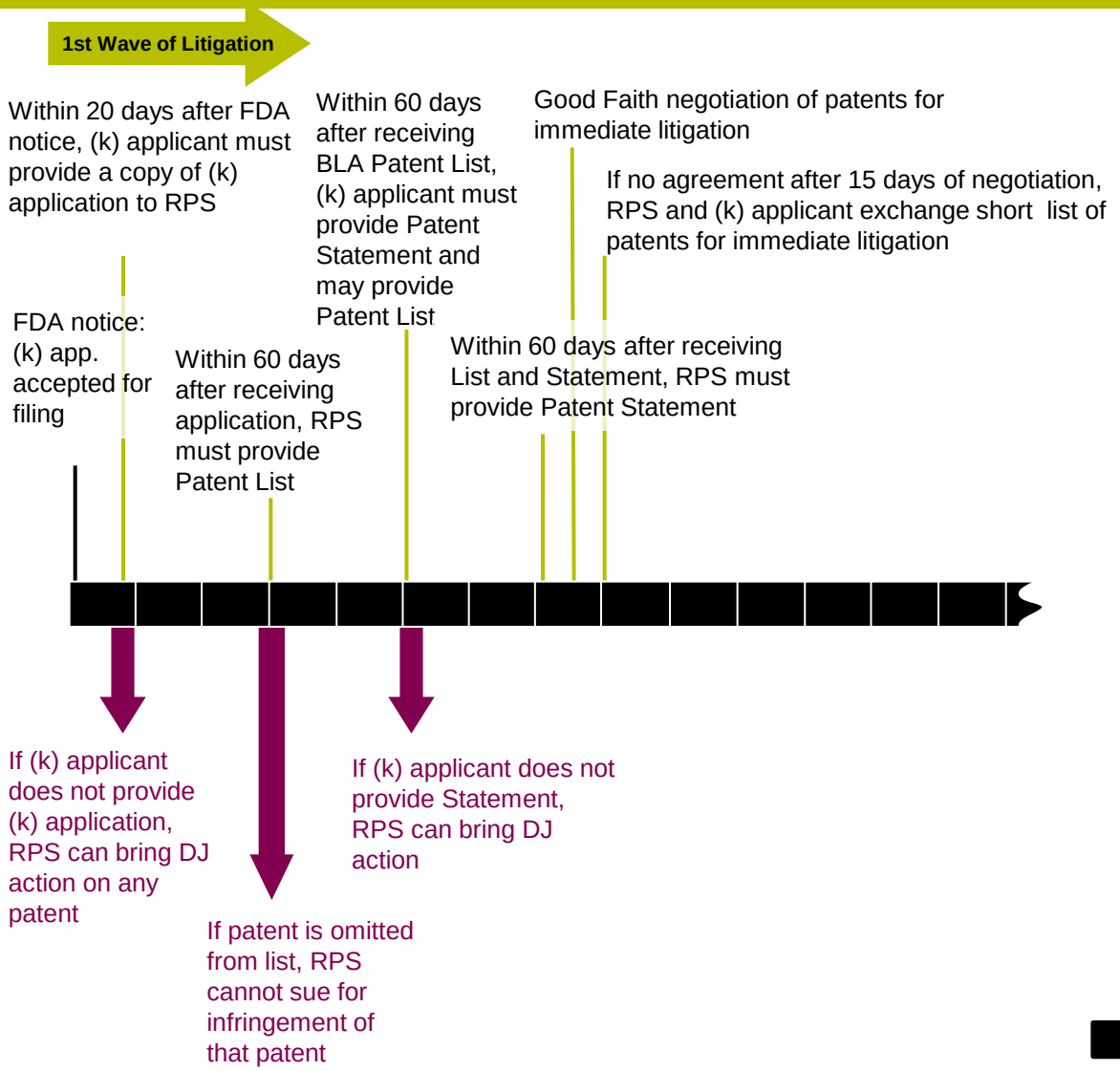
1st Wave of Litigation



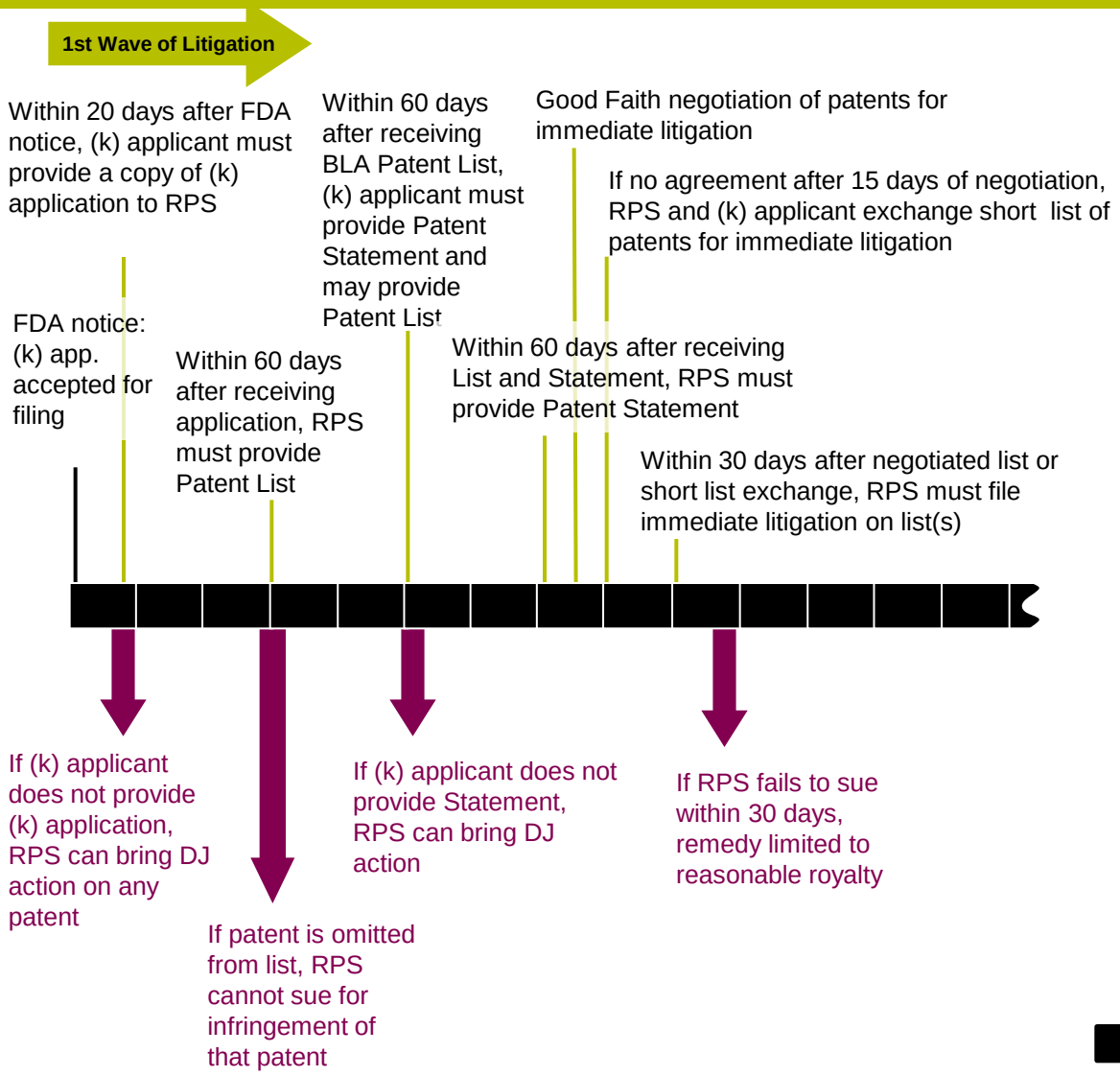
Pre-Launch Biosimilars Litigation



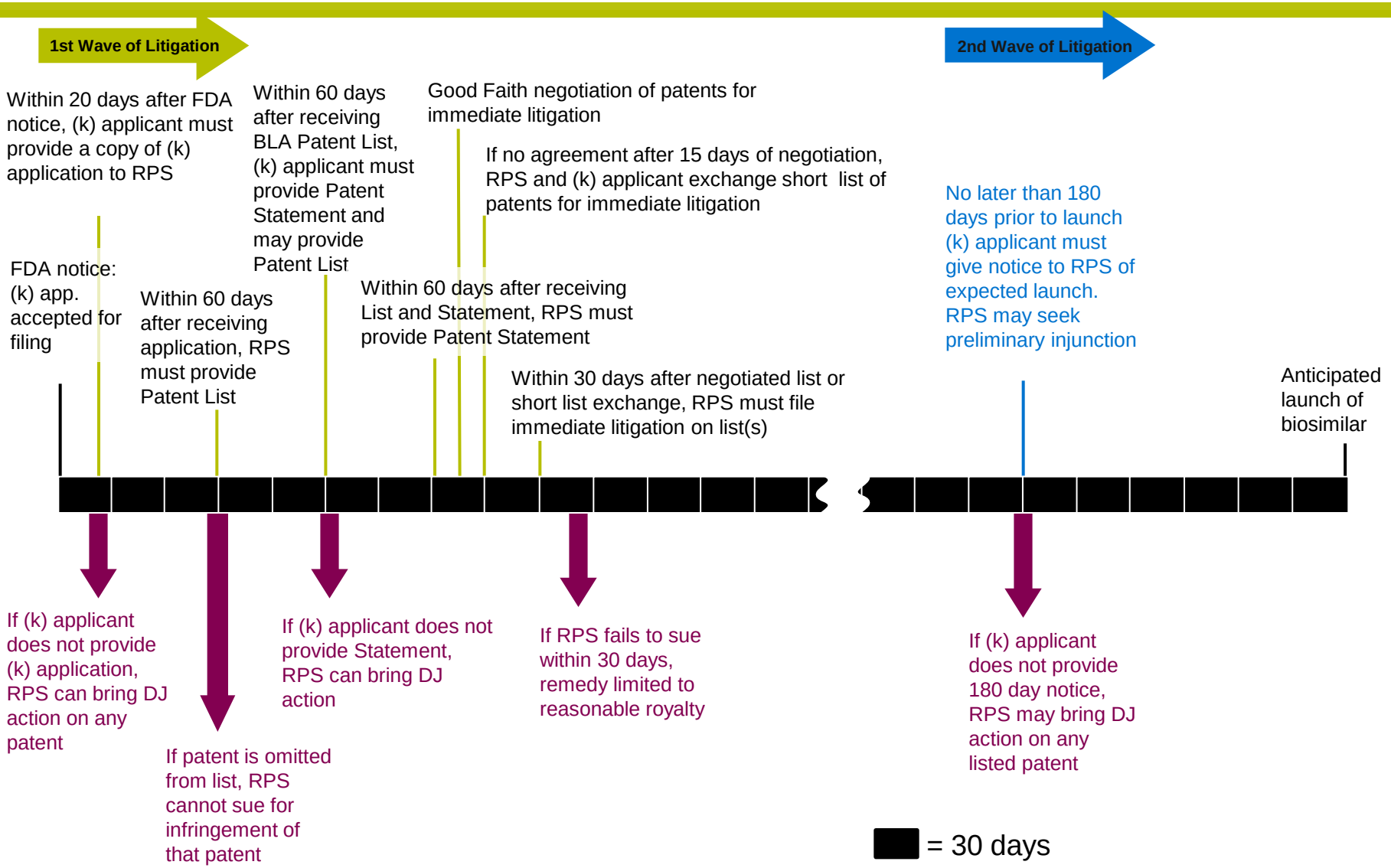
Pre-Launch Biosimilars Litigation



Pre-Launch Biosimilars Litigation



Pre-Launch Biosimilars Litigation



Biosimilars Litigation Strategy

- **(k) Applicant's Analysis:**
  - Decide whether to file a (k) application or full BLA
    - Perceived costs of disclosing (k) application to RPS
    - Perceived costs of pre-launch litigation
    - Possible benefit of challenging a foundational patent for future products
  - Consider whether to approach RPS for license early on
  - Consider timing of filing (k) application in reference product's exclusivity period
