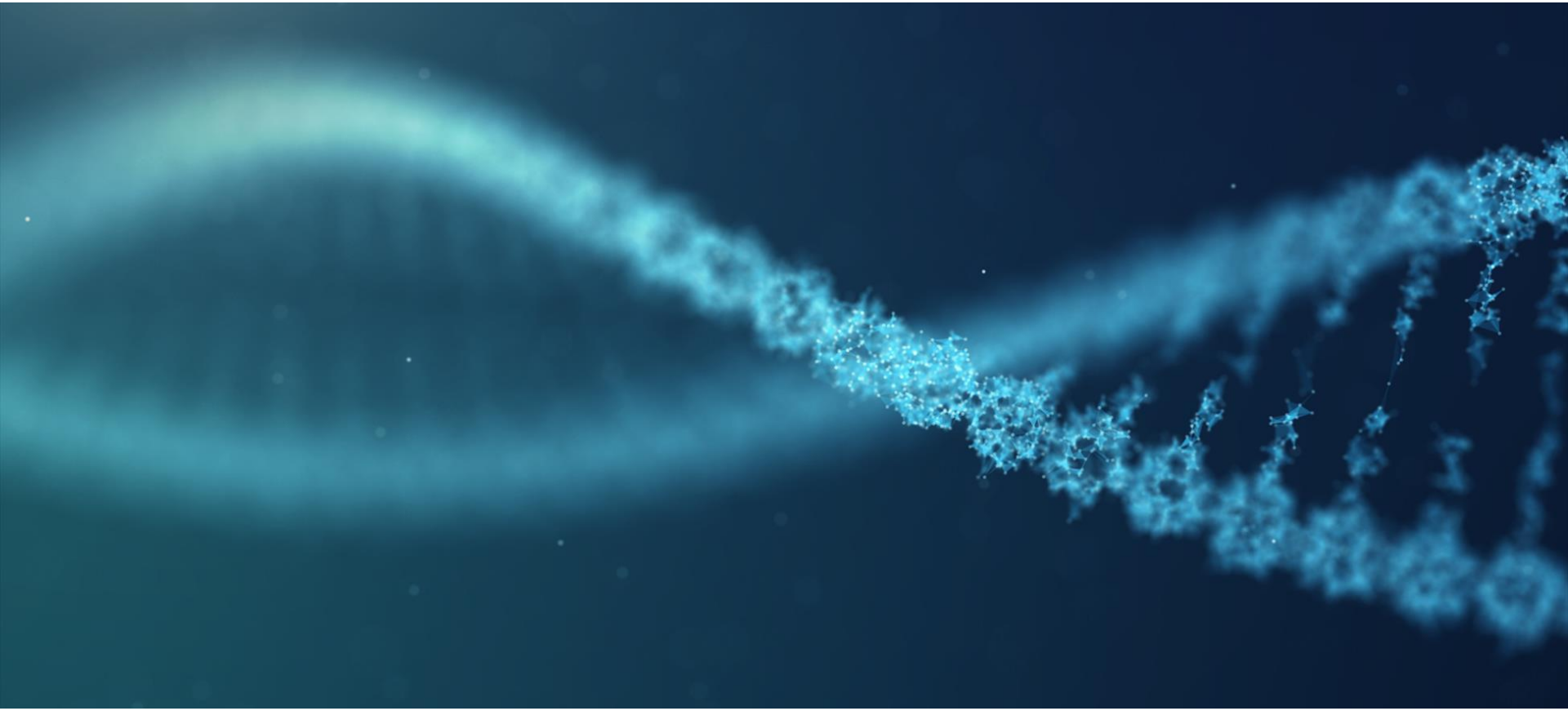
# KEY LEGAL ISSUES TO CONSIDER BEFORE LAUNCHING BIOLOGICS IN THE U.S. AND EUROPE

September 2019

GOODWIN Bristows



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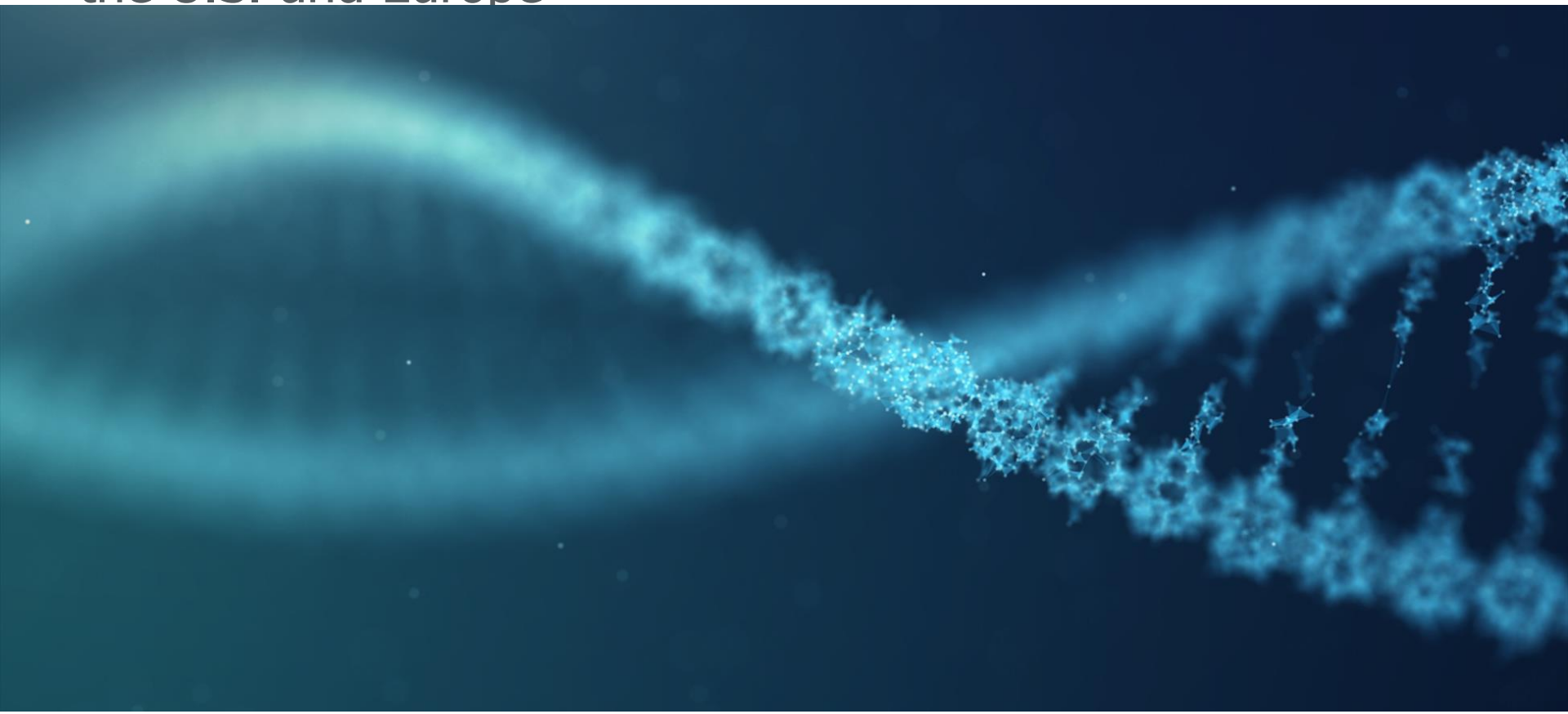
# Key Legal Issues to Consider Before Launching Biologics in the U.S. and Europe



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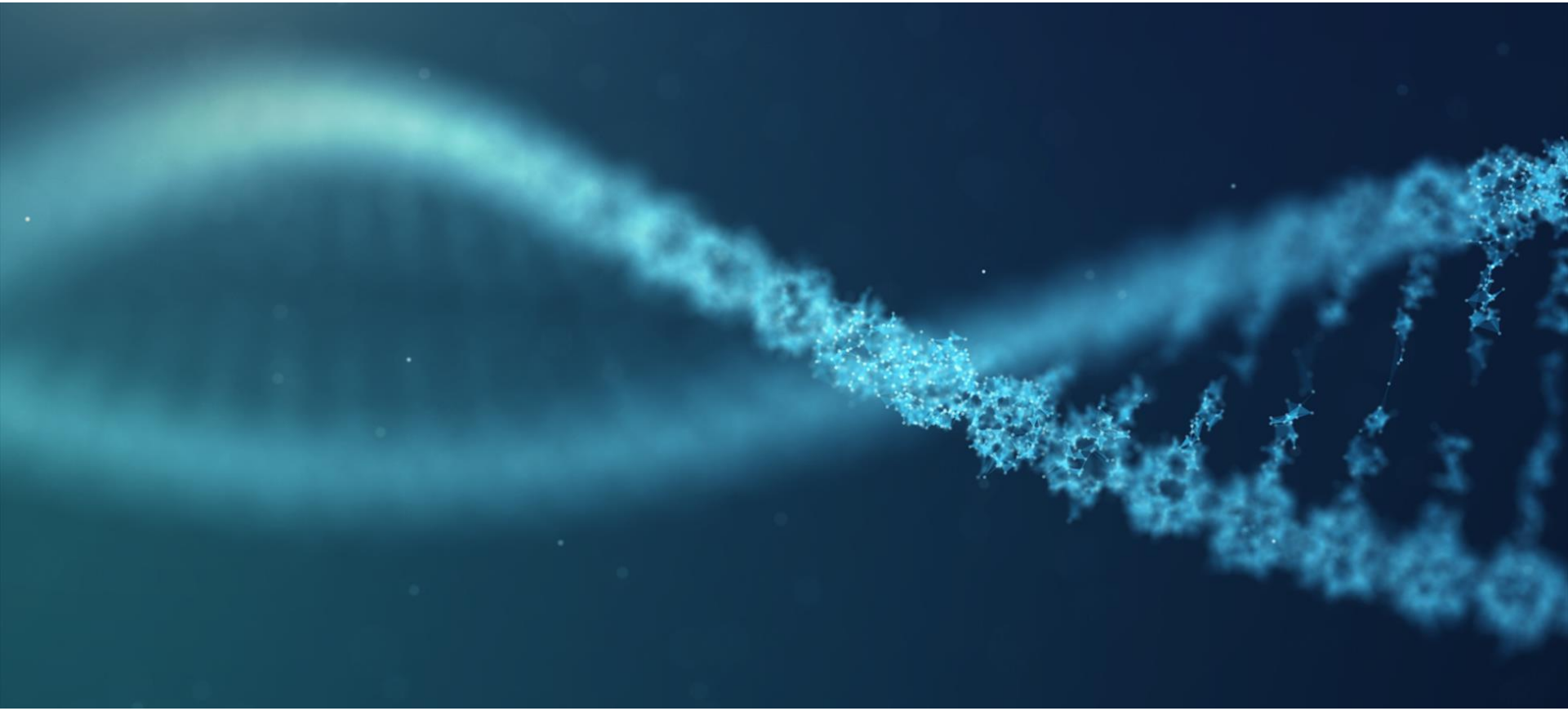
# Agenda

- Regulatory issues to navigate when filing an application for a biologic
  - What kind of application should be filed for a biologic product?
  - When should an application for a biologic product be filed?
  - How should an application for a biologic product be filed?
  - How long does it take to get approval and how much does it cost?
  - What do filers often get wrong and how to avoid these pitfalls?
- Business issues to consider when mitigating regulatory and litigation risks
  - U.S. perspective
  - EU perspective
- Questions?
- Lunch Break

# Agenda (continued)

- Litigation issues to consider when launching a biologic
  - Freedom to operate and due diligence
  - Overview of EU opposition, revocation and patent infringement proceedings
  - Overview of U.S. district court patent infringement litigation
  - Litigation in the USPTO
  - Citizens petitions in the FDA
- Questions?

# Regulatory Issues to Navigate When Filing an Application for a Biologic



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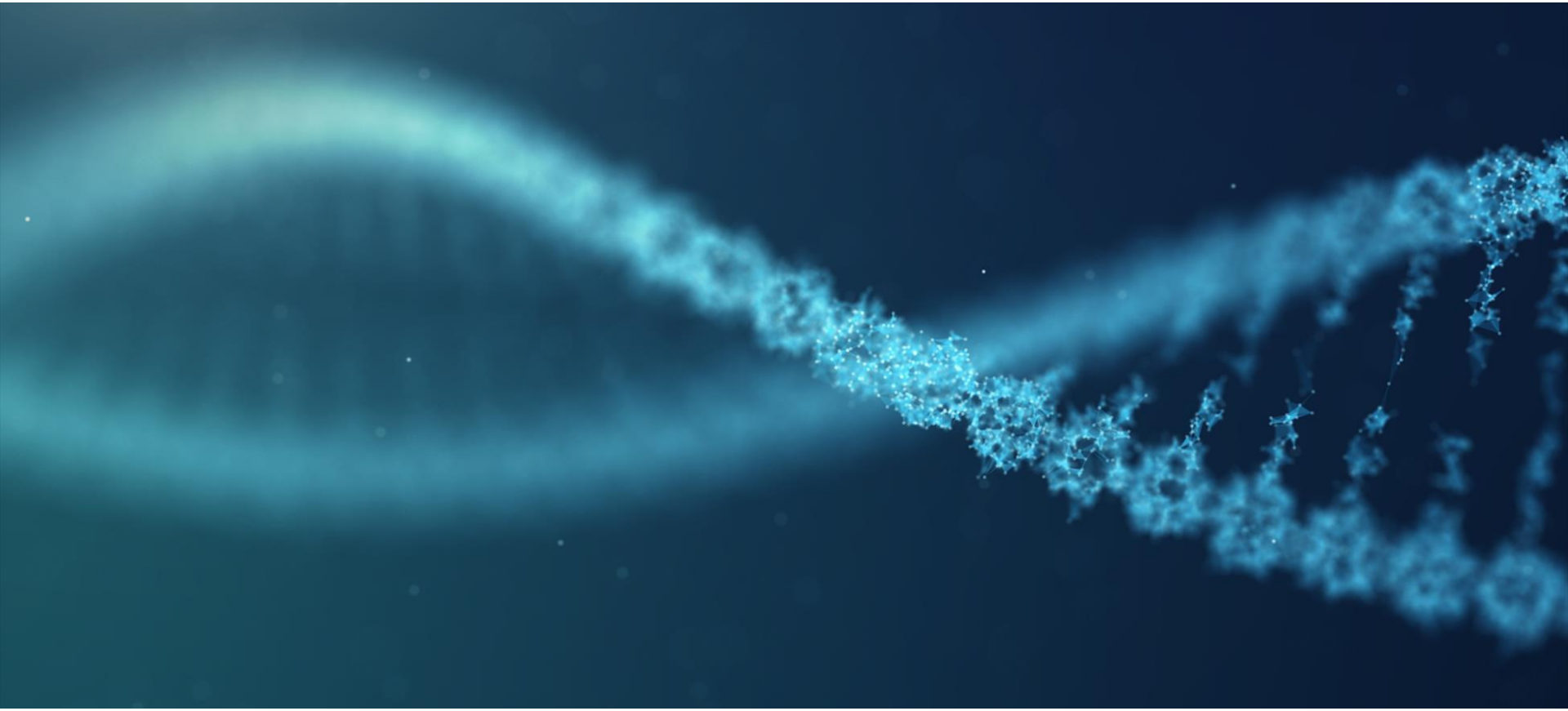
# Regulatory Issues to Navigate When Filing an Application for a Biologic

## What kind of application should be filed for a biologic product?



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# Different Applications for Different Products

- A new protein biologic?
- A "biobetter" that is similar to, but has therapeutic advantages over, an approved biologic?
- A "biosimilar" that is highly similar to an approved biologic?
- An "interchangeable" biosimilar that may be switched for an approved biologic?
- A new peptide?
- A generic peptide that is bioequivalent to an approved peptide?

