Stanford Law School

IP Law and the Biosciences Conference

Biologics in the International Arena

April 26, 2018

Panelists

- *Moderator:* Justin Watts–Partner, WilmerHale
- Jürgen Dressel
- Rebecca Eisenberg–Professor of Law, University of Michigan Law School
- Dr. Klaus Grabinski–Judge, German Federal Court of Justice
- Lord Leonard Hoffmann–Brick Court Chambers
- Jacob Sherkow–Associate Professor of Law, New York Law School

Agenda

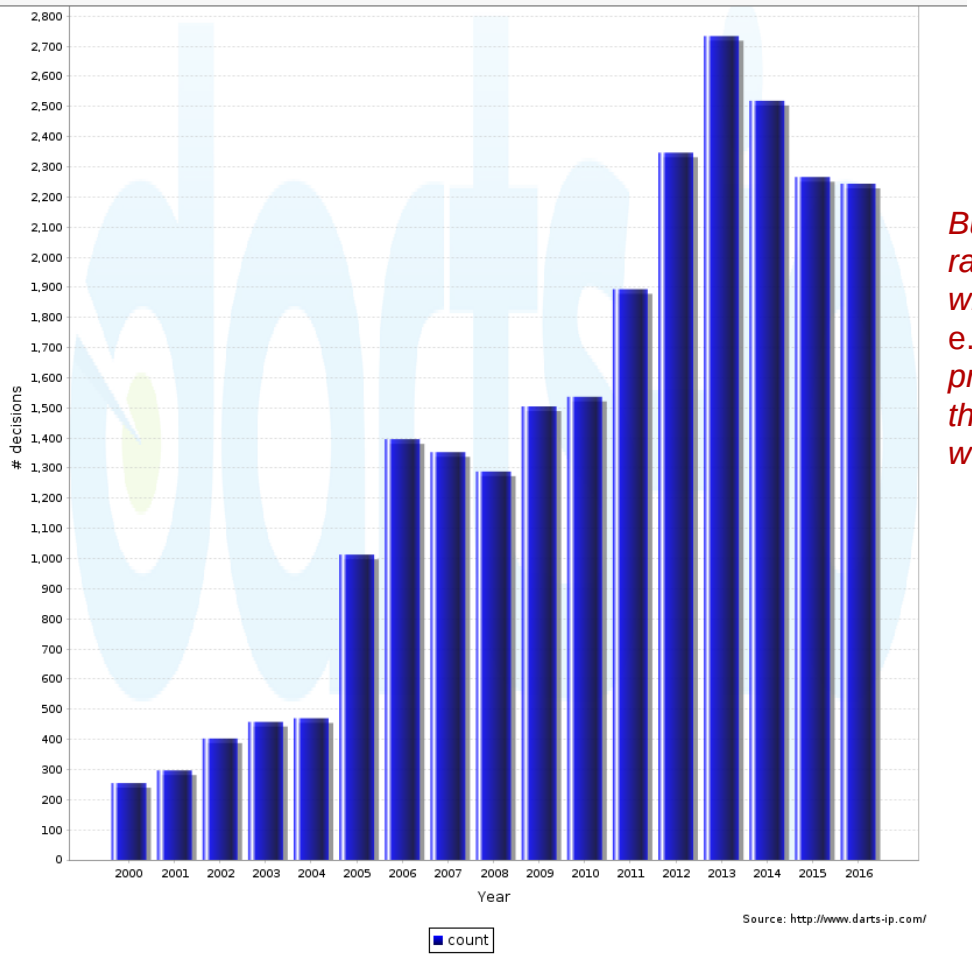
- Introduction
- Claim Construction
- Scope of Protection
- Novelty
- Inventive Step
- Sufficiency / Written Description
- Prosecution
- Litigation
- Infringement

Agenda

- **Introduction**
- Claim Construction
- Scope of Protection
- Novelty
- Inventive Step
- Sufficiency / Written Description
- Prosecution
- Litigation
- Infringement