    - Effect of at-risk launch
  - Consider role of pre-launch biosimilar patent litigation and how many patents to challenge
  - Consider pre- and post-grant challenges in PTO

Biosimilars Litigation Strategy

- **RPS and (k) Applicant: Assemble the team**
  - Identify in-house counsel with technical expertise but no prosecution responsibilities
    - Confidential access to biosimilars application
  - Identify key business person with responsibility for issue
  - Retain outside counsel with expertise
    - Consider how to address conflict issues

- **RPS and (k) Applicant: Identify all relevant patents**
  - Targets, therapeutic agents, specific function, methods of use, formulations, cell lines, drug delivery vehicles, manufacturing processes, biological materials used in production, technology platforms, treatment methods, etc.
  - RPS: Set up system to monitor in-licensing of relevant patents

- **RPS's Housekeeping = (k) Applicant's diligence**
  - Determine expiration dates and potential patent term extensions
  - Confirm all fees have been paid
  - Consider timing and scope of litigation hold

Biosimilars Litigation Strategy

- **RPS's Patent Analysis: Assess "homegrown" patents**
  - Evaluate strength, breadth and importance of patents
  - Confirm inventorship/ownership of patents arising out of collaboration to avoid any standing issue
  - Develop invention story
  - Determine current status of inventors (i.e., is your lead inventor about to be laid off?)