EACH HAS A DIFFERENT PATH AT U.S. FDA

# Four Kinds of Applications for Biologics/Peptides

- **Biologics License Application (BLA)**
  - New biologics
- **Biosimilar Application (aBLA)**
  - Biosimilars
  - Interchangeable biosimilars
- **New Drug Application (NDA)**
  - Typically for new "small molecule" drugs
  - Also used for new peptides classed as SMD's
- **Abbreviated New Drug Application (ANDA)**
  - Typically for generic "small molecule" drugs
  - Also used for generic versions of peptides

# Biologics License Application (BLA)

- "Biologic": therapeutic viruses, serums, toxin/antitoxins, vaccines, blood components, allergens & proteins (synthetic polypeptides >40 amino acids but <100 amino acids, and polypeptides <40 amino acids not "proteins")
- Must present **full clinical trial package to demonstrate safety and efficacy**
- New indications as well as new molecules
- BLAs must be filed for:
  - Novel biologics
  - Biobetters (example: Roche Gazya rituximab variant)
  - Biosimilars filed outside of abbreviated biosimilar regulatory pathway (example: Granix tpo-filgrastim)

# Biosimilar Application (aBLA)

- Biosimilars for which approval is sought under abbreviated pathway provided by Biologics Price Competition and Innovation Act (BPCIA)
- Must present analytical and clinical data package to demonstrate that the product is biosimilar to an approved reference product for an approved indication:
  - highly similar to reference product notwithstanding minor differences in clinically-inactive components, and
  - no clinically-meaningful differences in safety, efficacy and potency
- Not a "generic" biologic: marketed like a brand product

# Interchangeable Biosimilar (aBLA)

- Must prove biosimilarity AND:
  - biosimilar can be expected to produce the same clinical result as reference product in any given patient, and
  - for products to be administered more than once, risk in terms of safety or diminished efficacy of switching between biosimilar and reference product no greater than staying with reference product
- Automatic substitution at pharmacy of the biosimilar for reference product in most U.S. states
- In theory, automatic substitution should lead to rapid market uptake of the biosimilar

# New Drug Application (NDA) and Abbreviated New Drug Application (ANDA)

- Can be used for peptides that are not "proteins" and do not otherwise fall within definition of "biologic"
- NDA: similar to BLA – full safety/efficacy data package
- ANDA: approved as generic & need only demonstrate:
  - Peptide has the same structure, purity, dosage form, dosage strength, rate of administration as approved reference peptide product and
  - Bioequivalent to the reference product (pK/pD)
  - Limited to previously-approved indication(s)
- Generic peptides automatically substitutable by pharmacy similar to generic small-molecule drugs

# “Skinny” Product Labels

- For aBLAs, ANDAs, can seek approval for fewer than all indications approved for reference product
- Can also “carve out” portions of label associated with indications for which approval is NOT sought
- This can avoid patented methods of use or combination therapies and permit launch earlier than patent expiry
- Can streamline or avoid patent litigation that can be both costly and delay launch
- BUT portions of label important to safe use must remain; FDA can be conservative in this regard, but will negotiate

# Product Liability for Inadequate Labeling

- FDA requires small-molecule generic drugs to have same label as reference product (apart from carve-outs)
- "Product liability" lawsuits alleging injury from defective pharmaceuticals very common in U.S.
- Same-label requirement has shielded generic drug manufacturers from liability for "failure to warn" suits claiming manufacturer did not adequately warn of risks (*Mensing* shield)
- FDA does not have same-label requirement for biosimilars, unclear whether *Mensing* shield will apply
- Biosimilar manufacturer liable for marketing content

# Europe – What to File?

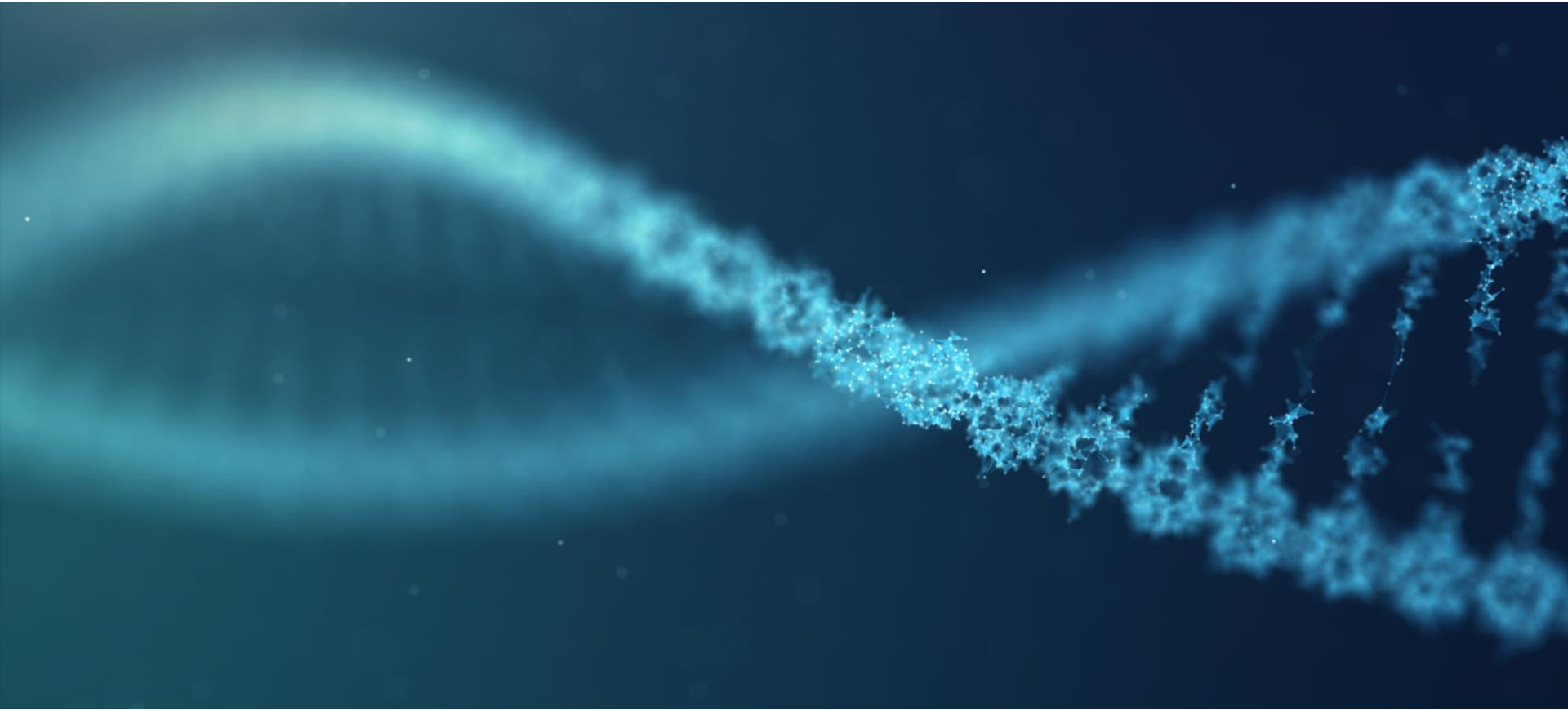
- **One Scheme**
- **Data packages & clinical trials**
  - Full application (article 8(3) of EU Medicines Directive)
  - Biosimilar application (article 10(4) of EU Medicines Directive)
- **Biosimilar guidelines**
  - EMA has developed a series of guidance to assist manufacturers in the development of biosimilars
    - Overarching guidelines
    - Specific guidelines

# Europe – What to File?

- **One scheme – continued**
- **Skinny labels**
  - General principle of consistency of labels – product of reference and biosimilar
  - Article 11 of EU Medicines Directive: "for authorizations under Article 10 [generic and biosimilar], those parts of the summary of product characteristics of the reference medicinal product referring to **indications or dosage forms** which were still covered by patent law at the time when a generic medicine was marketed **need not be included**"
  - General rule under the centralized procedure of one authorization per applicant for a specific medicinal product
  - Exceptions to the general rule: seek permission by the European Commission
    - Objective verifiable reasons relation to **public health** regarding the availability of medicines
    - Duplicate MA with less indications or pharmaceutical forms protected by patent
    - Commitment to extend the label as soon as the patent restrictions do not longer exist or withdraw MA with restricted label

# Regulatory Issues to Navigate When Filing an Application for a Biologic

## When should an application for a biologic product be filed?



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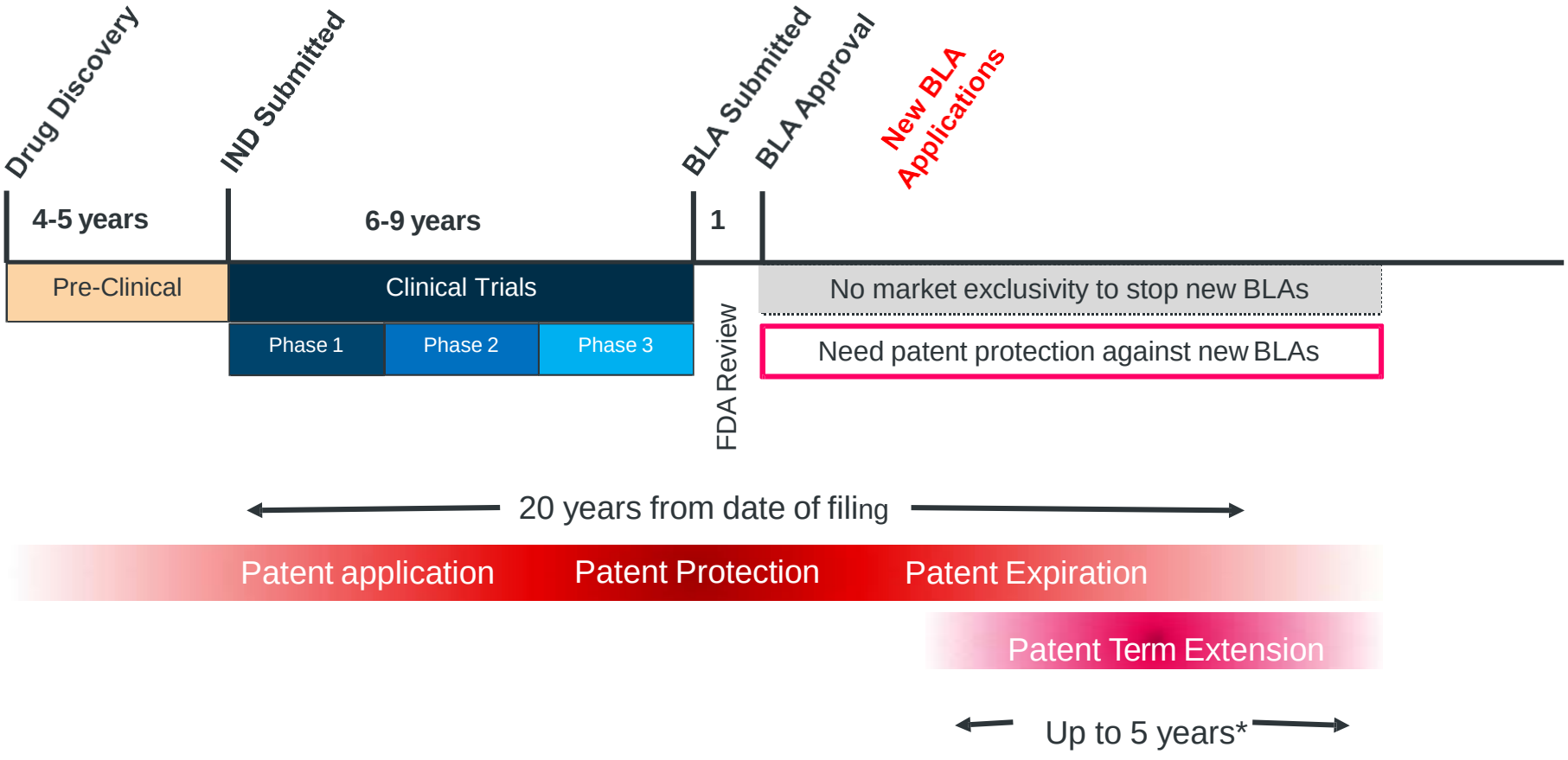
# Patent Term Also Determines Timeline

- Regulatory exclusivities run concurrently with patent protection
- Patent term in U.S. is 20 years from filing date
  - If provisional application filed, protection effectively extends to 21 years
- Patent term extension available for new biologic active ingredients:
  - Time between investigational drug application (IND) to approval can be long; PTE adjusts patent term to partially compensate
  - Patent to new active ingredient or method of use may be extended once
  - One patent covering product/label (pick strongest or longest?)
  - Extension up to 5 years, but cannot extend protection beyond 14 years from date of first approval

# BLA Approval Timeline




*Subject to a cut off at 14 years from date of BLA approval



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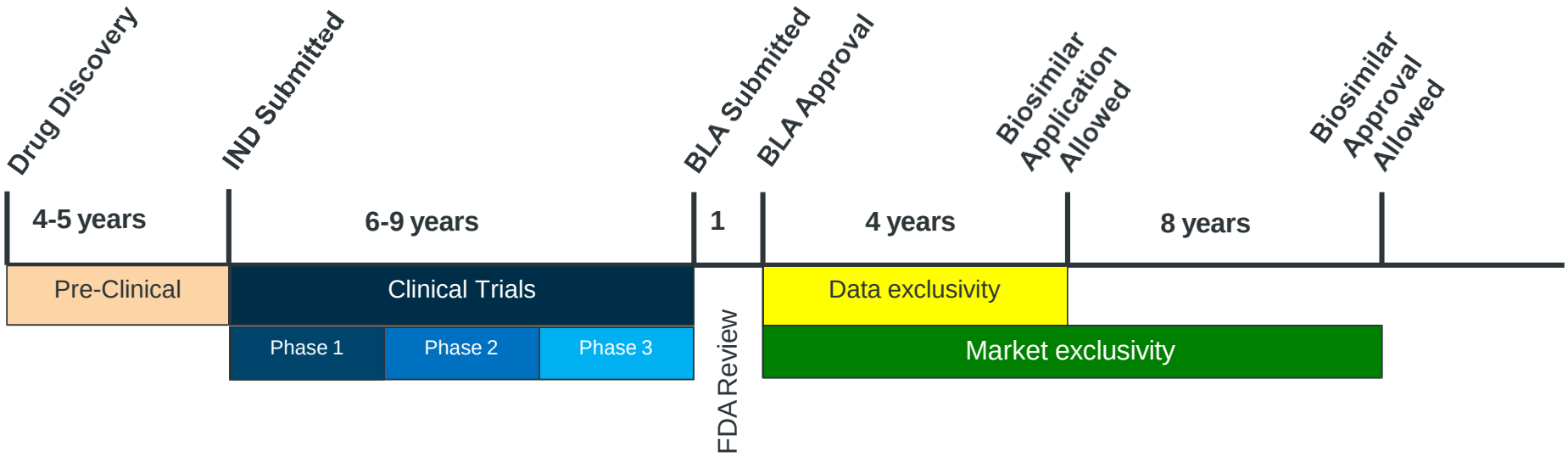
# Regulatory Exclusivities Determine Timeline

- BPCIA grants BLA holder 12 years of exclusivity from biosimilars approved under BPCIA:
  - aBLA may not be submitted earlier than 4 years from reference product approval date (data exclusivity)
  - aBLA may not be approved earlier than 12 years from reference product approval date (market exclusivity)
- 6 additional months of pediatric exclusivity may be added to the 4/12 year periods for qualifying pediatric clinical trial
- If biologic qualifies as an "orphan" drug, 7 years of market exclusivity is available
  - <200,000 patients or not expected to recoup costs

# Biosimilar Approval Timeline




20 years from date of filing

Patent application | Patent Protection | Patent Expiration

Patent Term Extension

Up to 5 years*

*Subject to a cut off at 14 years from date of BLA approval



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# Europe – When to File?