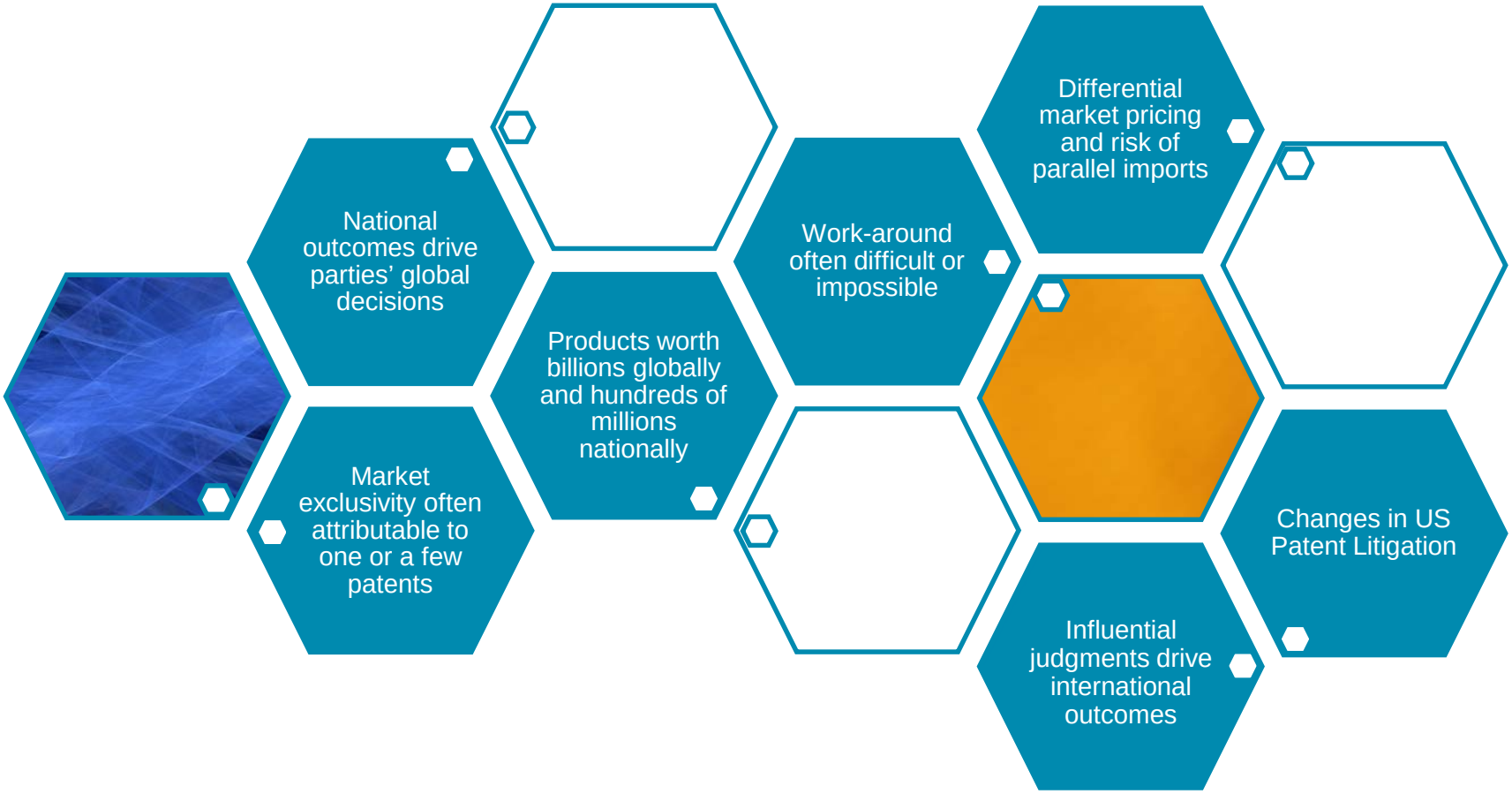
Patent Litigation is Increasing Globally

The number of first instance substantive patent infringement decisions worldwide from 2000 to 2016



But NB: all historical and success-rate statistics should be treated with caution. They may reflect, e.g., changes in data collection practice, and plaintiff's choices on the odds that make a case worth bringing.

Key Drivers of Global Litigation



US Remains Central to Strategy

- Largest single market by value
- Drivers to early litigation esp. Hatch-Waxman
- Respected court system
- Patentee friendly courts
- High damages awards
- Reasonably fast proceedings
- English language and home market of many multinationals

US Remains Central to Strategy, but …

- Although the US is often still the largest market, international markets have become increasingly important
- US District Courts have become less preferred – in 2016 there were 4,537 filings (-22%) and in 2017 there were 4,060 filings (-10%) – leading to use of alternative or additional fora, i.e., the ITC (50% increase in cases between 2014 and 2015) and overseas courts
  - *Alice* limits eligible subject-matter
  - *TC Heartland* limits choice of venue
  - IPRs threaten patent validity and delay District Court cases
  - *eBay v. MercExchange* continues to limit availability of injunctive relief
- Faster, cheaper jurisdictions can raise pressure for early settlement

