LOMBARD & GELIEBTER
INTELLECTUAL PROPERTY LAW

MECHANISM FOR RESOLVING PATENT DISPUTES UNDER THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT OF 2009

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What are Biologics?

- What most people think of as drugs are low molecular weight compounds with therapeutic use that can be made in a test tube
- Biologics are high molecular weight compounds with therapeutic use that can only be obtained or derived from living organisms
  - → Examples are hormones harvested from rat cells or antibodies cloned and harvested in bacterial cell cultures
  - → Market examples include Enbrel for arthritis, Herceptin for breast cancer and Humira for Crohn's disease
- The USFDA has an approval process to sell and market biologics

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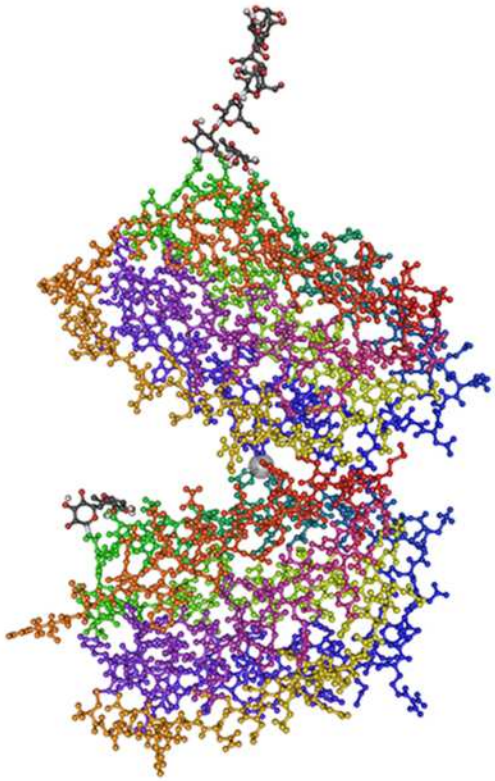
What Are Biosimilars?



Human interferon

- Essentially generic versions of biologics
- As biologics are much larger molecules than most chemical drugs, biologics can rarely be duplicated
- Duplication, however, may be unnecessary to replicate the therapeutic effect of a biologic
- Thus, close copies of biologics that have comparable therapeutic effect are approvable
- US and other countries have an approval process for biosimilars
- Many more countries are devising programs

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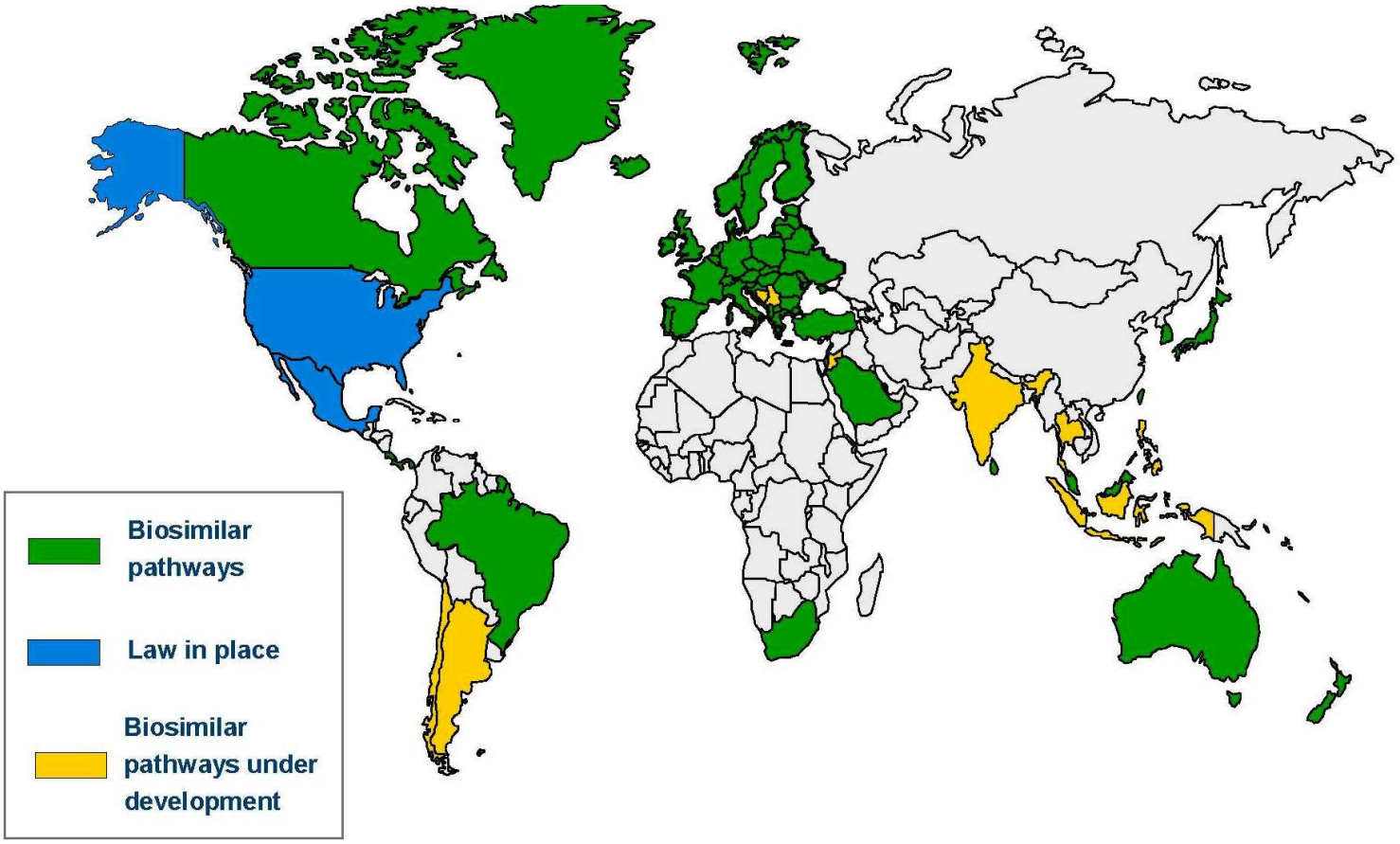
BIOSIMILAR PATHWAYS AROUND THE GLOBE