- RDP: 8 + 2 (+1) formula
- 8 Years Data Protection
  - **No reference** may be made to the data supporting the 'reference medicinal product'
- +2 Years Market Exclusivity
  - Reference may be made to the data supporting the 'reference medicinal product', and a MA may be granted but no product may be launched for a further 2 years
- + Potentially 1 More Year Market Exclusivity
  - The 2 year period may be extended by 1 more year if, **within the 1st 8 years**, the MA holder **applies for and obtains** an authorization for a new therapeutic indication which brings a **significant clinical benefit in comparison with**




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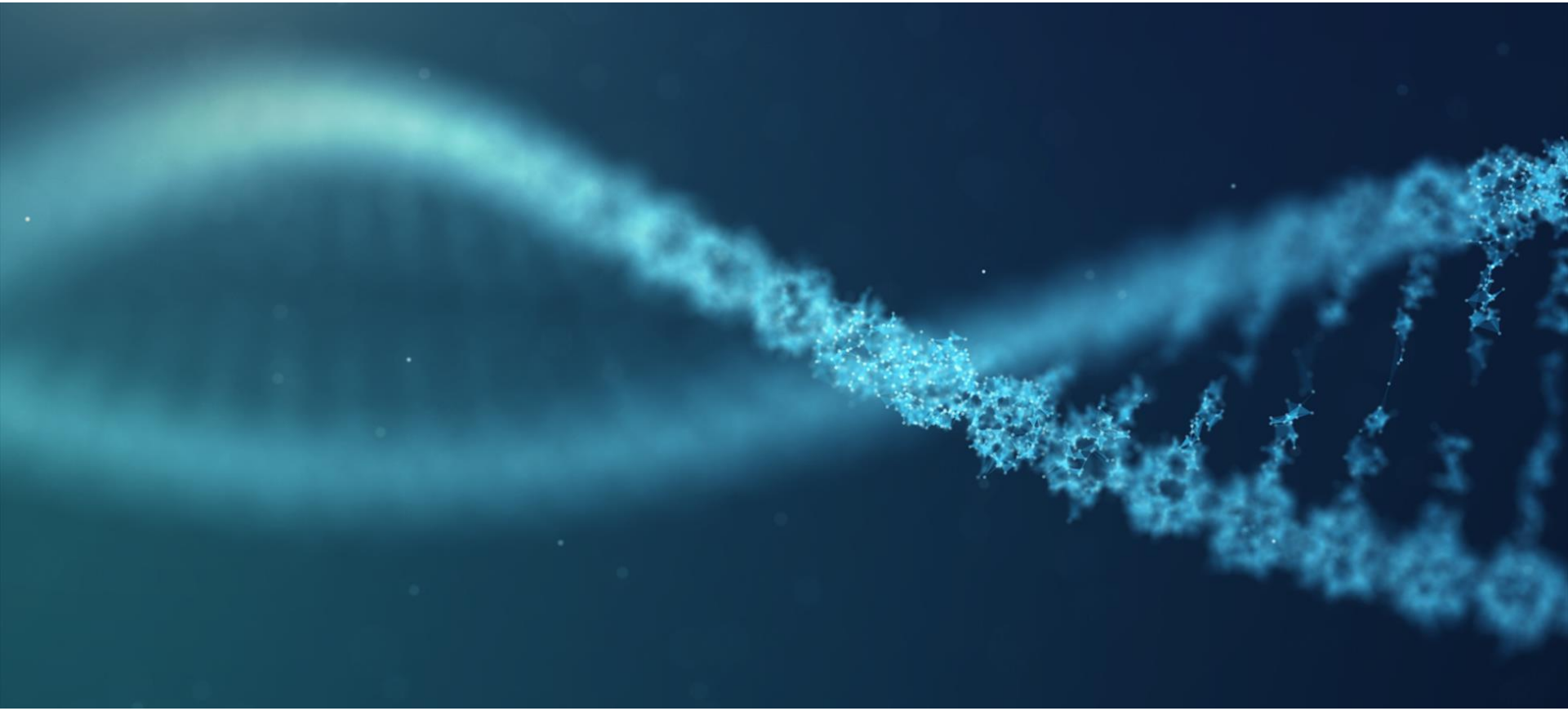
# Europe – When to File?

- **Patent term extensions – SPCs**
  - Partially compensate for erosion of 20 year patent protection
  - Term = (Time between patent filing and grant of 1st MA) – 5 years [subject to 5 year cap]
- **Orphan drugs – Orphan Market Exclusivity (OME)**
  - Product must have "orphan" status
  - If orphan status is maintained at the time MA application is evaluated = 10 years OME
- **Paediatric rewards**
  - Applications for new MAs need to provide pediatric data based on Paediatric Investigation Plan (PIP) unless a waiver or deferral is granted
  - Specific exclusion biosimilar medicinal products
  - Rewards:
    - Products with SPC/qualifying patent = 6 month SPC extension
    - Orphan medicines = 2 year OME extension
    - Off patent/ non-orphans = 10 year RDP/marketing protection for paediatric data (PUMA)

# Regulatory Issues to Navigate When Filing an Application for a Biologic

How should an application for a biologic product be filed?



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# U.S. – How to File for Regulatory Approval

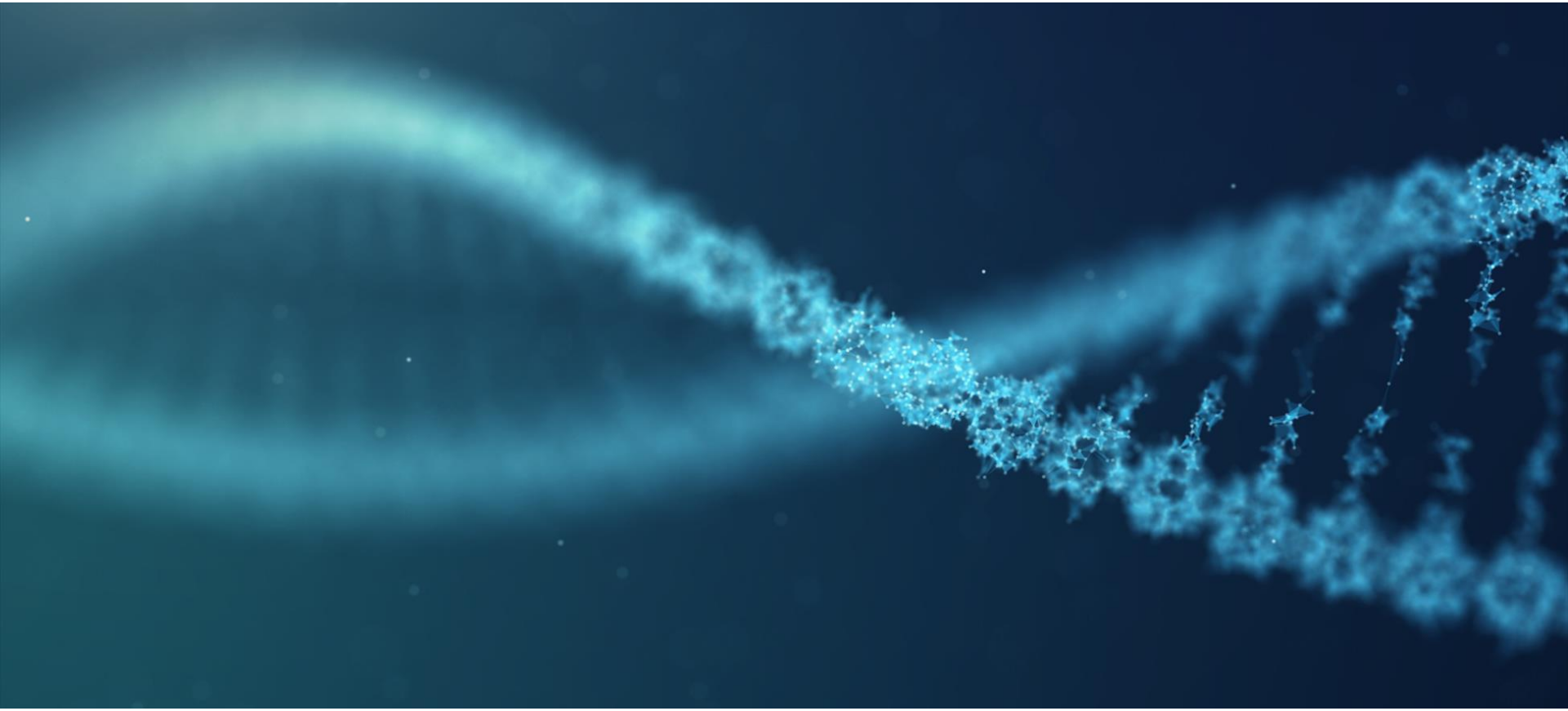
- Federal government, not states, regulate biologic approvals
- Food & Drug Administration is sole agency responsible for approving biologics, all applications filed with FDA
- Companies that manufacture, prepare, propagate, compound, process biologics (and other drugs) for the U.S. must:
  - Register with the FDA
  - List all drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution in the U.S.
  - Foreign establishments must identify a U.S. agent and importers at the time of registration.
- FDA licenses & inspects foreign manufacturing sites using same rigorous standard as U.S. facilities

# Europe – How to File?

- Nearly all biological medicinal products = centralised procedure
  - Procedure must be used by medicines produced by biotechnology and some other medicines can opt to use the centralised procedure
- If it does not fall within the mandatory scope of centralized procedure, MA can be approved nationally but very rare
- UK in the event of a "no-deal" Brexit:
  - MHRA will take over from EU
  - Existing centralised MAs automatically grandfathered into UK Mas on Brexit day – unless MA holder opposes
  - New MAs = separate UK national MA following separate application process

# Regulatory Issues to Navigate When Filing an Application for a Biologic

How long does it take to get approval and what does it cost?



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# Timeline for FDA Review of BLA/NDA/aBLA


**Priority review average 6-8 months**
**Standard review average 10-12 months**



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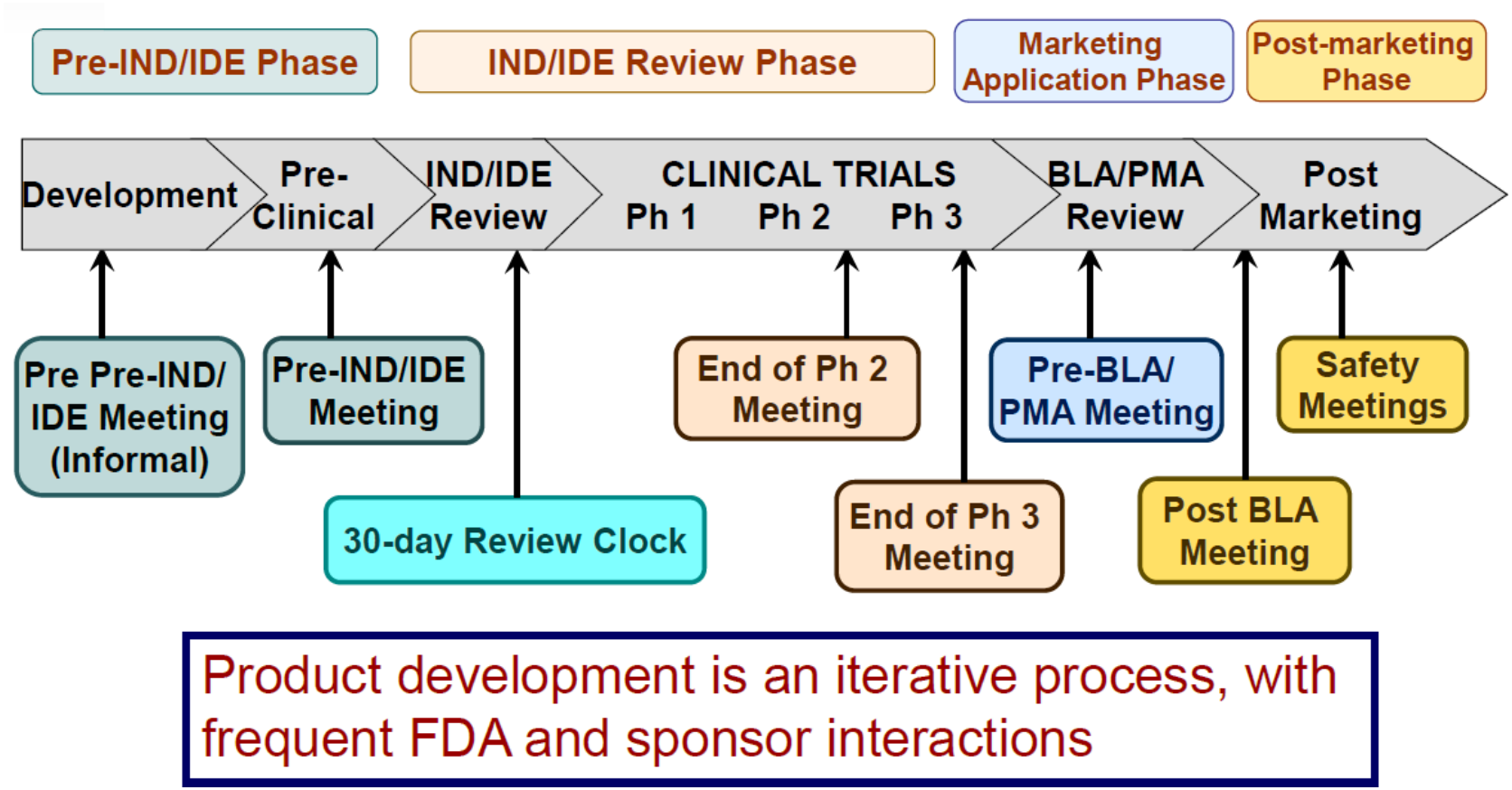
# Pre-Application Review Timeline




Product development is an iterative process, with frequent FDA and sponsor interactions

**Pre-IND phase: 4-6 years** **IND/Clinical Phase (up to filing date): 6-9 years**

Source: https://cersi.umd.edu/sites/cersi.umd.edu/files/S07%20-%2002%20CBER%20Fink%20Wensky%20Witten.pdf