Biosimilars Litigation Strategy

- **RPS's Patent Analysis: Assess in-licensed patents and licensing arrangements**
  - Evaluate strength, breadth and importance of patents
  - Communicate with patent owners
    - Time will be of the essence to meet deadlines for information exchange and filing suit
    - Coordination of information exchange
    - Confirm decision making process for selecting patents to list and authorizing suit
  - Consider whether to renegotiate patent licenses
    - Notification provisions
    - Obligation to enforce licensed patents against infringers?
    - Participation and cooperation in litigation
  - Confirm ownership/inventorship to avoid standing issues, esp. when university is licensor
    - What MTAs was inventor operating under? Any obligation to assign that wasn't fulfilled?
  - Understand invention story
    - Assess inventor as witness, including willingness to assist

Biosimilars Litigation Strategy

- **RPS and (k) Applicant: Investigate and possibly retain experts early on**
  - Head start in race for experts
  - Initial consulting relationship

- **RPS and (k) Applicant: Rank patents based on strength, patent term and tactical value to assemble patents for PTO proceedings, first-wave litigation and second-wave litigation**
  - Pioneering patent?
  - Extent of claim construction needed and likely appeal on claim construction issues?
  - Licensees as co-parties?
  - Venue issues with co-parties?

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Open Questions

- Will discovery requirements and cost of litigation create a disincentive to filing a (k) application?
- Will (k) applicants file their applications early in the reference product's data exclusivity period or late?
- Will (k) applicants have an incentive to bring in many patents or just 1?
- In addition to litigation based on filing of 351(k) application as an act of infringement, will there be other "waves" of litigation based on activities outside the scope of the 271(e)(1) safe harbor?

Simmons & Simmons

Patent Litigation in China – Navigating in an Unknown Jungle

Lewis Ho

Simmons & Simmons

March 2012

Simmons & Simmons

Topics

- Knowing your enemies in China
- Patent litigation in China
- Cases

Knowing your competitors in China

Patent and Regulatory Searches

ABC Company

China Watch Products – Regulatory and Patent Searches (as of 28 February 2012)[a]

1. MMM (English INN)

Common Name : INN and other unofficial or non-standard names in English and Chinese
Trade Name : MMM
Indication : treatment of pain associated with XX symptoms
Administration Method : tablets / injection / intravenous infusion

Result for Regulatory Search

Status of ABC Company's Application in China : tablet is already marketed by ABC Company in China /
No application from ABC Company is found in SFDA online database /
SFDA online database shows the Medical Device Importation Certificate held by ABC company expires on XXX.

Products already marketed by other companies in China : 6 (including API, tablets and sustained release tablets)

Products already applied by other companies in China : 4 (please see below)

No.	Applicant	Type of Application	Form	Current Status	Filing Date
2a.	XYZ COMPANY XYZ公司	NDA	MMM hydrochloride sustained release tablets	under CDE review	2010-12-01
2b.	TUU BIOMEDICAL TECHNOLOGY CO. LTD. TUU生物醫葯技術有限公司	NDA Supplemental application	Capsules	SFDA approval pending	2006-01-04
2c.	LMO COMPANY LMO 公司	NDA	Oral solutions	Review result unclear	2010-06-03

[a] Searches were conducted using the INN for each product (where available) and other unofficial or non-standard names in Chinese and/or English. Search terms marked * are unofficial or non-standard terms and search results using these terms are also marked *. See endnotes for product-specific comments.