Fermin Ruiz de Erenchun (F. Hoffman La Roche Ltd., Basel), *Evolving Regulatory Landscape for SBPs (Biosimilars) in Asia*, 2010.

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WHAT'S THE FUSS OVER BIOSIMILARS?

- Some of the application for biosimilars involves reference to data from studies on biologics
- This makes applications less burdensome than for an original biologic application
- Also makes biosimilar less expensive to develop since not as much data is needed
- The hope is that cost savings would be passed on to hospitals, physicians and consumers
- This was major reason law allowing for biosimilars was passed under President Obama's healthcare reform legislation

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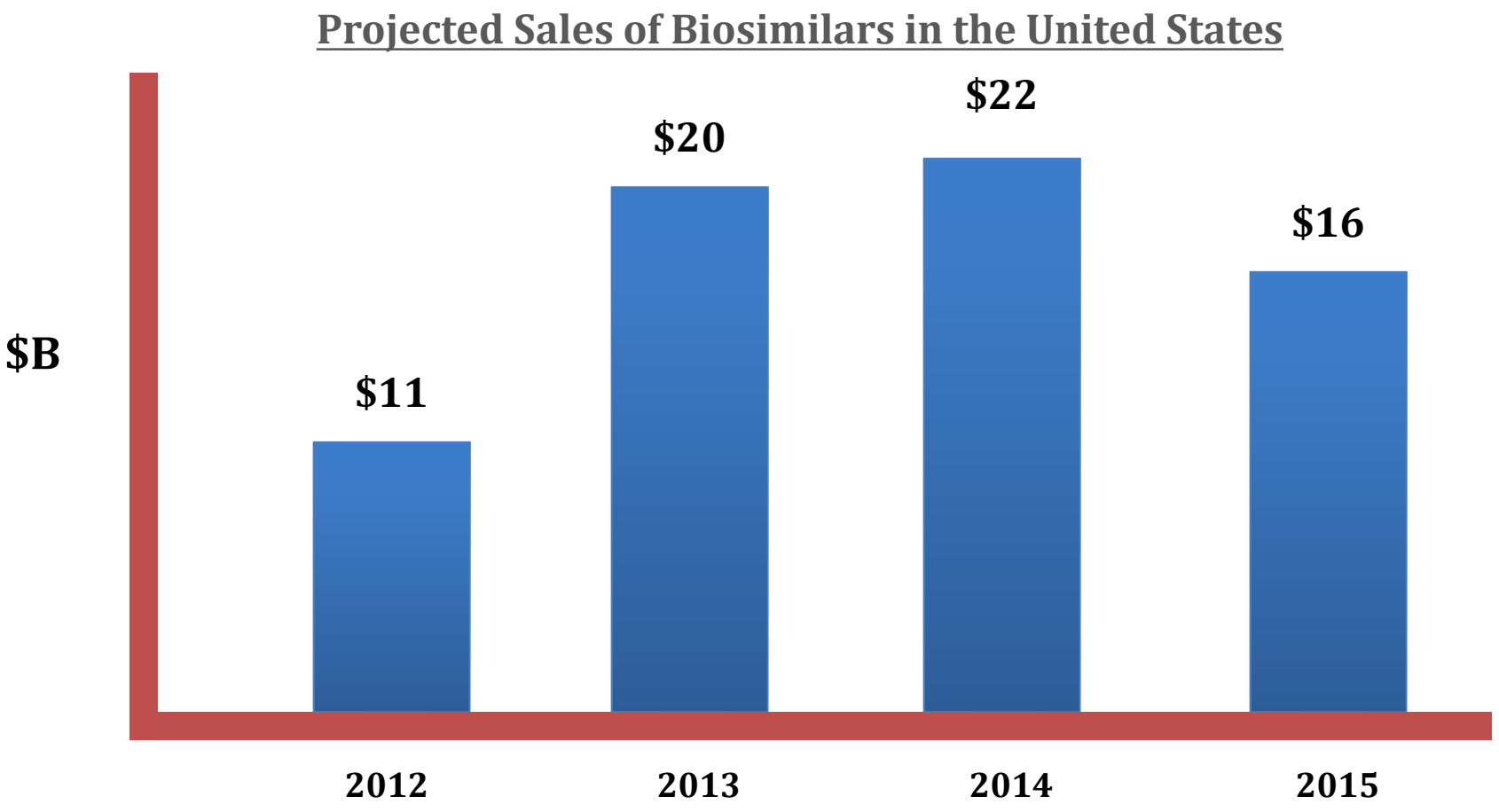