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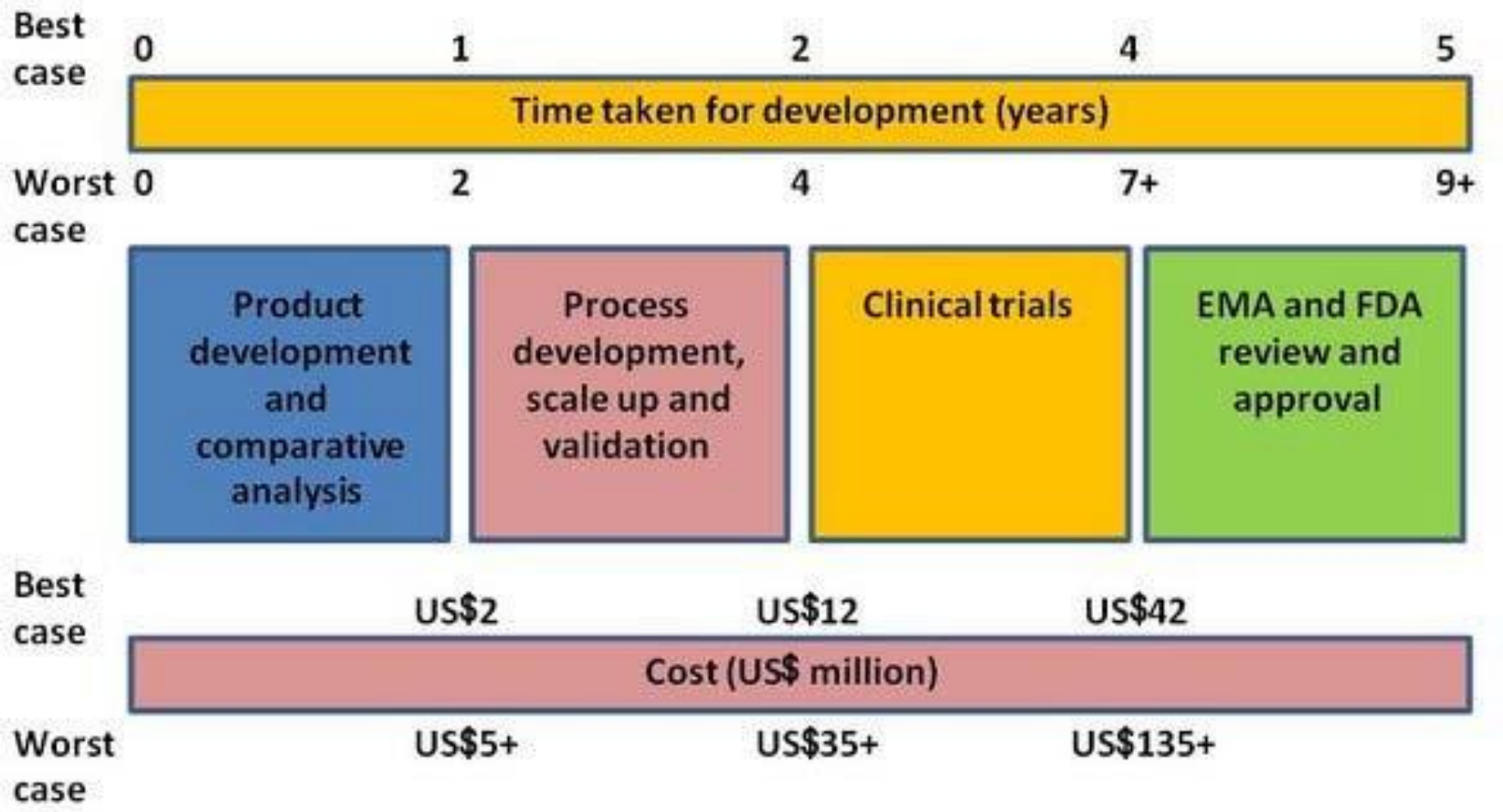
# Cost and Timeline for New Biopharma Discovery

| | Target to Hit | Hit to Lead | Lead Optimization | Non-Clinical | Phase 1 | Phase 2 | Phase 3 | Submission to Launch |
|---|---|---|---|---|---|---|---|---|
| Years | 1.0 | 1.5 | 2.0 | 1.0 | 1.5 | 2.5 | 2.5 | 1.5 |
| Cost ($) | $94 | $166 | $414 | $150 | $273 | $319 | $314 | $48 |

Typical investment: 10-15 years and $1.8B

Source of data: SM Paul et al. Nature Reviews: Drug Discovery 2010

# Cost and Timeline for Biosimilar Development




Source: http://www.gabionline.net/Biosimilars/Research/Development-of-biosimilars



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# Europe – Time Taken?

The centralised procedure


Generic medicinal products — 11-12 months

Biosimilar medicinal products — 15+ months



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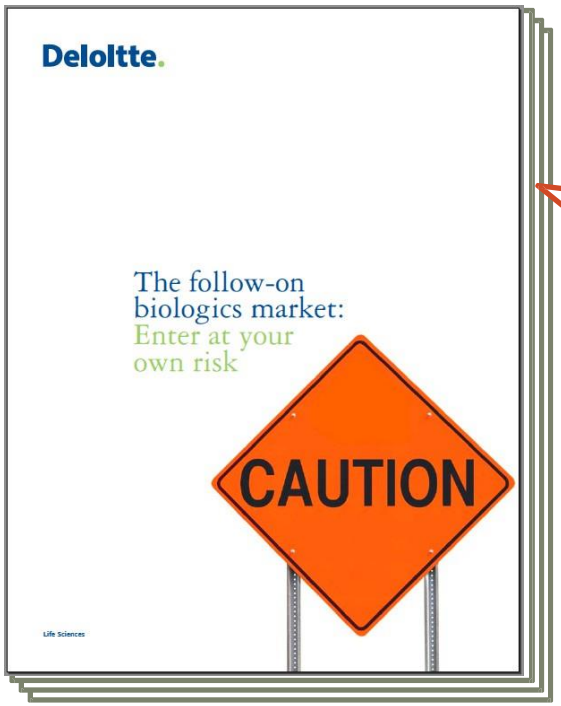
# Overall Cost?




FOB Manufacturers have varying views on the costs associated with product development. For example, John Lane, VP of Hospira, stated, "I would say for less complex proteins that we are looking at, you could expect anywhere between, maybe, $30 and $50 million, and for the more complex proteins, it is not inconceivable that you could approach $75 to $100 million if you do full development. In contrast, Sandoz's head, Jeff George, is less optimistic putting the cost as high as $250 million for difficult-to-copy large-molecule drugs.



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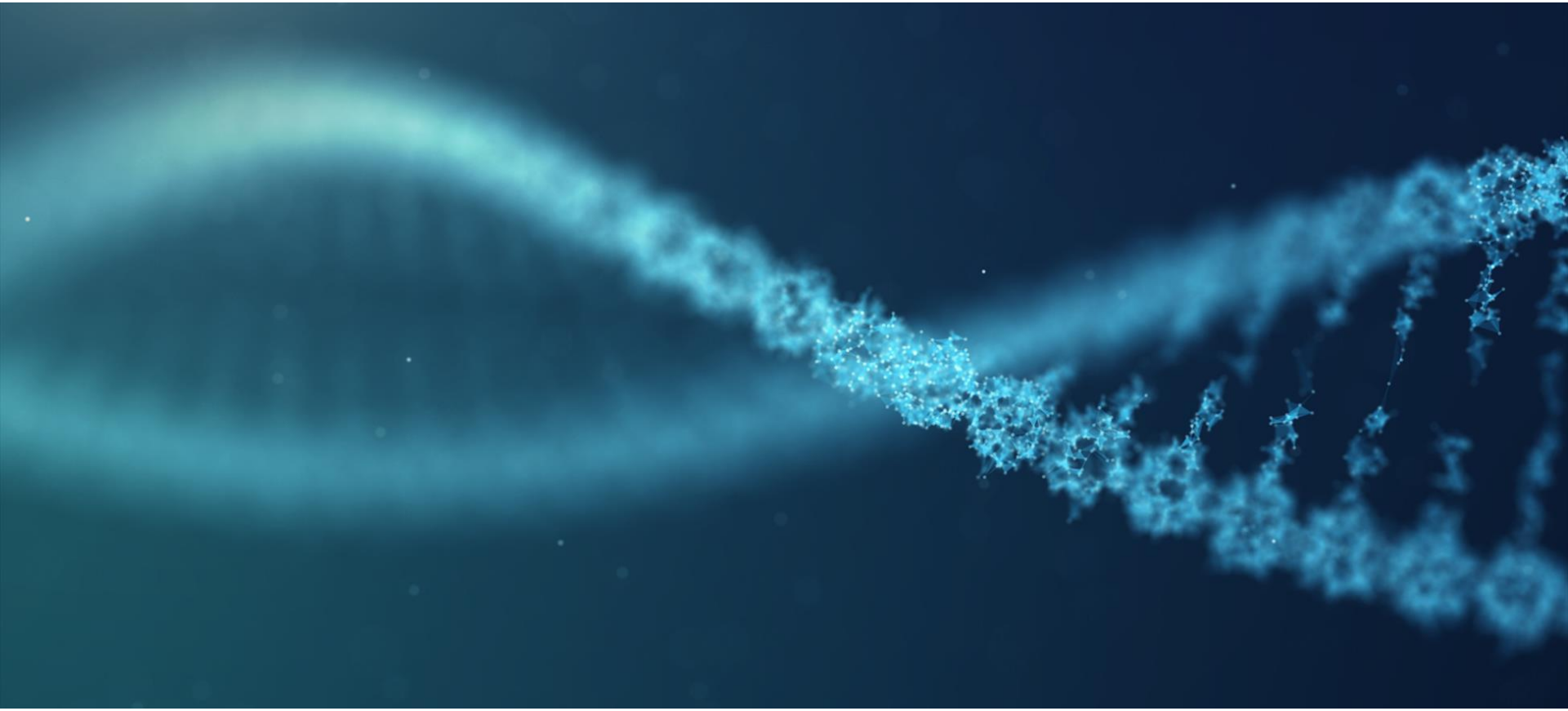
# Regulatory Issues to Navigate When Filing an Application for a Biologic

What do filers often get wrong and how to avoid these pitfalls?



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# Regulatory Pitfalls for the Unwary

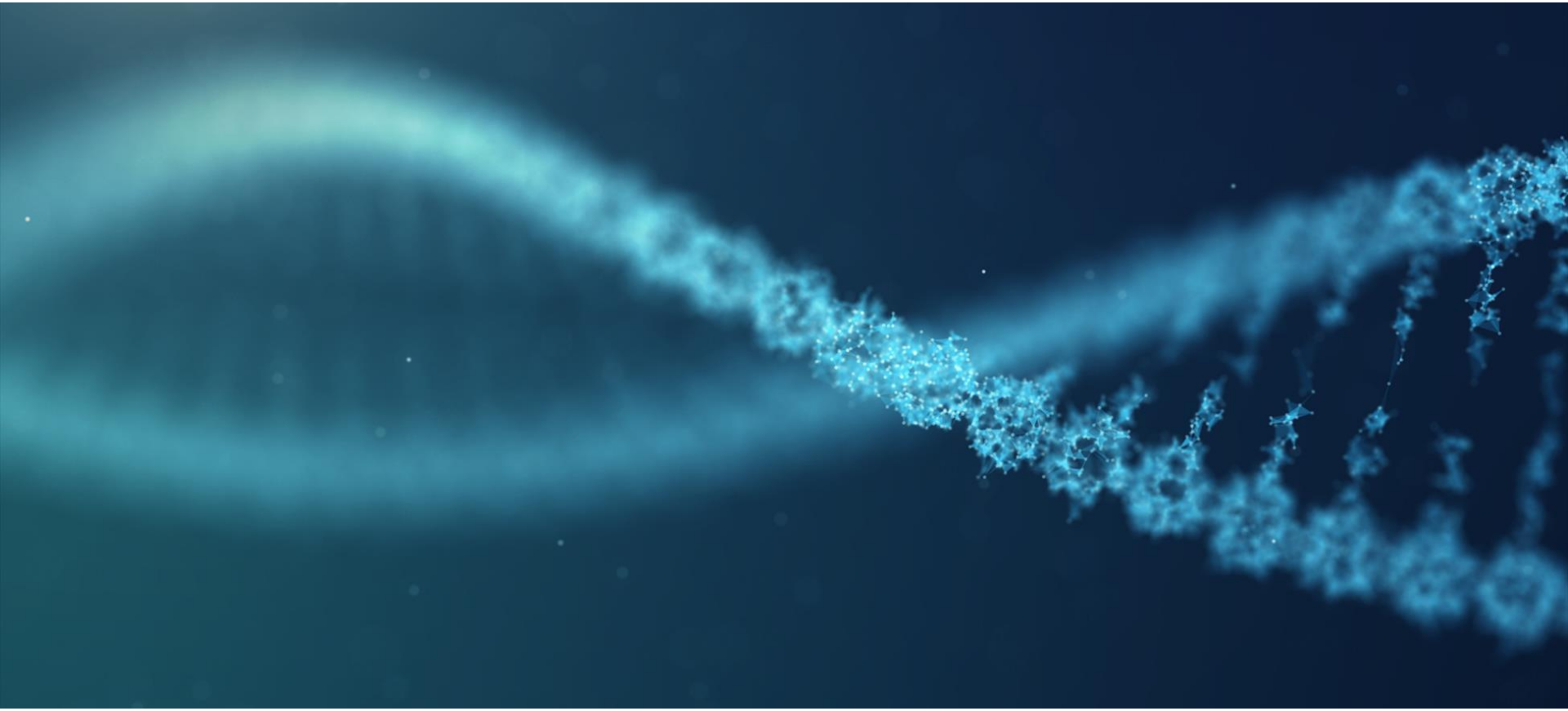
- FDA has been very conservative with the first wave of U.S. biosimilar approvals and has been very tough with enforcing cGMP requirements – make sure small violations do not derail approval timeline
- Pre-submission meetings w/ FDA essential to avoiding complete response letters that delay approval – meet early and often
- Statements made in application can and will be used in patent infringement litigation – your application must be aligned with your litigation strategy
- Carved-out labels can be crucially important in patent infringement litigation – understand which indications will remain in your label and consider conducting clinical trials on those, extrapolating later
- Carving out patented indications *after* public approval of full label can spur claims of induced patent infringement

# Europe: Pitfalls for the Unwary

- Common Challenges

- What **data** is required?
  - EMA tailored scientific advice pilot project to support the development of new biosimilars
  - EMA-FDA Parallel Scientific Advice
- **Manufacturing** challenges
- Complex **patent** landscape – Clearing the path