Simmons & Simmons

Knowing your competitors in China

Patent and Regulatory Searches

2d.	DEE PHARMACEUTICAL CO. LTD. DEE制药有限公司	IND	Granules	Under SFDA review	2011-12-2003

Result for Patent Search

Search terms: INN and other unofficial or non-standard names in English and Chinese

No.	Applicant/Registrant	Application/ Registration Number	Filing Date	Publication Date	Status	Brief Description
2.1	AAA PHARMACEUTICAL CO., LTD AAA制药股份有限公司	20041008XXX.X	2004.09.24	2005.05.18	Granted (2006.12.06)	Process for preparing MMM
2.2		20041009XXX.X	2004.11.10	2005.07.06	Granted (2008.03.05)	Dispersible tablet of MMM
2.3	BBB SCIENCE AND TECHNOLOGY CO., LTD BBB科技有限公司	20031012XXX.X	2003.12.08	2004.11.17	Withdrawn (2007.09.12)	MMM dripping pills and its preparation
2.4	CCC University CCC大學	20098012XXX.X	2009.04.02	2011.05.04	Pending	Use of a combination of udenafil and MMM or oxybutynin for the treatment of overactive

* Patent information obtained from the English and Chinese online databases of the Chinese State Intellectual Property Office from XX February 2012 to XX February 2012.
** Brief Descriptions are English translations of the Chinese patent document and are provided for reference only, please refer to the original Chinese text.

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Patent Litigation in China

Background of the PRC legal system

- Constitution – highest legal instrument
- Law
  - Formulated by National People's Congress ("NPC") and its standing Committee
  - e.g. Criminal Law, Contract Law, Patent Law, Labour Contract Law
- Administrative Regulations
  - Formulated by the State Council
  - Implementation of laws: e.g. implementing rules to Patent law/Labour Contract Law
- Local Regulations & Administrative Rules
  - Formulated by NPC at the provincial level
  - Ministries or commissions directly under the State Council e.g. Technology Transfer Regulations
- Judicial Interpretation from the Supreme People's Court
  - Binding on all Chinese courts

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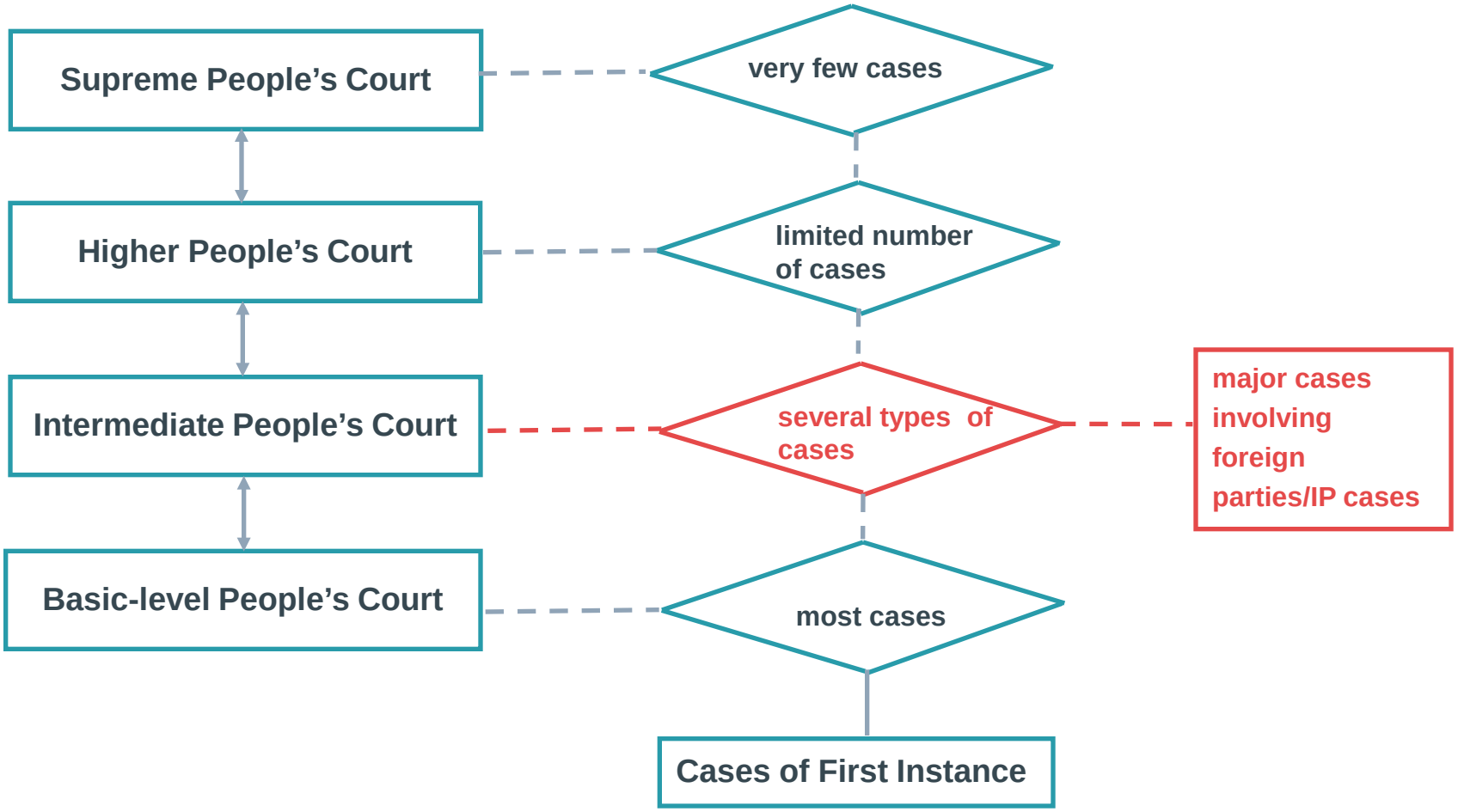
Levels of the PRC courts