Dean & Company, *The U.S. Biosimilars Market*, 2010.

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Requirements for US Biosimilar Filings

1) Studies showing biosimilar's safety, purity, and potency in uses for which biologic is approved
2) Studies showing biosimilar is comparable to biologic in toxicity, immunogenicity, pharmacokinetics, pharmacodynamics
3) Data showing biosimilar and biologic use same mechanism of action for BB's approved use
4) Data showing route of administration, dosage form, and strength of biosimilar are same as biologic
5) Data showing facility in which biosimilar is manufactured, processed, packed, and held meets standards set by USFDA

42 U.S.C. § 262(k)(2)(A)(i).

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Requirements for Korean Filings

1) Clinical, non-clinical studies showing comparability between branded biologic and biosimilar in quality, safety and efficacy
   - These qualities need not be identical
   - But applicant should show differences don't matter
2) Quality is best shown by characterization studies comparing physiochemical, biological and immunological properties
3) Characterization studies should also compare purity, contaminants, potency and strength
4) Details of the manufacturing process to show quality control

Korea Food & Drug Administration, *Guidelines on the Evaluation of Biosimilar Products*, 2010.

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Efficiencies in Multiple Submissions

1) Data supporting filing in one country may support filing in others and thus costs of additional filings are insubstantial
2) Multiple submissions will improve chances of approval
3) Approval and sales of biosimilar in one country may promote its acceptance in others (assuming approval)
4) Global sales of biosimilars maximizes use of company's sales forces, marketing programs and production facilities
5) Thus, if you file in your home country, you may consider filing in the US

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Resolving Patent Disputes Under The BPCIA

1) Application process under the BPCIA provides procedure for resolving potential patent disputes that is mandatory
2) Procedure involves applicant providing application and other information to biologic owner
3) Rationale is to allow applicant and biologic owner to work out patent disputes before litigation and to discuss licensing
4) Procedure begins almost immediately after filing of application and involves many steps
5) Procedure does not eliminate litigation