Availability of Injunctions Outside US

- In all major non-US patent litigation jurisdictions, an injunction will generally follow a finding of infringement and validity
  - There is no equivalent to *eBay v. MercExchange*
  - In some jurisdictions, injunctions are mandated following a finding of infringement; in others, injunctions are not mandatory, but still usual
- Injunctions are not always stayed pending appeal
- Preliminary injunctions may be available
- *Ex parte* injunctions may be available

England and Wales

- Large market
- Common law system (discovery, cross-examination, full oral argument)
- Patents Court in London (specialist court and judges)
- No jury
- Infringement and validity tried together
- Trial within 10 - 15 months
- Flexible remedies for non-patentees (*e.g.,* declarations of non-infringement, declarations of non-essentiality, multinational declarations and “Arrow” declarations)
- Patentee win rate 28%
  - Non-patentee claimant win rate 71%
  - 49% of cases had non-patentee claimant

Injunctions in England

- "Discretionary" – equitable remedy but not equivalent to analysis in US following *eBay v. MercExchange*
- Refused where "grossly disproportionate" (*Navitaire Inc. v. Easyjet Airline* [2006] RPC 4 123, *Virgin Atlantic v. Premium Aircraft* [2009] EWCA Civ. 1513)
- Is it disproportionate "even having regard to the requirements of efficacy and dissuasiveness" (per Article 3) – a heavy burden (*HTC Corporation v. Nokia Corporation* [2013] EWHC 3778 (Pat))
  - Examples in bioscience sphere:
    - Second medical use? Especially if only small proportion infringed
    - Breaches historic and unlikely to recur
- Recently, some patentees choose not even to ask for an injunction in cases concerning life-saving medicines

Germany

- Large market
- Civil law system – rarely any discovery or examination of witnesses, limited oral hearing (typically 1 - 2 hours)
- Bifurcation – validity and infringement tried separately
- Infringement in District Court: usually in very experienced courts of Düsseldorf, Mannheim, Munich, Hamburg
  - Typically 7 - 12 months to hearing, depending on court
- Validity in Federal Patent Court: Munich, 18 months - 2.5 years to hearing
- Disparate timetables create “injunction gap”
- Patentee infringement win rate 66%
  - 25% with nullity decision
- Injunctions are mandatory and rarely stayed

Injunctions in Germany

- S.139(1) Patent Act has historically been interpreted to mean that injunctions should be granted following a finding of infringement (subject to the possibility of stays in some circumstances)
- There are few exceptions:
  - SEPs
  - Emergency compulsory license was granted in *Shionogi v. Merck* (X ZB 2/17) and upheld by Bundesgerichtshof, involving a life-saving drug
  - Grace period exceptionally available when the immediate enforcement of injunctive relief would have to be deemed grossly disproportionate, Bundesgerichtshof in "*Heat exchanger*" (X ZR 114/13)

The Netherlands

- Key center for import and logistics
- Civil law system with no discovery, little if any examination of witnesses and limited oral hearing (half day)
- Specialist chamber in the District Court in the Hague
- Infringement and validity are heard together
- Trial within 9 - 12 months (and faster if expedited)
- Willing to consider pan-European jurisdiction
- Injunctions are mandatory (with exceptional public interest defense)
- Patentee win rate 33%

Unified Patent Court

- A single court (with local, regional and central divisions) that will have jurisdiction across ultimately 25 Contracting States in Europe
- There will be yet more litigation in Europe once the UPC commences, with new forum shopping strategies
- Opportunity for increased harmonization, better predictability of judgments and simplified enforcement in EU-market
- Not there yet
- Long transition provisions increasing complexity of litigations

Other Plaintiff Tools in Europe

- Saisie contrefaçon
  - Available in France, Italy, The Netherlands, Belgium
  - Seizure of evidence of infringement and description of infringing processes
  - Very common opening salvo in French proceedings
- Inspection of premises
  - Available in Germany, in particular for gathering evidence with regard to the infringement of production proceeding patents
- Border seizures
  - Can be easy to obtain in The Netherlands