# BUSINESS ISSUES TO CONSIDER WHEN MITIGATING REGULATORY AND LITIGATION RISKS



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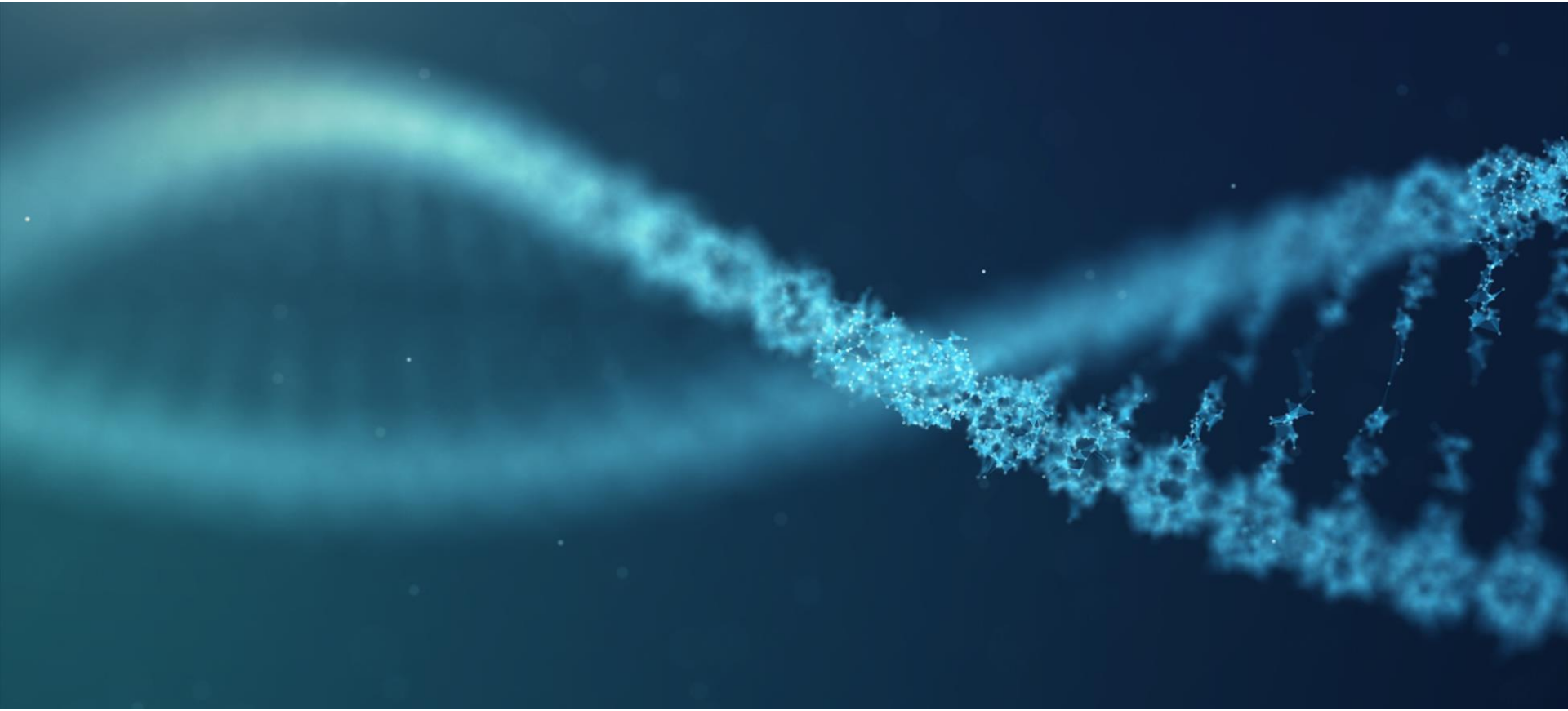
# BUSINESS ISSUES TO CONSIDER WHEN MITIGATING REGULATORY AND LITIGATION RISKS

## U.S. Perspective



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# Overview of U.S. Biosimilar Market

- United States
  - > 17 products approved
  - 7 marketed
- Europe
  - > 30 products approved
  - 26 marketed

- U.S. lags behind Europe

# Routes to the U.S. Market: Risk vs. Reward

- **API/Formulated Product Supplier**: Manufactures biologic/finished product
  - Supply agreements mitigate infringement, commercial risk, but still must consider manufacturing method, formulation patents
  - Target of U.S. discovery
  - Little U.S. marketing, regulatory experience required
  - Does not get lion's share of U.S. profits
- **Holder of BLA/aBLA**: Responsible for clinical trials, FDA approval
  - Requires sophisticated R&D capabilities & experience with navigating FDA approval process
  - Can command largest share of U.S. profits, but primary litigation target
- **U.S. marketer of biologic:** Sells product in U.S.
  - Need sales force and medical affairs/marketing teams
  - Bearing commercial risk = leverage to retain profits
  - Also primary litigation target, must police conduct of marketing/MA teams

# Three Biosimilars Have Multiple Market Entrants

- **Remicade (infliximab)**
  - Celltrion's Inflectra (November 2016)
  - Samsung Bioepis's Renflexis (July 2017)
- **Neulasta (pegfilgrastim)**
  - Coherus's Udenyca (January 2019)
  - Mylan's Fulphila (July 2018)
- **Neupogen (filgrastim)**
  - Pfizer's Nivestym (October 2018)
  - Sandoz's Zarxio (September 2015)
  - Teva's Granix (tpo-filgrastim follow-on biologic) (November 2013)

# Biosimilar Market Share as of January 2019

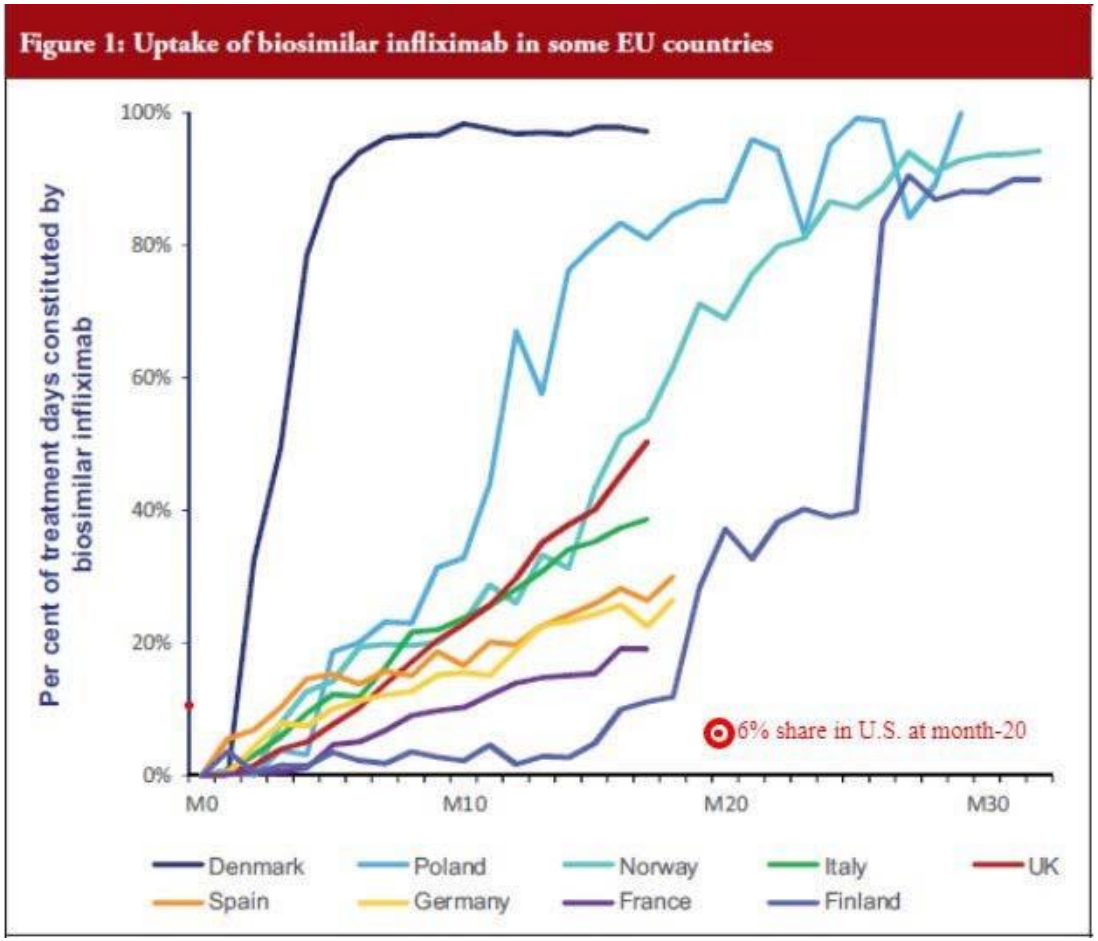
- **Infliximab: Remicade, 96.4%**
  - Inflectra, 3.2% (+25 months)
  - Renflexis, 0.4% (+17 months)

- **Filgrastim: Neupogen, 48.0%**
  - Zarxio, 31.7% (+39 months)
  - Granix (follow-on filgrastim), 20.3% (+61 months)
  - Nivestym 0% (+3 months) (WAC <30% than Neupogen, <20%  Zarxio)

- **Pegfilgrastim: Neulasta Onpro, 61.0%**
  - Neulasta: 38.2%
  - Fulphila: 0.8% (+6 months)
  - Udencya: (launched 1/2019)

Source: Doug Long, IQVIA Data, Presentation at the Association for Accessible Medicines' Access! 2019 meeting

# Infliximab: Case Study in Aggressive RPS Defense




Biosimilar infliximab uptake has been much slower in the U.S. than in Europe, despite the presence of two biosimilars on the market



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# Infliximab: Unfair Competition Lawsuit

- Pfizer has sued J&J/Janssen alleging anticompetitive tactics to shield Remicade product from competition from Inflectra biosimilar:
  - Exclusive contracts (restricting purchaser from stocking other infliximab products)
  - Bundling and rebate policies (offering rebates only if purchaser buys all of its product from J&J)
- Court (Eastern District of Pennsylvania) ruled that case has enough merit to proceed to trial in late 2020/early 2021
- Market is watching to see whether Court will find J&J's aggressive tactics to be lawful
- If lawful, will these anti-biosimilar tactics become commonplace?

# Interchangeability: Hope for Late Entrants?

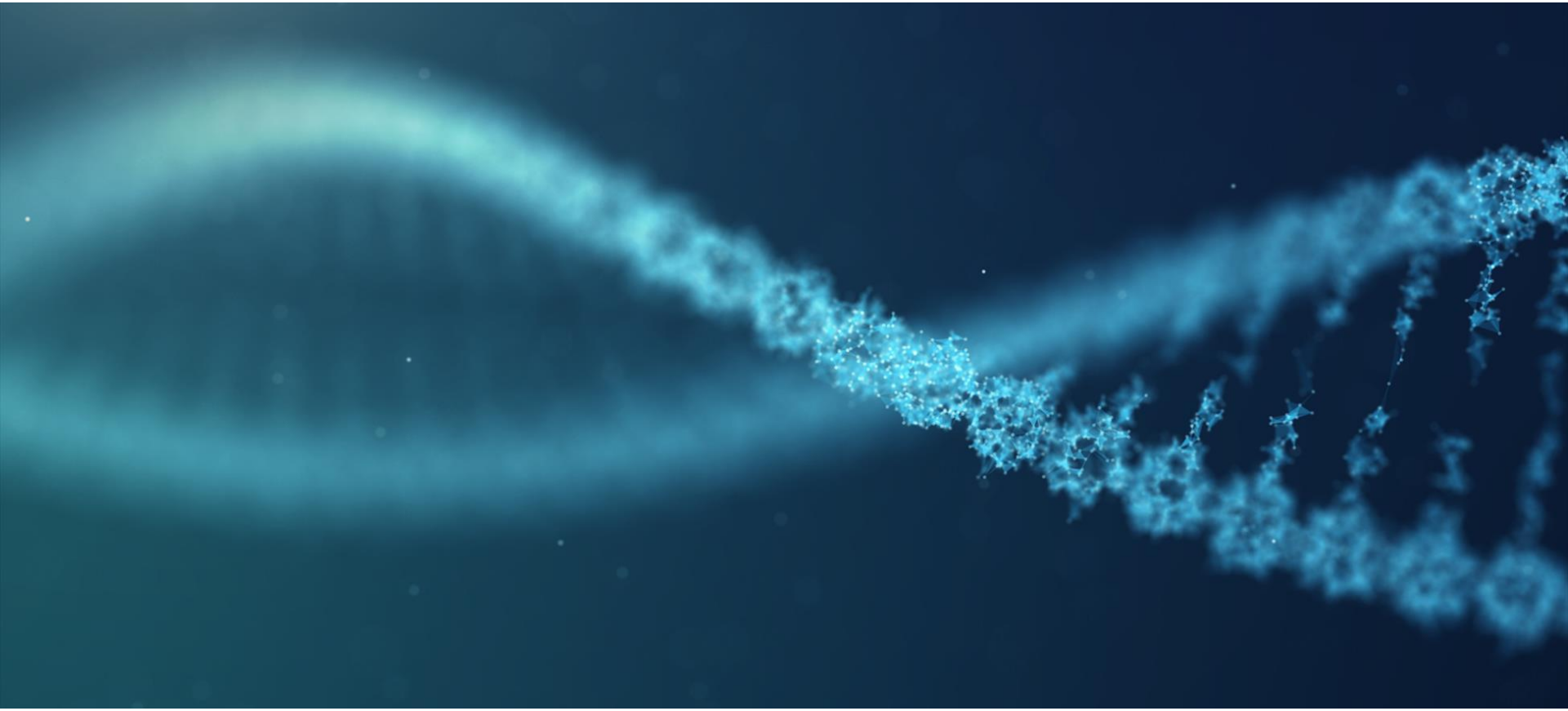
- AbbVie has settled with eight biosimilar entrants
- Settlements stack up U.S. entry between January and December 2023
- BI is still litigating, late to settlement party
- BUT BI is conducting a Phase III interchangeability study for Cyltezo:
  - Voltaire X: Clinicaltrials.gov ID NCT03210259
  - Study completion date: July 2020
  - Plaque psoriasis: Humira v. Cyltezo
  - Enrolled patients: 240-350
  - Only interchangeability study in compliance with FDA interchangeability guidance
- Humira is "pharmacy benefit" product, thus automatic substitution at pharmacy level may be powerful driver of Cyltezo uptake over earlier entrants

# Biosimilar v. Biosimilar Litigation

- AbbVie has settled with eight biosimilar entrants
- Coherus has the latest U.S. entry date: December 15, 2023
- Amgen has the earliest U.S. entry date: January 31, 2023
- Amgen also on the market in Europe, while Coherus does not yet have approval
- Coherus has sued Amgen for infringement of three U.S. formulation patents that issued in December 2018
- Coherus claims that Amgen's manufacture of formulated Amgevita in the U.S. for sale in Europe is an infringement
- Will we see more of this kind of tactic?
  - Late entrants seeking a piece of early-entry deals?
  - Early entrants seeking to block or delay later entrants?