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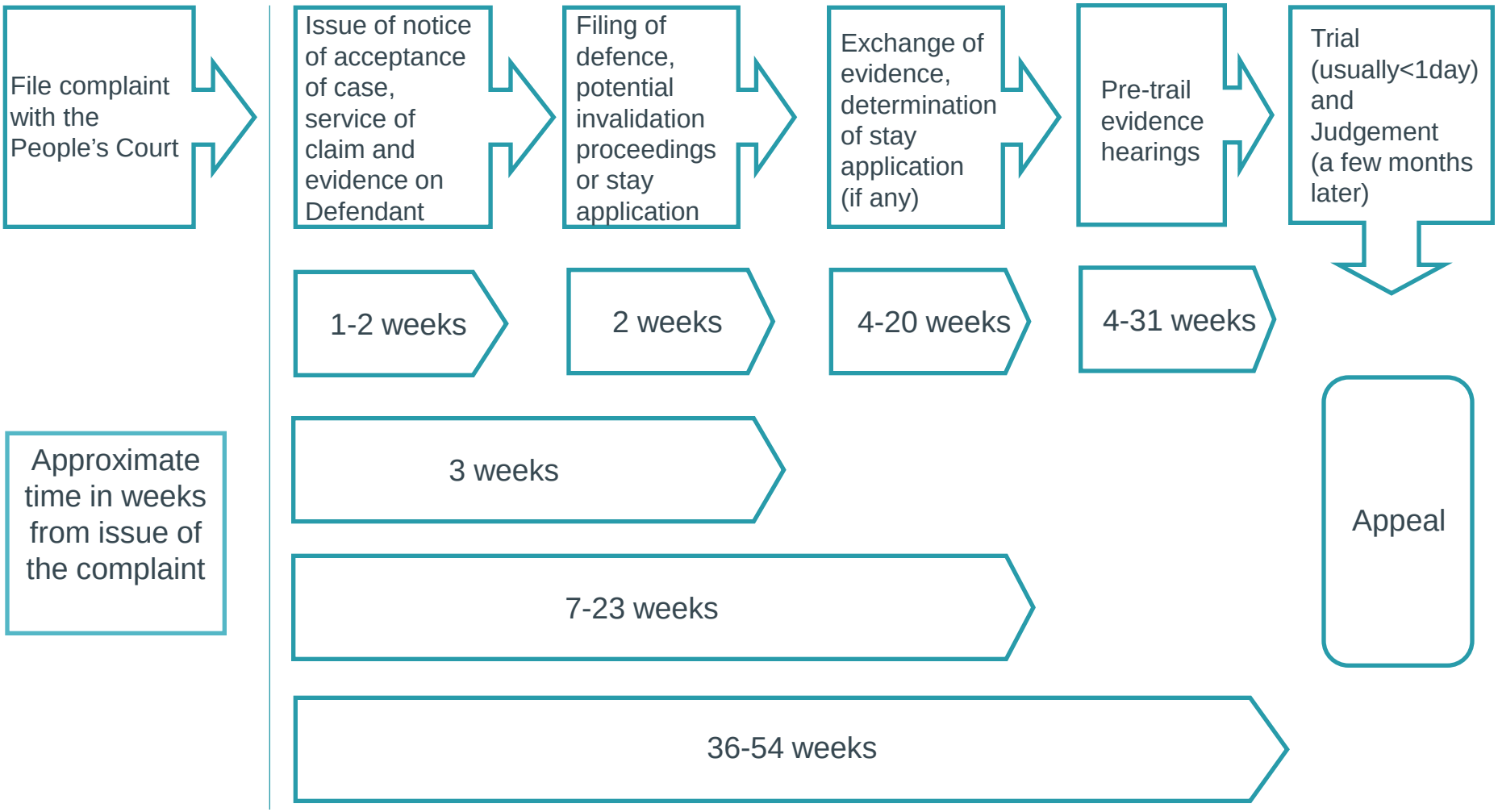
Court proceedings – steps