Japan

- Civil law jurisdiction; limited discovery procedures and little examination of witnesses
- Modified bifurcated system: validity and infringement determined together, but validity decision has only *inter partes* effect. JPO retains role in revoking patents
- Infringement heard in specialist IP divisions of Tokyo and Osaka District Courts
- Proceedings consist of a series of hearings at monthly intervals. Infringement and validity decisions within c. 12 months; damages assessment a few months later
- Preliminary injunctions only granted as part of the case on the merits, and they are slow: 6 - 9 month delay may see generic market entry at risk
- Final injunctions are granted save in exceptional cases (abuse of right)
- Overall patentee win rate: 23%

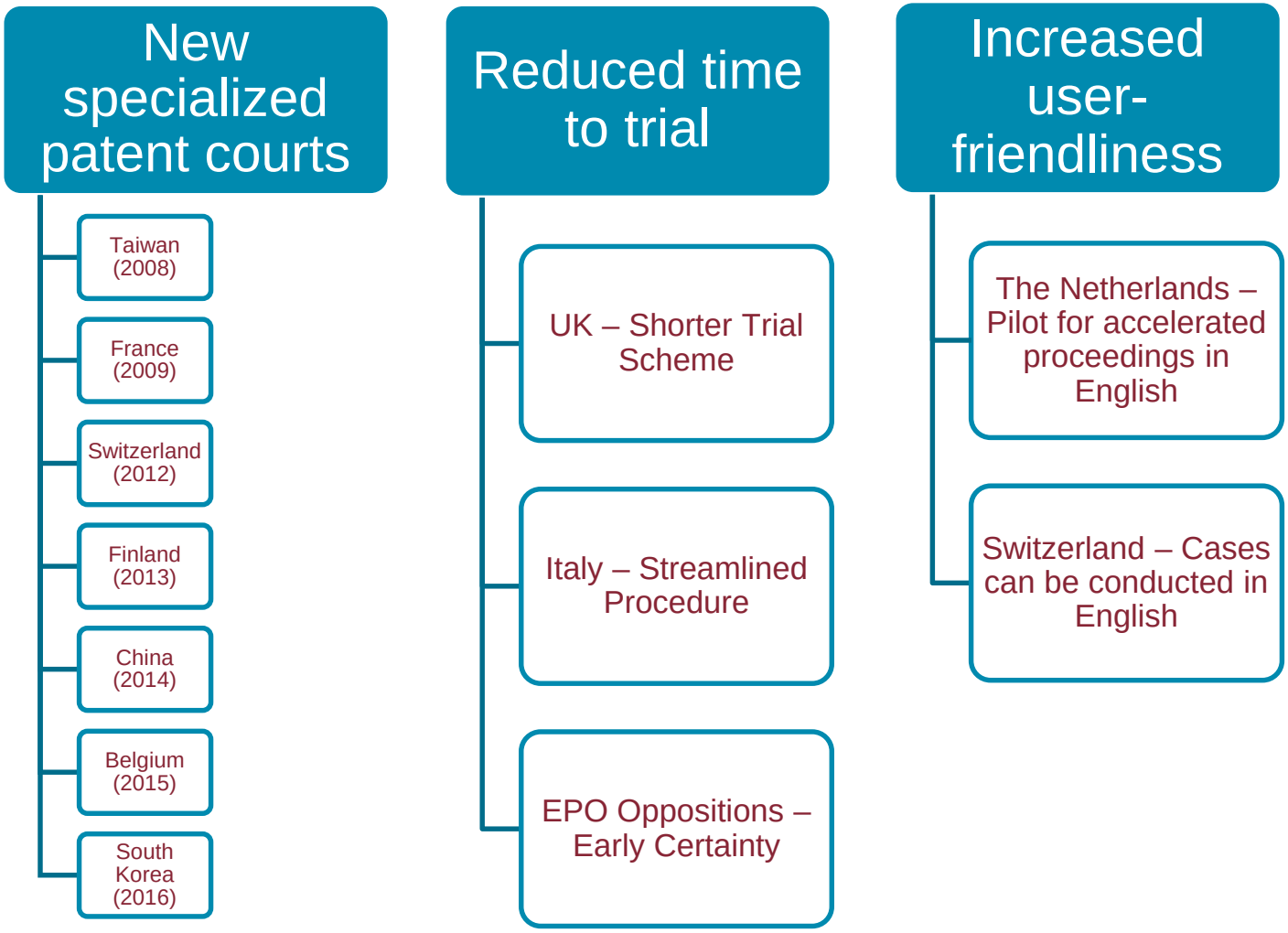
South Korea

- Civil law jurisdiction with no discovery and limited examination of witnesses
- Patent linkage system introduced by US-South Korea FTA; “Hatch-Waxman lite”
- Bifurcated system; however, infringement proceedings are usually stayed pending validity determination
  - Validity is heard in Korean Intellectual Property Tribunal (part of Korean IPO) in 6 - 9 months
  - Infringement is heard in one of five district courts (mostly in the specialist Seoul Central District Court) in 6 - 18 months
- Injunctions are granted save in exceptional cases (including where it is clear that the patent will be found invalid by the Korean Intellectual Property Tribunal, if infringement proceedings have not been stayed)
- Overall patentee combined win rate: 30%