# BUSINESS ISSUES TO CONSIDER WHEN MITIGATING REGULATORY AND LITIGATION RISKS

## EU Perspective



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# Business Issues – Market Overview

**The European patchwork of national laws**

- National laws preserve national interests, including healthcare budgets
- Broad harmonization of general principles under EU legal framework;  Regulations and Directives
- But little EU-level legislation governing the market past the point of product authorization by the European Medicines Agency
    - Pharmacovigilance rules
        - Protect patient safety
    - Free market rules
        - Free movement of goods creates the European "single market"
        - Intellectual property rights are generally an exception to this and recognize borders
        - But parallel trade is permitted once products are on the market with consent
    - Anti-trust rules

# Business Issues – Market Overview

## Pricing and reimbursement

- Pricing and reimbursement = national level
- Pricing policy impacts on uptake, e.g. –
  - Horizon scanning: UKMi provides information on future generic and biosimilar medicines
  - Interchangeability guidelines – Finland, the Netherlands and Germany
  - Italian example:
    - Cultural resistance which has been changing over the years
    - Regional differences in uptake due to different policies
    - Incentives to use lower-cost biologics plus rules promoting prescription of biosimilar in naïve patients lead to higher uptake

# Business Issues – Market Overview

## Substitution

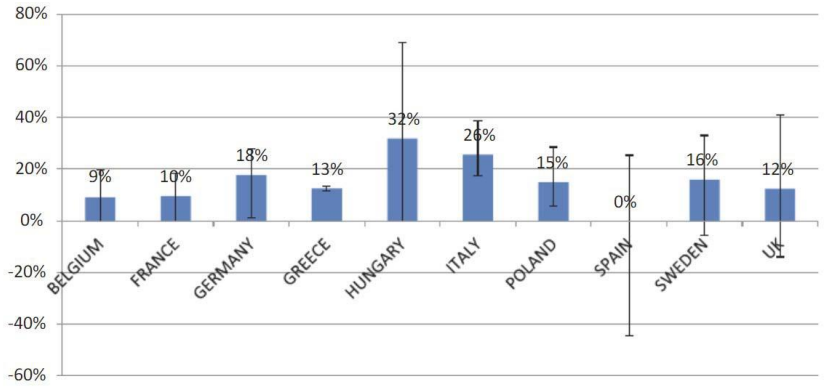
- **Interchangeability**: the possibility of exchanging one medicine for another that is expected to have the same clinical effect
- Done by:
  - **Switching**: prescription level at the initiative of the prescriber; or
  - **Automatic substitution**: done when dispensing without consulting the prescriber.
- Controlled at a national level, e.g.

| Country | Switching | Automatic substitution |
|---|---|---|
| UK | **Yes** – with HCP approval, if monitored and information available to patients | **No** |
| France | **Yes** – so long as patient consents, monitoring in place and traceable | **Yes** – both at start and during treatment, but subject to HCP not excluding |

# Business Issues – Market Overview

## Market penetration

- Understanding drivers of biosimilar uptake becomes a critical issue to inform policy decision-makers
- Incentive policies to enhance uptake remain an important driver of biosimilar penetration, while biosimilar price discounts have no impact




Average biosimilar price discount by country in (%) over originator products.

Source: *"Key drivers for market penetration of biosimilars in Europe"*, C Rémuzat *et at*, Journal Of Market Access & Health Policy, 2017, Vol. 5, No. 1, 1–15



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# Business Issues – Competition from Others

**The perils of clearing obstacles too early**

- European Patent Office patent revocation by post-grant opposition is very slow
  - Timeline varies between 3-8 years with appeal depending on board
- National litigation systems can be used to achieve local certainty
- Some countries – e.g. United Kingdom – encourage early clearance of obstacles
  - Competitors can be punished in preliminary injunction assessments if clearance steps have not been taken
- But there is a problem: regulatory approval for products runs on a timeline that is also uncertain
- Once obstacles are cleared, the gates are open to all
- Litigation is expensive, should you invest without certainty on approval?
- But the rewards of being first to market are great

# Business Issues – Litigation Considerations

## PI risk and timescales

A typical PI risk map for Europe


*NB in this example, revocation proceedings were well advanced in the UK and NL, hence low PI risk in those jurisdictions*



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# Business Issues – Litigation Considerations

**Compensation under PIs later lifted**

- Most European countries recognize that a preliminary injunction application involves an imperfect assessment of the merits of infringement and validity
- The result is a mechanism for the injuncted party to gain compensation if it later wins at trial
  - The aim is to restore (to a degree) the commercial position that party would have enjoyed had it entered the market instead
- Some litigation jurisdictions in Europe offer a compensation mechanism that attempts perfect recovery
  - But there are inherent difficulties in assessing a counterfactual
    - Would other competitors have entered the market?
    - What would be the size of market share?
- Other jurisdictions offer a blunter package: bond or guarantee, assessed in the round

# Business Issues – Litigation Considerations

## Litigation budgets and fee shifting

- Litigation is expensive
  - In the United Kingdom, a complex patent action involving  infringement and validity can cost up to £2 million
  - Hard-fought litigation in biologics can push the figure even higher. Public court filings indicate that AbbVie spent £7.5 million fighting the  UK court battle on Humira against Fujifilm
- Cost recovery (fee shifting) is not universal in Europe
- Even if mechanisms exist, they are imperfect
  - Costs may be assessed for "reasonableness"
  - Coordination costs cannot be claimed
  - Not all costs are financial

# Thank You

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**Jonathan Schur**
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## Additional Experts

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Bristows



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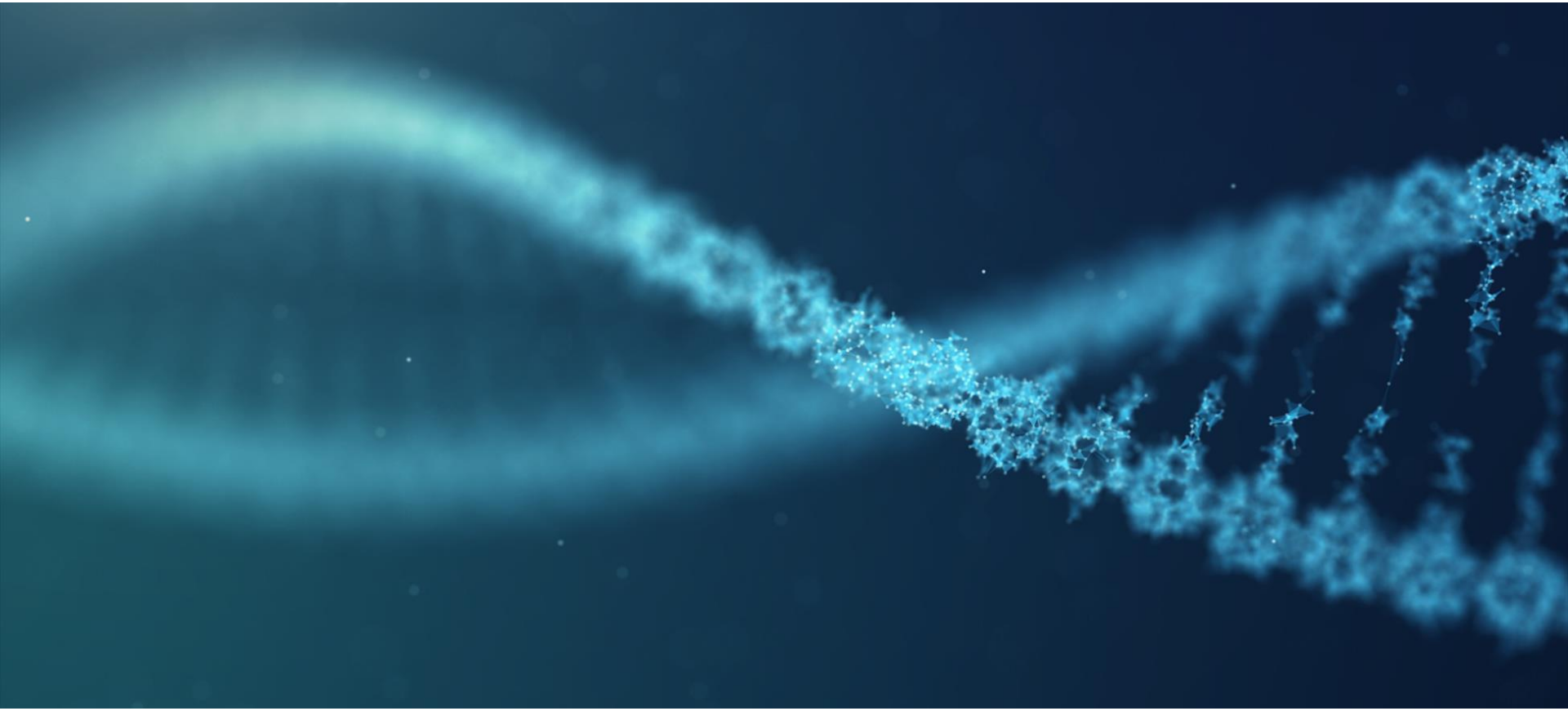
# LITIGATION ISSUES TO CONSIDER WHEN LAUNCHING A BIOLOGIC



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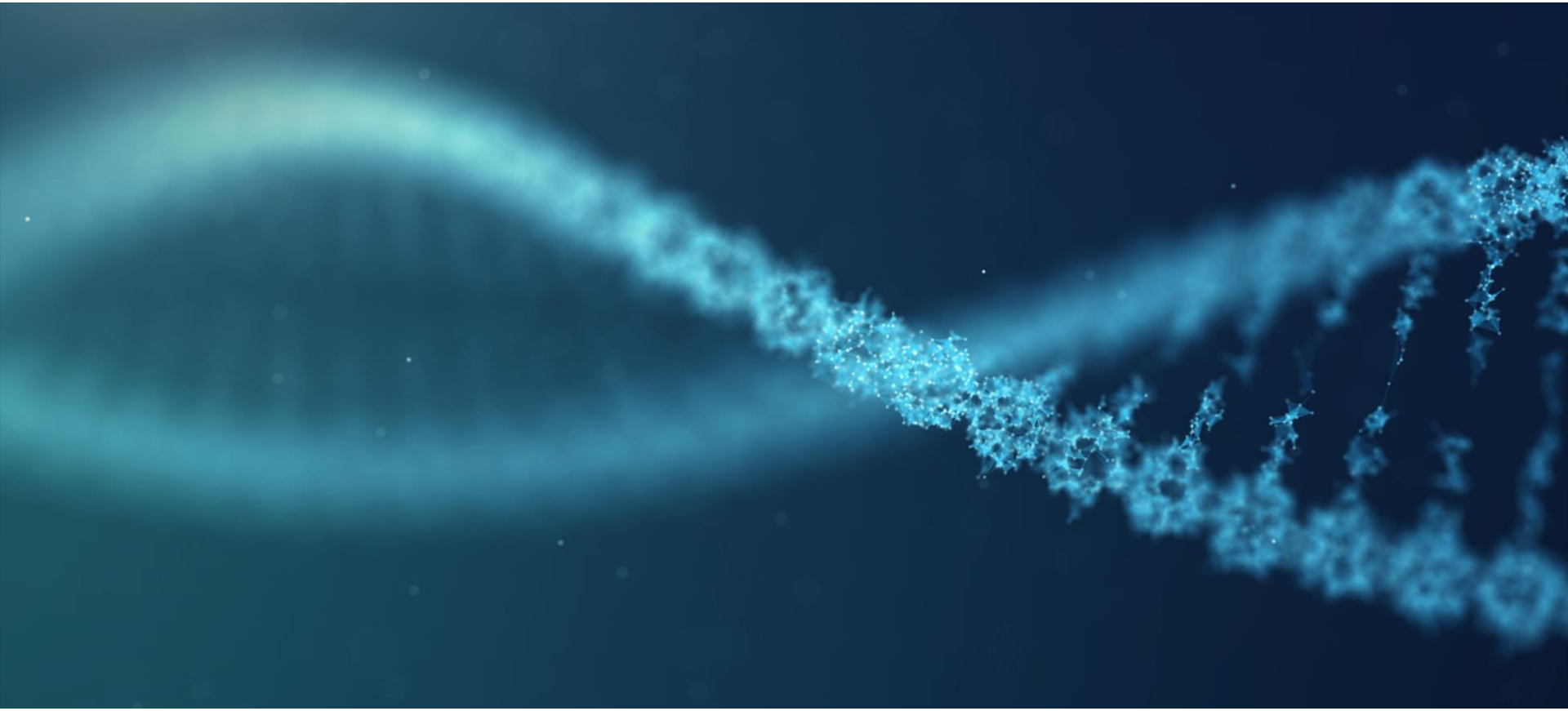
# LITIGATION ISSUES TO CONSIDER WHEN LAUNCHING A BIOLOGIC
## Freedom To Operate and Due Diligence



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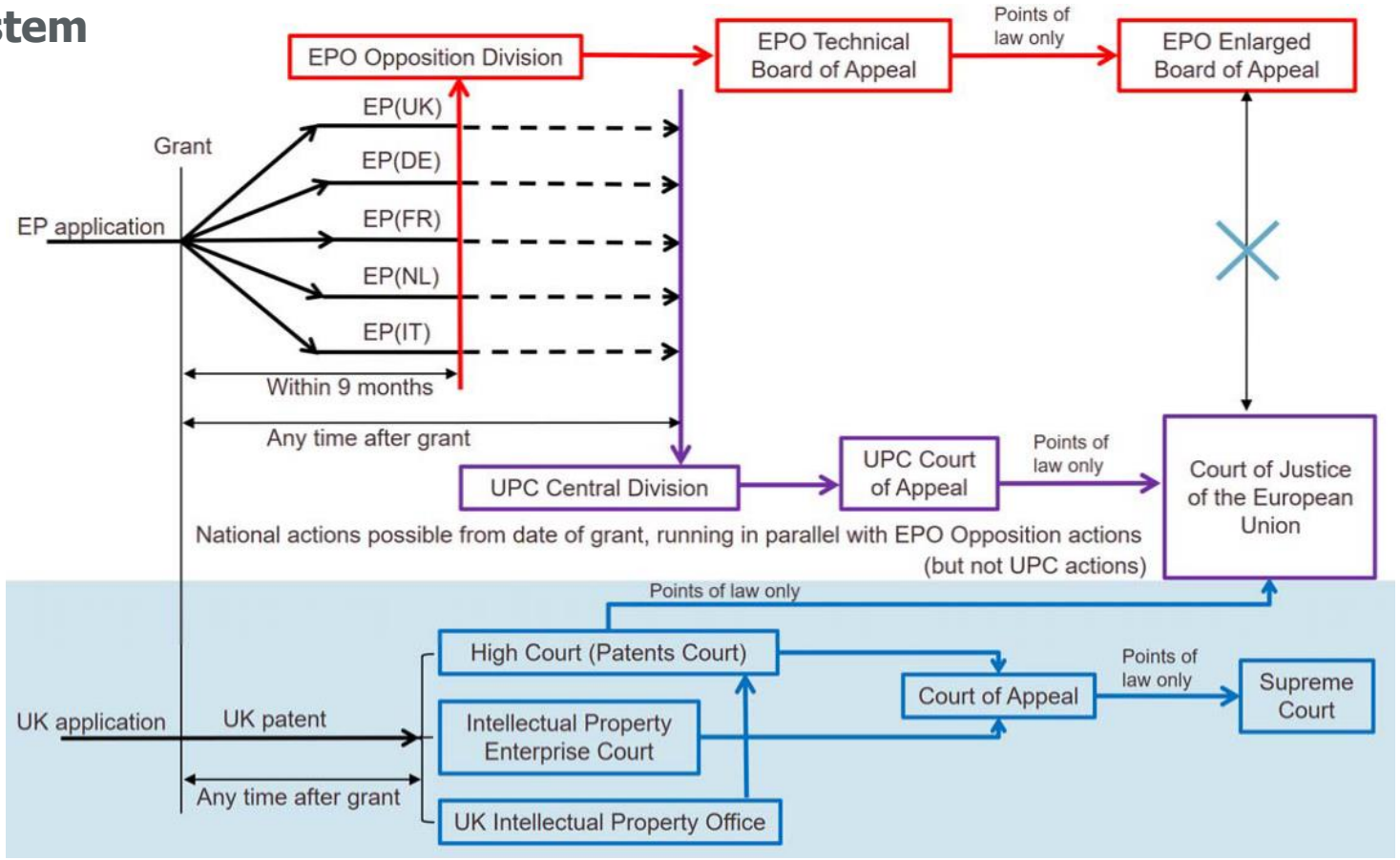
# Europe: Freedom to Operate and Due Diligence