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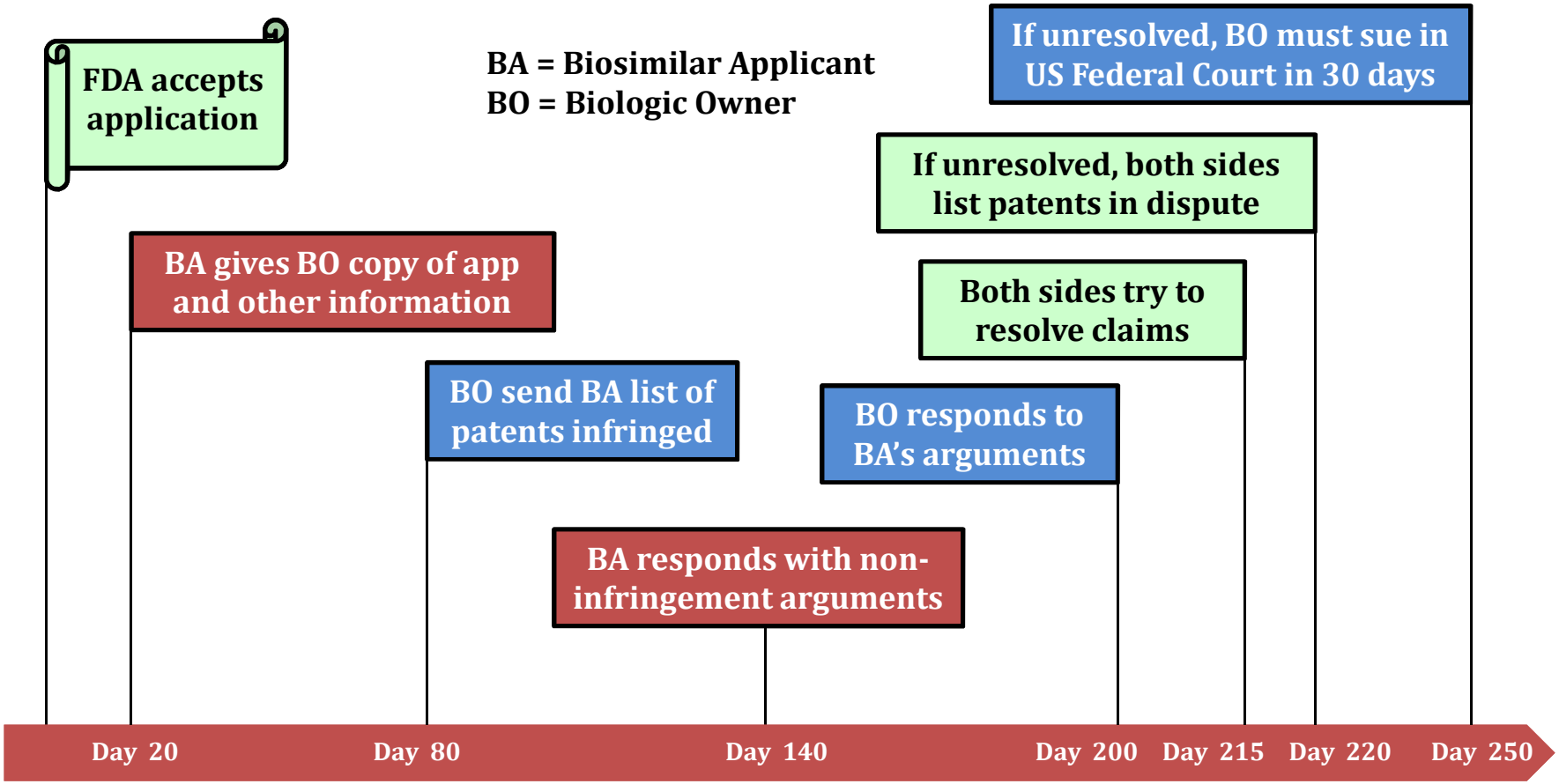

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Information Given to Biologic Owner

- **Within 20 days after application is accepted for filing by FDA, applicant must give biologic owner a copy of the application**
  - → **Applicant must also provide information describing process used to manufacture biosimilar**
  - → **Applicant has discretion to provide other information**
- **Statute restricts biologic owner's access of information to:**
  - → **One or more outside counsel designated by owner who does not engage in patent prosecution related to biologic**
  - → **One in house attorney employed by biologic owner provided s/he does not engage in patent prosecution**

42 U.S.C. § 262(l)(2)(A)

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OWNER IDENTIFIES PATENTS INFRINGED

- **Within 60 days of receiving application and other info from applicant, biologic owner must identify infringed patents**
- **Owner must also provide list of patents it is willing to license to applicant**

42 U.S.C. § 262(l)(3)(A).

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APPLICANT RESPONDS TO ALLEGATIONS

1) **Within 60 days of receiving biologic owner's list of infringed patents, applicant must provide a written response**

   → **Must describe on a claim by claim basis why applicant does not infringe and/or why patents are invalid or unenforceable**

   → **Must be detailed and provide factual and legal basis**

2) **Applicant must indicate whether it agrees to license those patents offered by the biologic owner**

3) **Applicant must state that it does not intend to begin commercial marketing of biosimilar before date identified patents expire**

   → **It is unclear whether the applicant's failure to provide this statement exposes it to immediate federal litigation**

42 U.S.C. § 262(l)(3)(B).

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Owner Responds to Non-Infringement

Within 60 days after receipt of the applicant's non-infringement statement, the biologic owner must:

1) **Describe on a claim by claim basis, the factual and legal basis why its patents are infringed**

2) **Respond to applicant's invalidity/unenforceability claims**

42 U.S.C. § 262(l)(3)(C).

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Both Sides Required to Negotiate

- **Within 15 days of the biologic owner's response, both sides are required to negotiate in good faith to resolve infringement issues**
- **If there is no resolution, both sides exchange lists of patents they intend to litigate within 5 days**
- **Any litigation must then be brought in a United States federal court within 30 days of the exchange of patent lists**

42 U.S.C. § 262(l)(4)-(6).

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