Highlights of the PRC litigation system

- No rule of binding precedent
- No jury trial
- PRC Courts principally rely on documentary evidence and require notarization and legalization for overseas evidence
- Court-appointed experts to determine infringement issues
- Oral evidence is rarely relied upon
- No cross-examination of witness
- No oral or written discovery

Split trial for infringement and invalidation actions

- Infringement actions are heard by the courts
- Invalidity challenges by the Patent Re Examination Board (the PRB) under the State Intertellectual Property Office (the SIPO)

Invalidation actions

- Commonly invoked by defendants when faced an infringement claim
- Heard by the Patent Review Board in Beijing
- Infringement court has a discretion whether or not to stay the action

Invalidation actions - Procedures

- Heard by 3 examiners of the Patent Review Board
- Takes 9 to 12 months for oral hearing
- Evidence originated overseas must be notarized and legalised
- No time limited for patentee to adduce evidence
- Changes on the procedures
  - Tactics by generics manufacturers to file multiple sets of invalidation claim based on the same ground becomes impossible
  - Patent Review Board has discretion to proceed with a invalidation case even the applicant withdraws

Jurisdiction challenge

- Commonly invoked by defendants in infringement actions
- Must be brought in writing before the deadline to file the defence

Infringement actions

Territorial jurisdiction

- Where the infringer is domiciled OR the place of infringement
- Forum shopping is permissible

Expert evidence

- Litigants are at liberty to adduce expert evidence
- Local experts are preferrable
- Chinese courts usually entrust their designated experts or intellectual property certification organisations to conduct judicial adjudication when determining the scope of patent during patent infringement actions
- Well-recognized intellectual property certification organisations:-
  - Beijing Huake IP Certification Centre
  - Shanghai IP Judicial Certification Centre

SPC Judicial Interpretation on patent infringement actions

- Issued by the PRC Supreme People's Court in December 2009
- Binding on all Chinese courts, aims to create a unified approach among all Chinese courts in handling patent infringement trials

Main features of the Judicial Interpretation

Claims interpretation

- PRC Patent Law: "the extent of protection of a patent shall be determined by the terms of the claims. The description and appended drawings may be used to interpret the claims."
- Chinese courts should rely on the understanding of the claims, specifications and drawings by an ordinary skilled person in the art to determine the scope of the claims.
- If scope of the claims is not clear and the ambiguity cannot be resolved from the patent, courts may rely on textbook or common knowledge of the ordinary skilled person in interpreting the claims
- Trend: Chinese courts more ready to accept expert opinion regarding meaning of the description and drawings as understood by an ordinary skilled person in the art, as opposed to the literal meaning

Main features of the Judicial Interpretation

Doctrine of equivalents

- If the scope of a claim asserted by a claimant includes a technical feature which is equivalent to the feature stated in the claim, Chinese courts may determine the scope according to the equivalent features as asserted by the claimant

Main features of the Judicial Interpretation

File wrapper estoppel principle

- The file wrapper estoppel principle requires the courts, in interpreting claims and assessing infringement of a patent, to exclude the technical features which have been voluntarily given up by a patentee during patent prosecution or invalidation proceedings
- Chinese courts may now interpret the relevant contents of a claim by reference to the patent prosecution file
- If a patentee has, in the course of prosecution or invalidation proceedings, voluntarily made amendments or statements which narrow or limit the claims, Chinese courts should not support an assertion from the patentee that the scope of the claim includes the technical features which have been abandoned