**Patent litigation in Europe is (presently) a two-tier system**

- European Patents
  - Single central application to the European Patent Office
  - Results in a bundle of national patents: EP (UK), EP (NL), EP (FR), EP (DE) etc.
  - 9-month window to initiate a centralized post-grant validity attack at the EPO
  - After that, patents must be revoked country-by-country
- National Patents
  - An alternative to European Patents
  - Applications made nationally to local patent offices
  - Overlap with European Patents subject to rules preventing double-patenting
  - Granted national patents must be revoked in country of origin

# Europe: Freedom To Operate and Due Diligence

**In future, patent litigation in Europe could be a three-tier system**



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# Europe: Freedom To Operate and Due Diligence

**Patent litigation in Europe**

- Limitations on visibility of patent obstacles
  - No patent linkage or listing of relevant patents
  - Patent applications visible upon publication, 18 months after filing
  - But rules on European Patent divisional applications make life difficult:
    - Divisional applications can be filed at any time within the pendency of the parent application
    - Can lead to a cascade of divisional applications (parent, child, grandchild etc.), the latest members of which are invisible (submarine divisionals)
- Patent owners can enforce portfolio selectively
- But note that some jurisdictions prevent "drip feeding" of patents into litigation
- Freedom to operate assessments made more difficult by doctrine of equivalents in some jurisdictions
- Ultimately, true certainty only occurs after litigation

# U.S.: Freedom to Operate and Due Diligence

**A one-tier system**

- U.S. patents, but several different important classes to consider:
  - Product patents: molecule API composition (e.g., purity) and formulation
  - Method of use patents: therapeutic indications, dosage regimens, combinations
  - Method of manufacture patents: particularly important in biologics

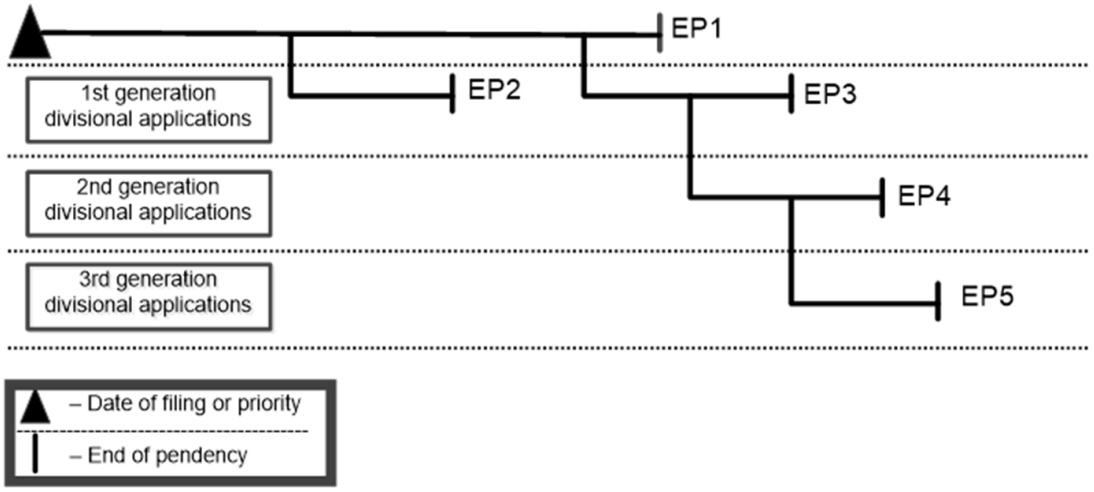
# U.S.: Freedom To Operate and Due Diligence

**How does one determine which patents cover a reference biologic for an FTO analysis?**

- Review ongoing *inter partes* review, post grant review, and district court litigation activity for initial list of patents, if available
- **Sequence searching** – can be challenging to determine complete universe
- **Keyword searching** – useful for method of use and process searching

# Europe: Thicket Growth and Evergreening

- R&D spend on biologic drugs is bigger than ever
- Commercial success is bigger than ever
- Is it any surprise that the number of patents for biologic drugs is so high?
- The rules on divisional patenting at the EPO encourage thicket growth



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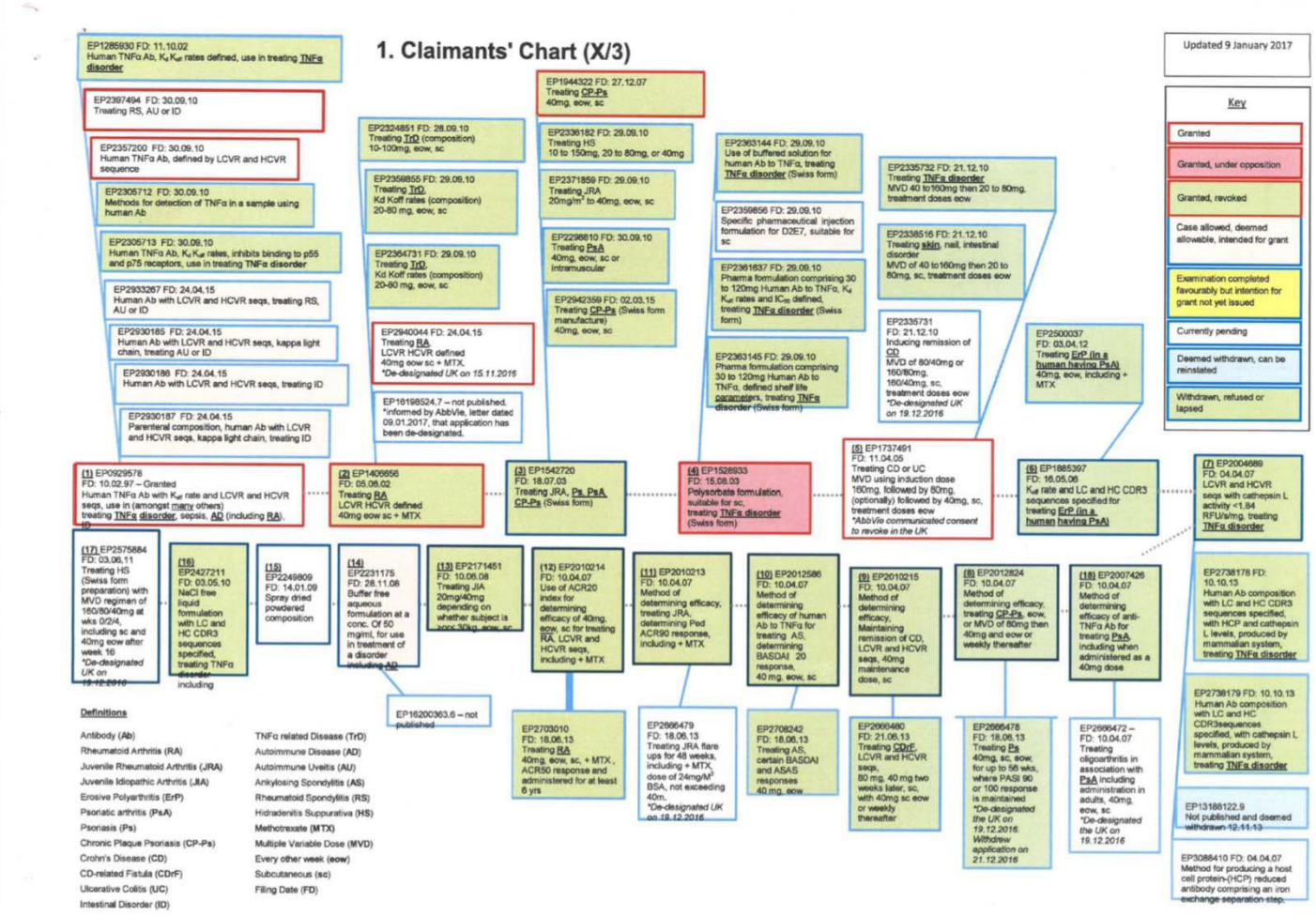
# Europe: Thicket Growth and Evergreening



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# U.S.: Thicket Growth and Evergreening

- Biologics manufacturers have vast patent portfolios on their products:
  - Molecule
  - Formulations
  - Upstream processes
  - Downstream processes
  - Methods of use
- Tens or more than a hundred patents may cover a given biologic product
- Patent-holders may assert claims based on any or all of these patents against biosimilar applicants, depending on the outcome of the patent dance

# U.S.: Thicket Growth and Evergreening

**Growing a Thicket Using Divisionals and Continuations at the USPTO**

- Obtain claims not able to pursue in parent application (different claim class)
- Maintain pending applications - newly discovered/asserted prior art
- Double patenting issues - multiple patents with different patent terms

# U.S.: Thicket Growth and Evergreening

**AbbVie v. Boehringer Ingelheim (adalimumab)**

- 74 asserted patents
- BI pursuing an "unclean hands" defense, alleging:
  - AbbVie "engaged in a **pattern** of pursuing **numerous overlapping and non-inventive patents** for the purpose of developing a '**patent thicket**,' using the patenting process itself as a means to seek to **delay competition** against its expensive and lucrative adalimumab product. That strategy has generated … **more than 100 patents**."
  - Many of the asserted patents "share common specifications and have overlapping and nearly identical claims"
  - These patents "do not represent innovation, but rather are attempts to claim methods of treatment, methods of production, and formulations derived from the prior art for the purpose of **creating a patent thicket or estate that competitors must**, as AbbVie has publicly stated, '**contend with' to sell the active ingredient**" in Humira, which was covered by a patent that expired in December 2016

# U.S.: Thicket Growth and Evergreening

AbbVie v. Boehringer Ingelheim (adalimumab)

- To support its "unclean hands" defense, BI sought discovery of R&D documents dated outside the default six-year period under the local rules
- The court **rejected** BI's argument that the case is "unusual, given the number of patents and claims at issue, and the evolution of a '**patent thicket**' over a lengthy period of time"
- But the Court ordered AbbVie to produce documents "for the time preceding the six-year period" regarding R&D because "[r]esearch and development information that leads in a plausible and logical fashion to 'conception and reduction to practice'" is relevant to the litigation

# Europe: Thicket Clearance

Branch by branch

- Use patent revocation proceedings to clear branches one-by-one
  - But this is expensive
  - And time consuming
  - And does not guarantee certainty owing to the way in which divisional patents can be filed




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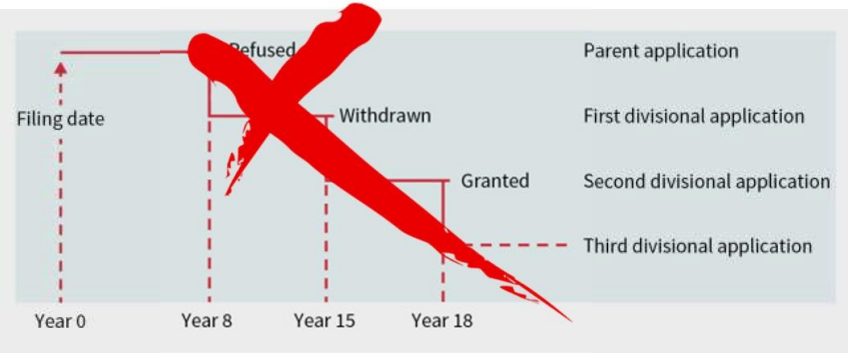
# Europe: Thicket Clearance

## Slash and burn

- A new remedy exists in one or two EU
- countries: the **Arrow declaration**
  - Granted in the Netherlands
  - and the UK (since 2016)
- How does it work?
  - Court-ordered declaration that applicant's product belongs in the state of the art in the state of the art, or is an obvious modification of that art, at the priority date of the patent family in question
  - Provides immunity from infringement for that patent



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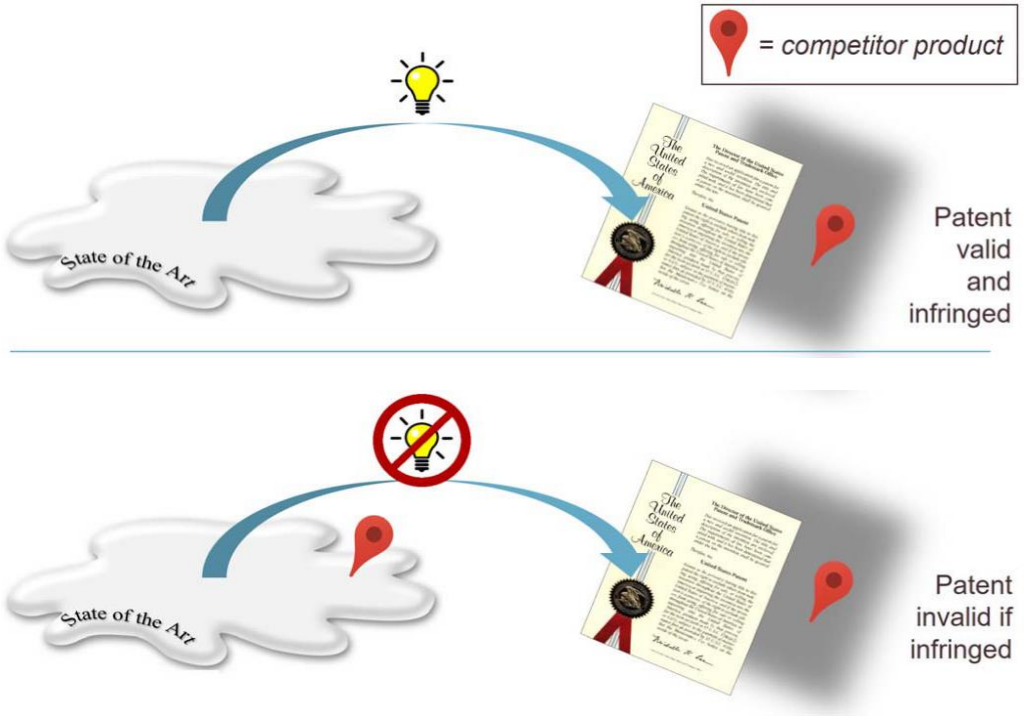
# Europe: Thicket Clearance