China

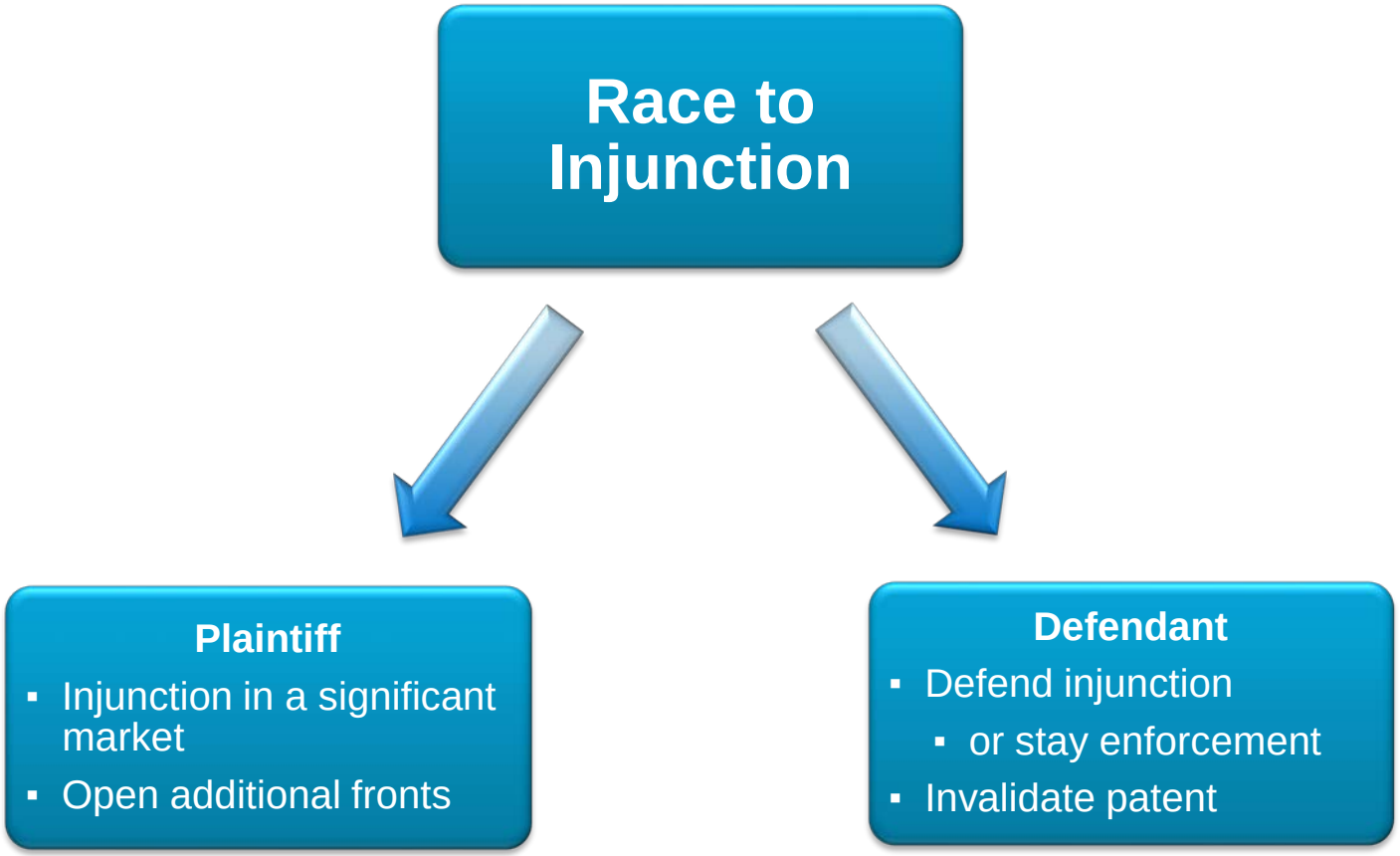
- Vast and growing market
- Since accession to WTO in 2001, exponential growth in patent litigation
- Encouraging foreign parties, quasi-independent courts
- Civil law jurisdiction with no discovery and limited examination of witnesses (which is given little weight), with the trial usually lasting 3-5 hours
- In the process of introducing patent linkage; some features already in place *e.g.,* "Chinese orange book"
- Bifurcated system with validity and infringement tried separately – stays of infringement proceedings are not usual
  - Validity is heard in Patent Re-examination Board in 12 months
  - Infringement is heard in Beijing, Shanghai and Guangzhou specialist IP courts (or IP divisions of local courts) in 6 - 12 months
- Injunctions are granted save in exceptional cases (public interest, or significant harm to the interests of the parties, or impractical to enforce)
- Overall patentee combined win rate: 33%