Main features of the Judicial Interpretation

Clarification of scope of process patents

- The PRC Patent Law states that a process patent is infringed if a defendant uses a patented process or uses, sells, offers for sale or imports any products "obtained directly from patented process"
- The Judicial Interpretation clarifies that products "obtained directly from patented process" include raw materials obtained from the patented process or any subsequent products obtained from the raw materials through further processing
- Implications: a product will be found to infringe a process patent as long as the infringing process step forms part of the process in the production chain, not necessarily the last step

Main features of the Judicial Interpretation

Concept of contributory infringement

- The PRC Patent Law does not provide any legal basis for asserting contributory infringement
- Wide consensus that contributory infringement can be based upon Article 148(1) of SPC Judicial Interpretation on the Civil Procedure Law, which states that a person who instigates or assists others to perform an act of infringement shall be co-infringer and shall be held liable jointly and severally
- Parties in a conspiracy for using a patented product as a component to manufacture another product will be held jointly liable for manufacturing a patented product

Main features of the Judicial Interpretation

Reversal of burden of proof for "new" product

- Under Article 61 of the PRC Patent Law, if the invention is a process for obtaining a new product, the same product produced by a person other than the patentee is obliged to prove in a patent action that its products were obtained from a process which is different from the patented process.
- The provision helps patentees in proving infringement of a process patent
- The Judicial Interpretation states that the term "new" product means a product which was not known to the public (inside or outside China) before the filing date of the patent
- Implication: enforcement of a process patent after expiry of the corresponding compound patent

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Cases

Case study – infringement

Beijing Tonghua An Tai Ke Bioengineering Co., Ltd. v Lilly France S.A.S., Eli Lilly and Company and Others (Beijing No. 1 Intermediate People's Court) (2005)

- Facts
  - The Plaintiff, Beijing Tonghua An Tai Ke Bioengineering Co., Ltd. ("Tonghua") filed for a patent in respect of "Chimeric proteins with intramolecular chaperone sequences and their use in insulin production" on 31 March 1998. The patent was registered on 20 April 2005.
  - The Defendants manufacture and sell insulin lispro injections under the brand of "优泌乐" ["Humalog"]. Insulin lispro is a synthetic insulin replacement.
  - The Plaintiff claimed that the insulin precursors used in the insulin lispro injections are the chimeric proteins incorporating insulin precursors, as protected under its patent.
  - The Plaintiffs also claimed that under Article 57(2) Patent Law (old), where a patent infringement case involves the infringement of a method for manufacturing a new product, the entity manufacturing a similar product (ie the Defendant) must prove that their manufacturing process is different from the patented process.

Case study – infringement

Beijing Tonghua An Tai Ke Bioengineering Co., Ltd. v Lilly France S.A.S. , Eli Lilly and Company and Others (Beijing No. 1 Intermediate People's Court) (2005)

- Decision
  - The court rejected the Plaintiff's claim.

  Infringement

  - The court compared the technical plan of the patented invention with the technical plan of the Defendants' product. The Plaintiff's evidence in this respect was limited to the patent in question, a document obtained from the Internet titled "Carolina, Puerto Rico ELI LILLY Biotechnology Bulk Production Facilities", and the Defendants' patent specification for the insulin lispro injections.
  - The court considered that the Internet document did not provide sufficient information to allow the court to effectively compare the technologies.
  - The court also considered that the Defendants' patent specification for the insulin lispro injections did not involve the technical plan of the recombinant genetic technology for the Plaintiff's lispro product. There were also other types of recombinant genetic technology used in the manufacture of insulin.

Case study – infringement

Beijing Tonghua An Tai Ke Bioengineering Co., Ltd. v Lilly France S.A.S., Eli Lilly and Company and Others (Beijing No. 1 Intermediate People's Court) (2005)

- Decision (Continued)

  Reversal of burden of proof

  - Article 57 of the Patent Law (old) applies where (i) the product directly obtained as a result of the patent is a new product; and (ii) such new product is the same as the Defendant's product.
  - The court considered that the Plaintiff's product was a type of insulin. The court considered that insulin is a widely known product, and documents provided by the Defendants showed that"优泌乐" was being imported into China as a replacement for insulin in 1997, which pre-dated the Plaintiff's patent application. The court therefore held that the Plaintiff's product was not a "new product".
  - The Plaintiff's request that the Defendants provide information on the method for producing the insulin lispro was therefore rejected by the court.

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Q&A

Thank you

Lewis Ho, Partner, Beijing

T +86 10 6113 7599
E lewis.ho@simmons-simmons.com

simmons-simmons.com
elexica.com