



IP Protection Strategies for Biologics

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Presentation Topics

Types of Patent Strategies

1. *PM(NOC)* Procedure
2. Infringement Action

1. PM(NOC) Procedure

Process Under the NOC Regulations

- 1st person (innovator) obtains NOC and submits patent list
 - Patents can only be listed against a NOC if they claim:
 1. Medicinal Ingredient
 2. Formulation of Medicinal Ingredient
 3. Dosage Form of Medicinal Ingredient
 4. Use of Medicinal Ingredient
- 2nd person (generic) applies for NOC and must address all patents on the list by either:
 - i. Accepting NOC will not issue until patent expiry; or
 - ii. Allege, *inter alia*, patent is invalid or that drug will not infringe patent

1. PM(NOC) Procedure

Concerns for SEB Patents

- For many biologics process of manufacture is invention
- PM(NOC) Regulations do not allow process patents to be listed.

Patent Drafting Strategy

- Ensure patent claims medicinal ingredient (or use thereof), formulation, and/or dosage form

Presentation Topics

Types of Patent Strategies

1. PM(NOC) Procedure
2. **Infringement Action**

2. Infringement Action

What is Involved?

- Full scale action:
 - Discovery
 - Expert testimony at trial

Uncertainty

- Very few cases dealing with SEBs or biologics

Issues to Consider for Trial

- a) Patent Infringement
- b) Patent Validity

2. Infringement Action – Issues to Consider for Trial

a) Is There Infringement?

Patent holder must prove infringement

If infringer has access to chemical makeup or process used to make SEB easier to determine if infringement has occurred

- SEB may be identical to Innovator Biologic

- Infringer may have made small trivial change

 - amino acid change in variable region

 - will change be captured by *Improver doctrine*

2. Infringement Action – Issues to Consider for Trial

Hurdle: SEB seller may not have access to compound details

- SEB manufacturer may reside outside Canada and may refuse to produce product details
- Patent holder may need to:
 - Compel evidence from SEB manufacturer/distributor; or
 - Compel evidence from Health Canada about SEB NDS/ANDS

2. Infringement Action – Issues to Consider for Trial

b) Validity

- Even if patent claims infringing product, court may find patent invalid (e.g.):
 - *Anticipation*
 - *Obviousness*
 - *Duty of Candor and Good Faith*
 - *Sufficiency*
 - *Utility*
 - *Sound prediction*
 - *False Promise of Patent*

Overview of 2 Cases Involving Biologics

Commissioner of Patents Decision No. 1296

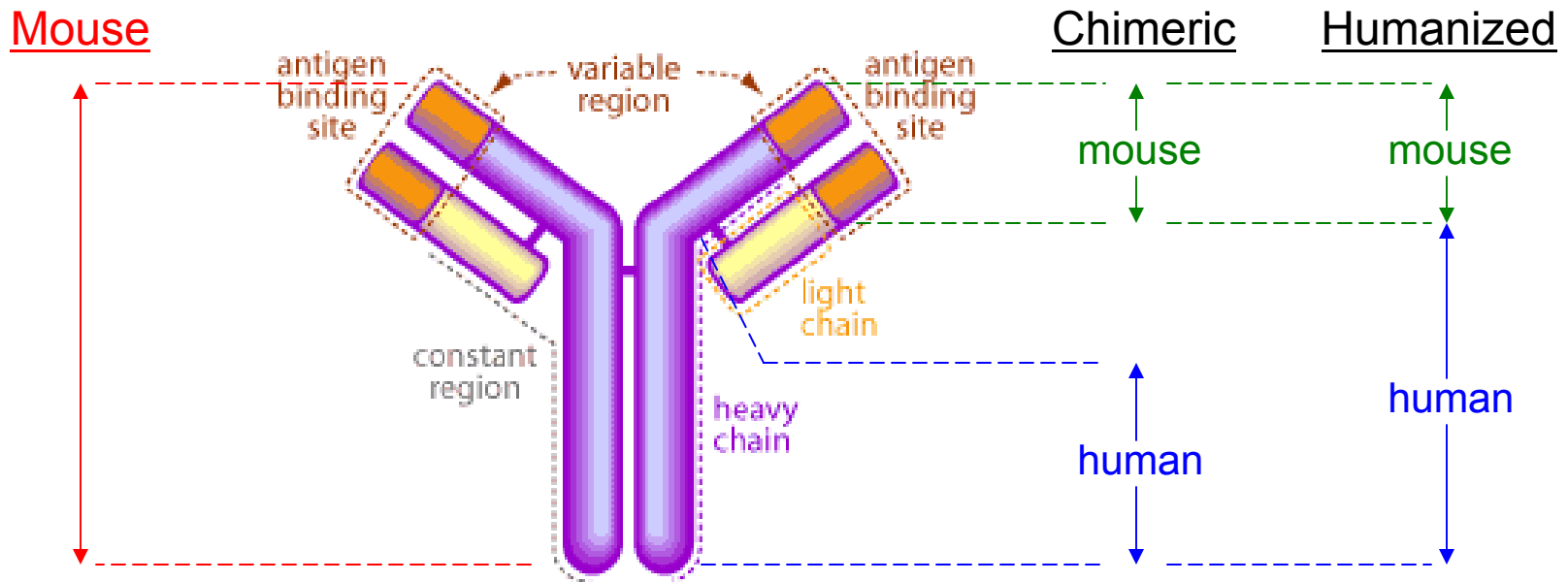
Facts:

- Applicant claimed invention for antibodies used to treat leukemia
- 3 types of antibodies were claimed:
 1. Mice Antibodies
 2. Chimeric Antibodies
 3. Humanized Antibodies

Overview of 2 Cases Involving Biologics

Commissioner of Patents Decision No. 1296

1. Mice Antibodies
2. Chimeric Antibodies
3. Humanized Antibodies



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Facts:

- The invention proposed to optimize the utility of the mice antibodies by engineering it to generate chimeric and humanized versions
 - Mice antibodies could trigger an adverse human immune response
 - Had only tested and disclosed mice antibodies

Overview of 2 Cases Involving Biologics

Commissioner of Patents Decision No. 1296

Decision:

- Patent Appeal Board (“PAB”) found that a person skilled in the art – a molecular immunologist and clinical oncologist specializing in leukemia therapies – could prepare the chimeric antibodies claimed
 - Therefore, chimeric antibodies were covered under the patent since they met the “enablement” requirement

Overview of 2 Cases Involving Biologics

Commissioner of Patents Decision No. 1296

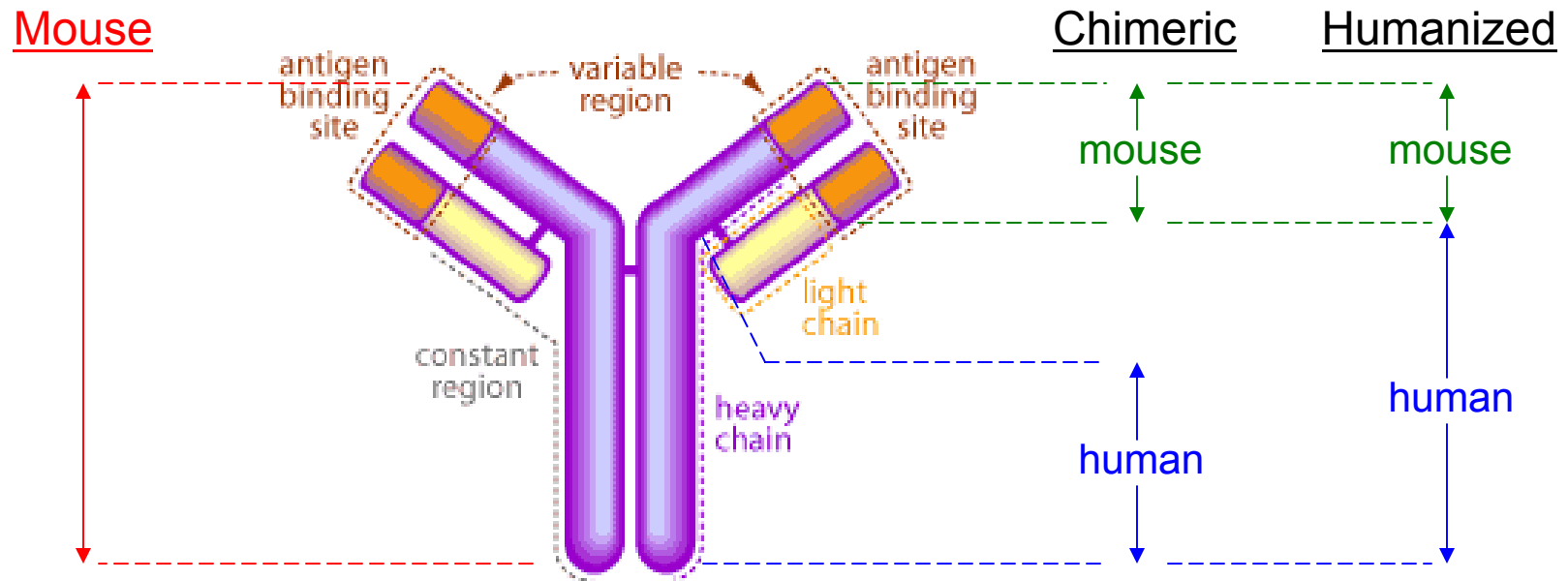
Decision:

- However, after reviewing patent and prior publications PAB found that a person skilled in the art would not be able to produce the humanized antibodies claimed
- Therefore, patent specification did not meet enablement requirement for humanized antibodies

Overview of 2 Cases Involving Biologics

Commissioner of Patents Decision No. 1296

1. Mice Antibodies
2. Chimeric Antibodies
3. Humanized Antibodies



Overview of 2 Cases Involving Biologics

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Potential Implications:

- Essentially, PAB found that patent covered the mice and chimeric antibodies for treating leukemia, but not the humanized antibodies
- If patent holder had developed and was selling humanized antibodies on market no patent protection for this biologic!
- Also humanized SEB would not be covered by the patent
- This is PAB decision, not a trial in the Federal Court
 - *Kirin-Amgen Inc. v. Hoffman-La Roche Ltd.* (2000), 11 CPR (4th) 78 (F.C.A.)

Overview of 2 Cases Involving Biologics

Kirin-Amgen Inc. v. Hoffman-La Roche Ltd.

Facts:

- Plaintiffs (Kirin-Amgen) held a patent for erythropoietin (“EPO”), which was similar in structure and function to human EPO produced by kidneys to stimulate bone marrow to produce red blood cells
 - Patent claimed EPO product having higher molecular weight (“MW”) on SDS-PAGE than human urinary EPO
- Sued Defendant (Hoffman-La Roche) for infringement by distributing their own recombinant EPO product, RECORMON

Overview of 2 Cases Involving Biologics

Kirin-Amgen Inc. v. Hoffman-La Roche Ltd.

Facts:

- Defendant alleged that patent invalid due to insufficiency on the grounds that:
 1. There is no standard human urinary EPO to compare with the MW of the claimed invention
 2. Tests outlined in patent to measure the MW lack precision to enable person skilled in the art to determine whether a recombinant EPO product infringes patent

Overview of 2 Cases Involving Biologics

Kirin-Amgen Inc. v. Hoffman-La Roche Ltd.

Decision:

- i. Patent sufficiently described, for a person skilled in the art, human urinary EPO to be drawn from a “pooled-source” of human urinary EPO rather than from particular individual
- ii. Tests outlined were not to provide determination of a precise MW, but simply to assess comparative molecular weights of a recombinant and human urinary EPO for infringement purposes
- iii. Defendant’s recombinant EPO did infringe patent since it possessed higher MW as claimed in invention

Overview of 2 Cases Involving Biologics

Kirin-Amgen Inc. v. Hoffman-La Roche Ltd.

- Court of Appeal affirmed trial judgment

Thank You

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