International Courts Are Changing

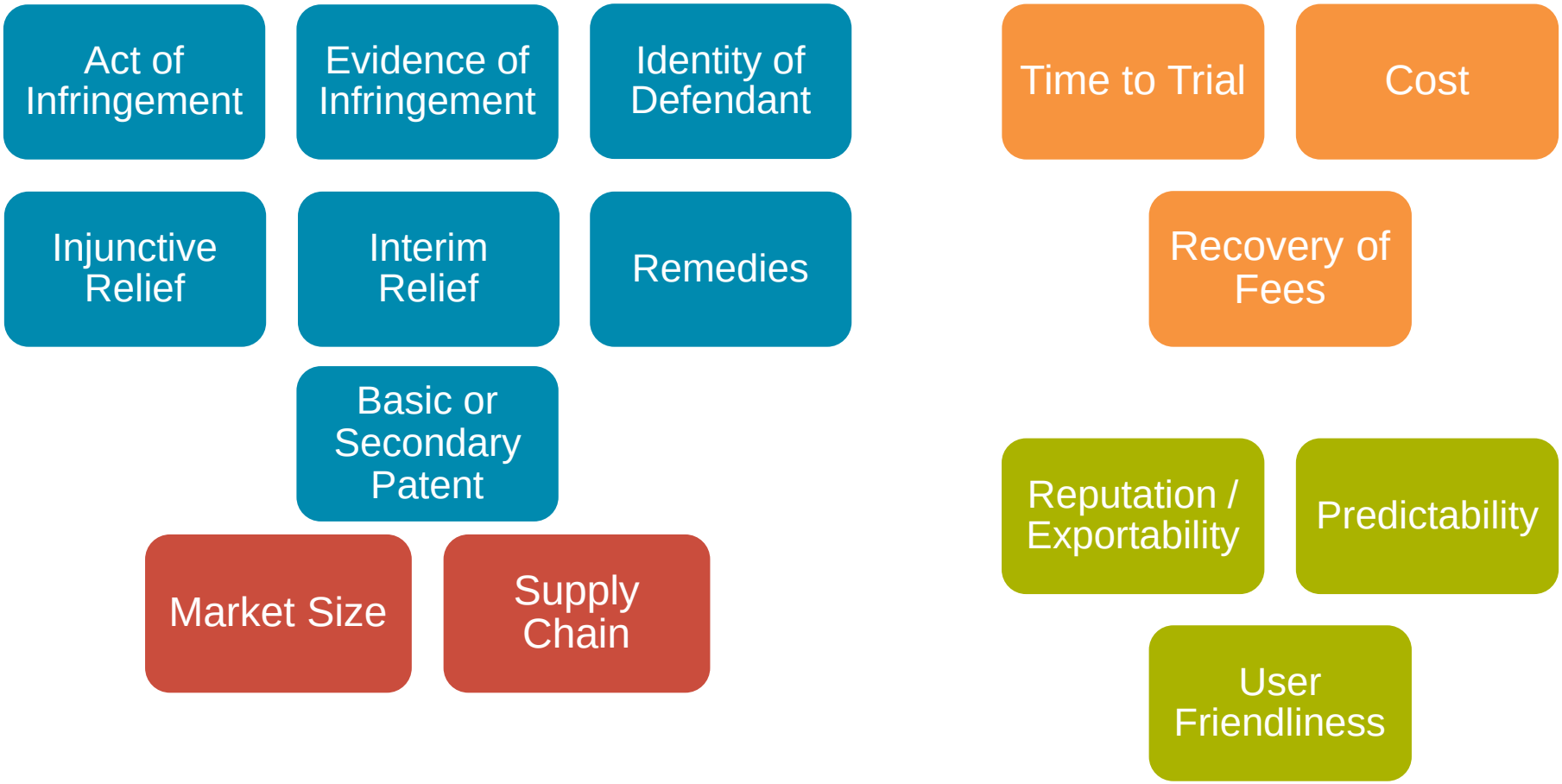


Global Patent Litigation Strategy

Global Patent Litigation Strategy

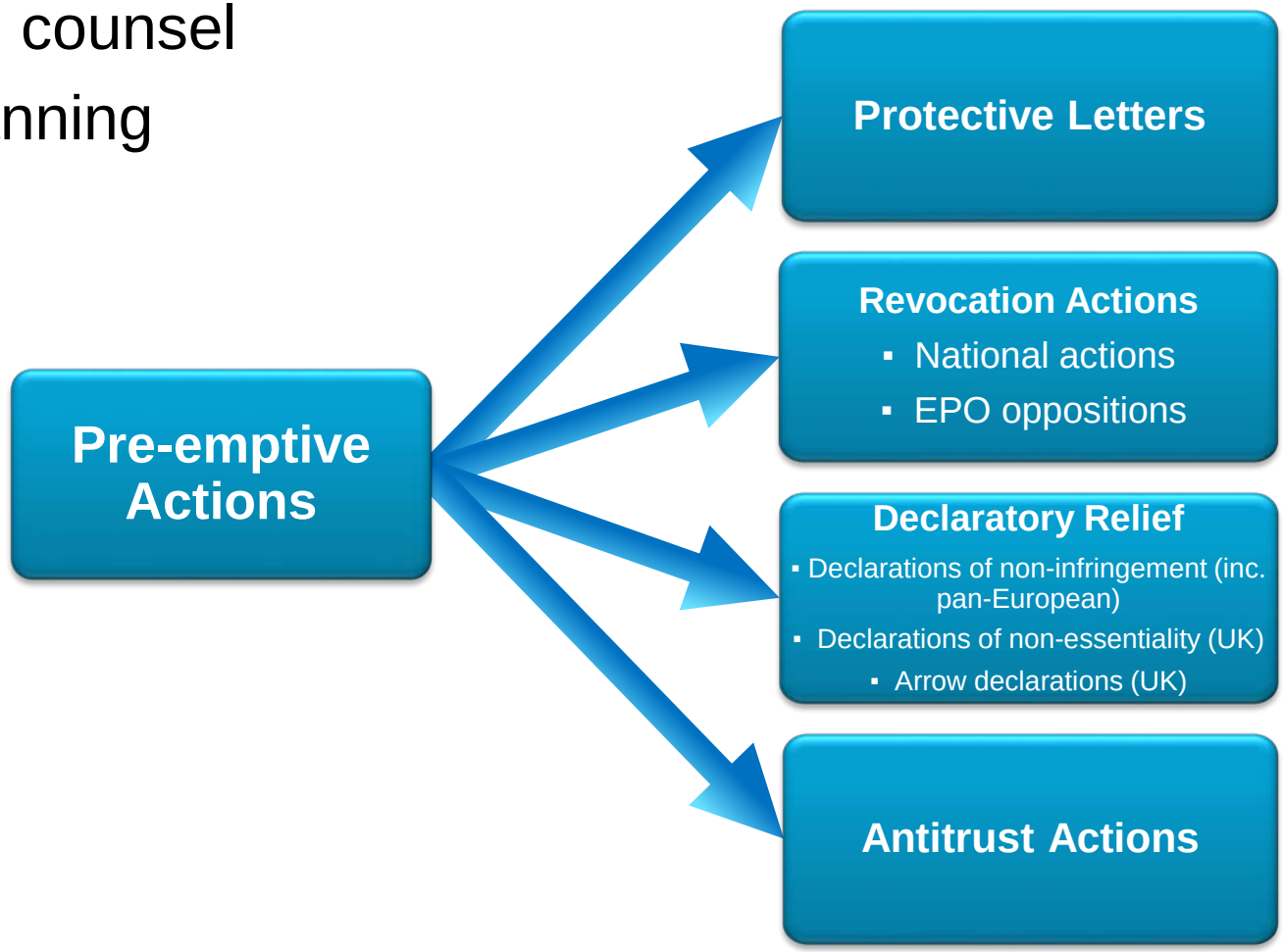


Factors in Selecting a Forum



Defendant Strategy - Defend

- Instruct local counsel
- Scenario planning



Defendant Strategy - Retaliate

- Infringement actions on existing or acquired patents
  - Threat of injunctions strengthens negotiating position
- Invalidity actions against non-asserted patents
  - Challenge to other valuable patents strengthens negotiating position
- Open new geographical fronts
  - In more favorable jurisdictions
- Strategy depends heavily on type of dispute: originator-originator, originator-biosimilar or originator-generic?

Antitrust and Regulatory Actions

- Important additional front in global IP disputes relating to licensing or supply models or enforcement strategies
- Substantial role in tech sector – and competition authorities increasingly interested in pharma sector
- Competition authorities have regard to each other's investigations and decisions
- Coordinated approach is required globally

Case Study

Hypothetical Claim

An anti-[XYZ] antibody or antibody fragment for the treatment of cancer.

Agenda

- Introduction
- **Claim Construction**
- Scope of Protection
- Novelty
- Inventive Step
- Sufficiency / Written Description
- Prosecution
- Litigation
- Infringement

Claim Construction

An anti-[XYZ] antibody or antibody fragment for the treatment of cancer.

- Does the claim require therapeutic effect?
- What does it mean to have “therapeutic effect” against cancer?

Agenda

- Introduction
- Claim Construction
- **Scope of Protection**
- Novelty
- Inventive Step
- Sufficiency / Written Description
- Prosecution
- Litigation
- Infringement

Scope of Protection

An anti-[XYZ] antibody or antibody fragment for the treatment of cancer.

- Is the scope of protection limited to antibodies and antibody fragments?
- Antibody-drug conjugates
- Antibody fusion proteins

Agenda

- Introduction
- Claim Construction
- Scope of Protection
- **Novelty**
- Inventive Step
- Sufficiency / Written Description
- Prosecution
- Litigation
- Infringement

Novelty

An anti-[XYZ] antibody or antibody fragment for the treatment of cancer.

- Effect on novelty where prior art discloses the antibody and that it is used to treat cancer

Agenda

- Introduction
- Claim Construction
- Scope of Protection
- Novelty
- **Inventive Step**
- Sufficiency / Written Description
- Prosecution
- Litigation
- Infringement

Inventive Step

An anti-[XYZ] antibody or antibody fragment for the treatment of cancer.

- Claiming an antibody where epitope is known to have therapeutic interest
- Is a specific suggestion to investigate cancer sufficient to render the claim obvious?
- Preclinical tests (*e.g., in vitro* tests, mouse xenograft models) & incomplete clinical trials and reasonable expectation of success
- International standard of plausibility?

Agenda

- Introduction
- Claim Construction
- Scope of Protection
- Novelty
- Inventive Step
- **Sufficiency / Written Description**
- Prosecution
- Litigation
- Infringement

Sufficiency / Written Description

An anti-[XYZ] antibody or antibody fragment for the treatment of cancer.

- Specification support for claim
- Relationship with inventive step analysis
- Breadth of “cancer”

Agenda

- Introduction
- Claim Construction
- Scope of Protection
- Novelty
- Inventive Step
- Sufficiency / Written Description
- **Prosecution**
- Litigation
- Infringement

Prosecution

An anti-[XYZ] antibody or antibody fragment for the treatment of cancer.

- Inventor's Dilemma: Has enough been done to constitute an inventive step?
- Waiting for results to support a broader claim: relying on imperfect predictors of clinical success
- International standard?

Agenda

- Introduction
- Claim Construction
- Scope of Protection
- Novelty
- Inventive Step
- Sufficiency / Written Description
- Prosecution
- **Litigation**
- Infringement

Litigation

An anti-[XYZ] antibody or antibody fragment for the treatment of cancer.

- Burden and sufficiency of proof for efficacy
- Imperfect predictiveness of screening cascades, surrogate parameters and animal models
- Cancer types that emerge years later that are not responsive to treatment
- Test for “non-responsiveness”

Agenda

- Introduction
- Claim Construction
- Scope of Protection
- Novelty
- Inventive Step
- Sufficiency / Written Description
- Prosecution
- Litigation
- **Infringement**

Infringement

An anti-[XYZ] antibody or antibody fragment for the treatment of cancer.

- Trends as first indication patents expire and upon biosimilar entry
- Identifying new indications
- Liability for cross-label use and off-label use

Closing Remarks