## Slash and burn: the *Arrow* declaration



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# U.S.: Thicket Clearance

**Case Management For Patent Thickets**

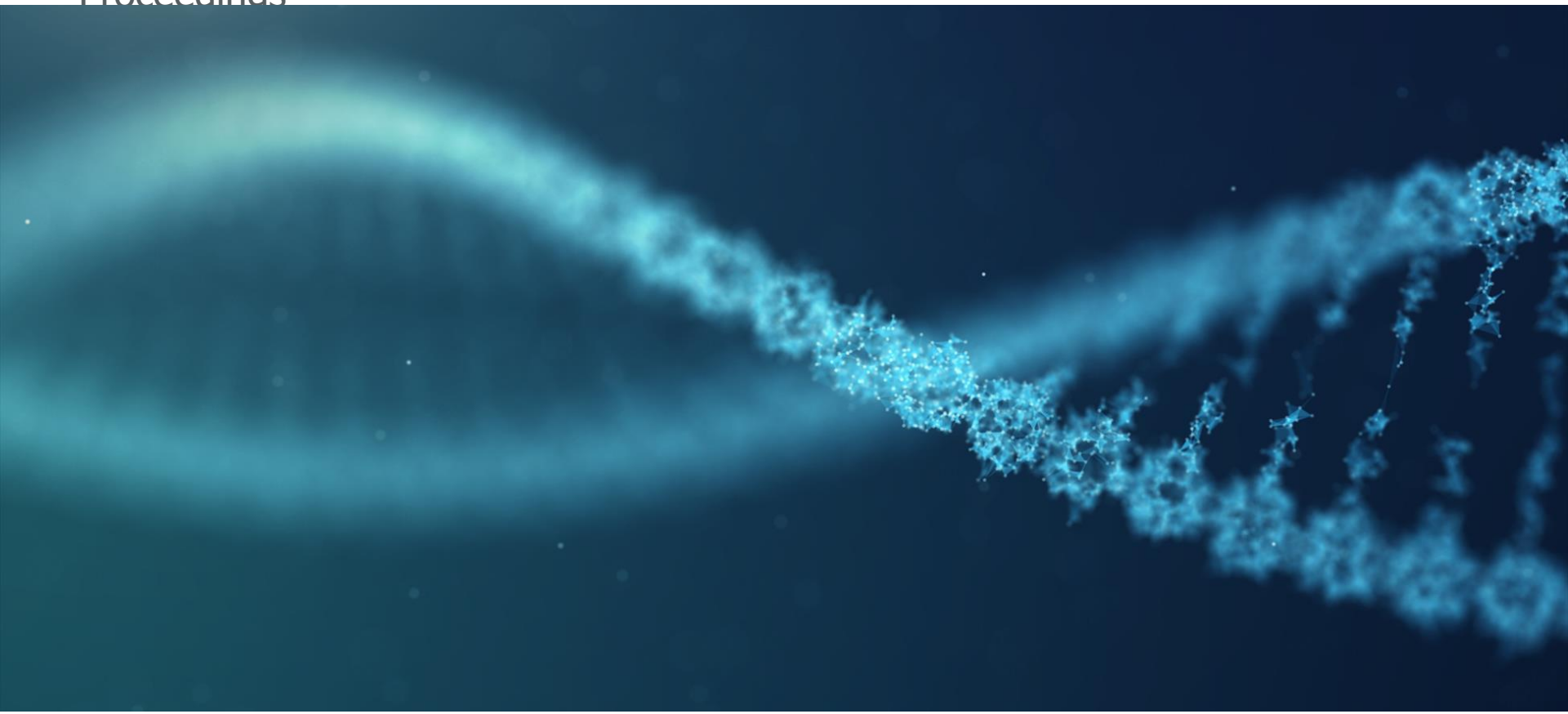
- With patent thickets resulting in a high number of patents asserted in a given case, courts are looking at ways of narrowing the issues
- *Genentech v. Amgen* (D. Del.) (bevacizumab):
  - Court directed the parties to reduce the number of asserted patents from 26 to no more than 8 by a date certain
  - Parties agreed to "an initial phase of discovery" whereby the parties would take depositions of each other's corporate designees under FRCP 30(b)(6)
  - Court would like to "make an early determination" regarding whether Genentech can seek damages for activity that Amgen argues is protected by the safe harbor
  - Trial set for June 1, 2020
  - In a memorandum order regarding case management: "The court is a limited resource. Every set of litigants is entitled to use its fair share of this resource – but only its fair share. The litigants in this action are coming perilously close to exceeding that limit."

# U.S. Thicket Clearance

- Early clearance using IPRs, PGRs to cancel claims
- Assert invalidity of the claims in district court patent infringement litigation
- Patent avoidance: non-infringement defense strategies should be built into development process

# LITIGATION ISSUES TO CONSIDER WHEN LAUNCHING A BIOLOGIC

## Overview of EU Opposition, Revocation and Patent Infringement Proceedings



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# Europe: Overview of Patent Litigation Proceedings

## The EPO Opposition System

| Parameter | Description | Star rating |
|---|---|---|
| **Procedure** | • File Notice of Opposition centrally at the EPO<br>• Exchanges of written submissions<br>• Oral hearing before the OD<br>• Appeal to the TBA<br>• Multiple opponents possible | |
| **Timing** | • Within 9 months of grant | *** |
| **Duration** | • Typically between 2 and 8 years | * |
| **Cost** | • €20K upwards | *** |
| **Quality** | • Low at OD; better at TBA | ** |
| **Predictability** | • Poor at OD; better at TBA | ** |
| **Impact** | • High if successful – kills all patents in the EP bundle | ***** |

Europaisches Patentamt
European Patent Office
Office européen des brevets



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# Europe: Overview of Patent Litigation Proceedings

## National patent litigation systems: the United Kingdom

| Parameter | Description | Star rating |
|---|---|---|
| **Procedure** | • Sue for revocation at court or UKIPO<br>• Exchanges of written submissions<br>• May be interim hearings on procedural points<br>• Trial<br>• Appeal | |
| **Timing** | • At any time | ***** |
| **Duration** | • 1-2 years | *** |
| **Cost** | • £1.5 - 3 million | * |
| **Quality** | • High | **** |
| **Predictability** | • Reasonable | *** |
| **Impact** | • National clearance<br>• Potential export value | ** |

# Europe: Overview of Patent Litigation Proceedings

## Case study: some key national jurisdictions compared

| | UK | Germany | The Netherlands |
|---|---|---|---|
| **Judge quality** | High – specialised court | High – specialised court | High – specialised court |
| **Duration of first instance proceedings** | 12-18 months | 12-15 months | 10-12 months if accelerated (in theory) |
| **Cost** | Expensive | Cost efficient | Cost efficient |
| **PI prevalence** | Not uncommon | Common | Not uncommon |
| **Stays pending EPO proceedings** | Rare | N/A | Not uncommon |
| **Infringement / validity squeeze** | Available | Not available | Available |
| **Notable features** | Barristers<br>Cross-examination of witnesses;<br>Arrow declarations;<br>Cross-border DNI | Bifurcated system | Pre-action evidence seizure;<br>Arrow declarations;<br>Cross-border injunctions |

# Europe: Overview of Patent Litigation Proceedings

## Potential New European Litigation System: The Unified Patent Court (UPC)

| Parameter | Description | Star rating |
|---|---|---|
| **Procedure** | • Revocation action at UPC Central Division<br>• Exchanges of written submissions<br>• Interim Conference sets procedure<br>• Trial<br>• Appeal | |
| **Timing** | • At any time | ***** |
| **Duration** | • 12 months at first instance<br>• Could be long delays on appeal | *** |
| **Cost** | • Unknown – predicted to be between €0.5 and 5 million depending on value | **** |
| **Quality** | • Unknown – predicted to be variable | *** |
| **Predictability** | • Unknown – unpredictable | *** |
| **Impact** | • Clearance across UPC member states<br>• Most valuable patents predicted to be outside the system | ***** |

# Europe: Overview of Patent Litigation Proceedings

## Remedies: preliminary injunction risk

A typical PI risk map for Europe


*NB in this example, revocation proceedings were well advanced in the UK and NL, hence low PI risk in those jurisdictions*



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# Europe: Overview of Patent Litigation Proceedings

## Compensation for wrongful PI

- If PI later lifted following a trial on the merits (i.e. because patent invalid or not infringed)
- Some redress usually available but rules and amount of compensation vary
- Damages inquiries rare: pure money questions tend to settle
- Strategic questions:
  - In jurisdictions where PIs can be ordered by consent, should a defendant invite the injunction without launching at risk?
    - Gains a payout after trial if patent owner loses
    - Is there a downside?
  - In jurisdictions where a third party claim for compensation is possible, should a defendant join the injuncted party in proceedings, share the cost and take a share of the compensation?

# Europe: Overview Of Patent Litigation Proceedings

**European strategy – a defendant's toolkit**

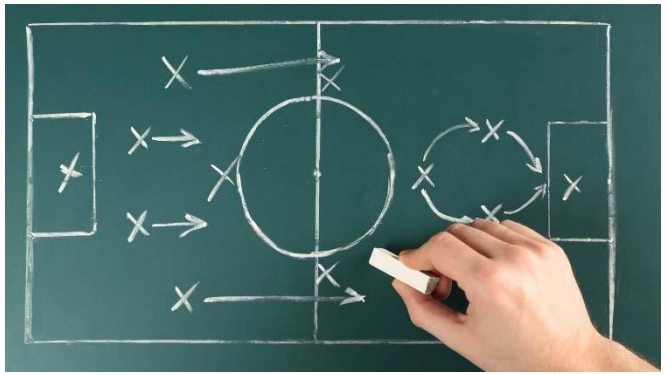
- Delay grant of patent
  - Third party observations during prosecution
- Defuse the PI
  - Protective letters where possible to preclude *ex parte* relief
  - Provocative measures in countries with urgency requirements
  - Proactively file revocation proceedings to call validity into doubt?
- Cross-border relief
  - Cross-border declaration of non-infringement possible provided validity is not in issue
- Delay torpedo
  - Cross-border DNI may enable a slow jurisdiction to hold up an entire enforcement programme (e.g. in Italy following the General Hospital case)
- Make use of documents disclosed / discovered in other jurisdictions (UK & U.S.)

# Europe: Overview of Patent Litigation Proceedings

**Tools for persuading courts**

- Negative validity decisions from UK courts
  - Thorough, detailed judgments good for export
- Negative PI decisions in which injunction applications rejected
- *Arrow* declarations from English or Dutch courts
- EPO decisions from the Opposition Division
- Good quality expert witnesses on technical points
- Opinions from retired judges on points of law
- Good legal teams….!

# Europe: Overview of Patent Litigation Proceedings

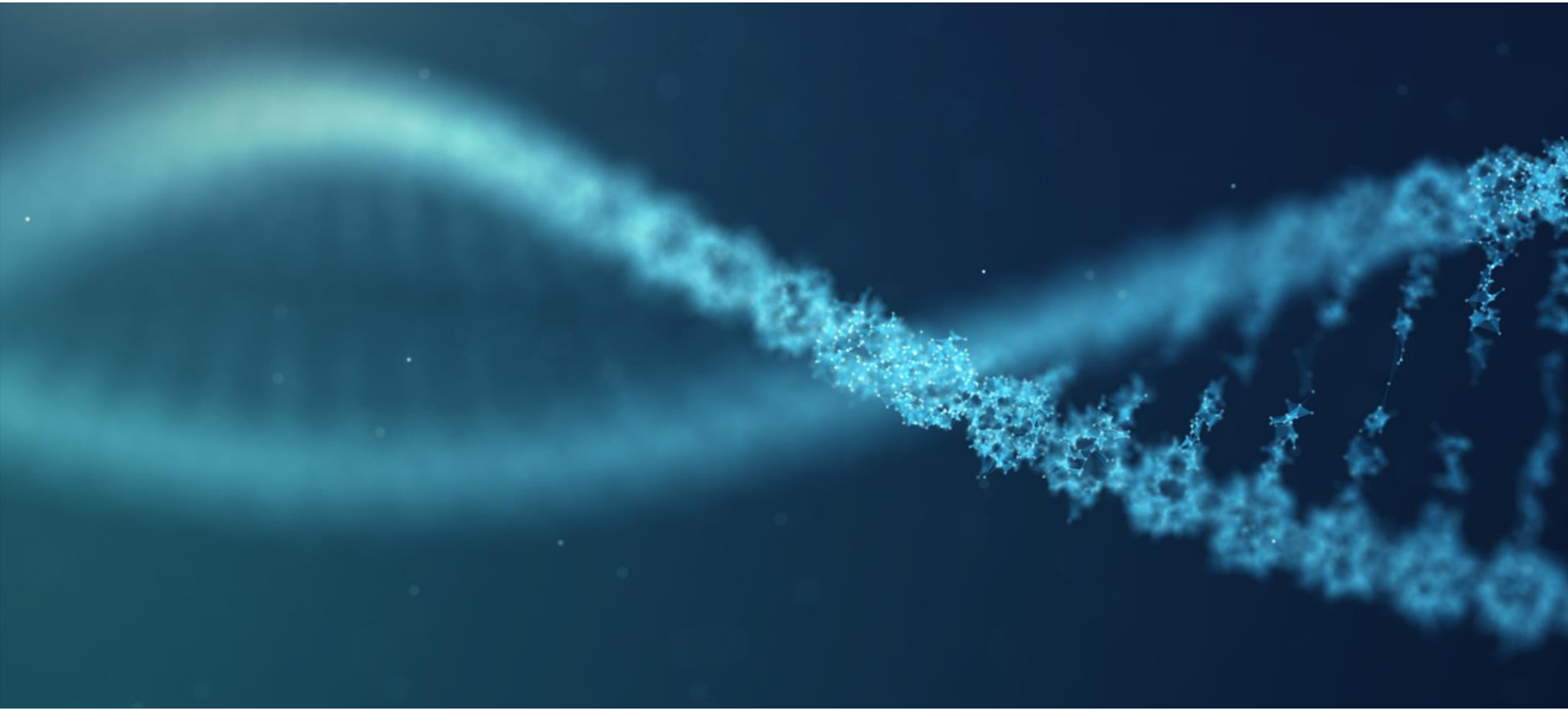


Strategy and tactical playbook

- Due diligence
- Proactive or reactive?
- Where to begin?
- When to begin?
- Fast or slow?
- Interplay with European Patent Office proceedings
- Fight or settle?
  - Terms of settlement
  - Anti-trust considerations
- Logistics set-up and route to market

# LITIGATION ISSUES TO CONSIDER WHEN LAUNCHING A BIOLOGIC

## Overview of U.S. District Court Patent Infringement Litigation



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# U.S. Overview of Patent Infringement Litigation and Post-Grant Review of Patent Validity

**Overview of District Court Litigation**

- In the Biologics Price Competition and Innovation Act (BPCIA), Congress added section 271(e)(2)(C) to the Patent Act to create an act of artificial infringement for filing an abbreviated application under section 351(k) of the Public Health Service Act

- Litigation in federal district court. Parties involved:
  - Reference product sponsor (RPS), who filed a biologics license application (BLA) demonstrating that the biological is "safe, pure, and potent"
  - Biosimilar applicant, who filed an abbreviated biologics license application (aBLA) demonstrating biosimilarity (and/or interchangeability) to an approved BLA product

# U.S. Litigation under the BPCIA

- Patent dance strategies:
  - Opting out of the dance entirely
  - Partially completing one or more of the steps
  - Completing all of the steps of the dance

# BPCIA Patent Dance Statute

Not later than 20 days after the Secretary notifies the [aBLA] applicant that the application has been accepted for review, the [aBLA] applicant … shall provide to the reference product sponsor a copy of the application …, **and such other information** that describes the **process or processes used to manufacture** the biological product that is the subject of such application; and … **may** provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

42 U.S.C. § 262(*l*)(2)(A)-(B)

# Key Steps in the Patent Dance and Timing

| Event | Time |
|---|---|
| Applicant provides copy of aBLA and manufacturing information | Within 20 days after FDA accepts aBLA |
| RPS provides 3A list of patents | Within 60 days |
| Applicant provides 3B statement containing its non-infringement, invalidity, and unenforceability contentions and/or statement not to launch before patent expiry | Within 60 days |
| RPS provides its 3C statement containing its disclose infringement, validity, and enforceability contentions and parties begin negotiating which patents to litigate | Within 60 days |
| Parties either agree or disagree of list of patents | Within 15 days |
| RPS files complaint for patent infringement | If parties agree on list: within 30 days; otherwise within 35 days |

**Max time: 245-250 days (~8 months from FDA acceptance)**

# Patent Dance Provides for Two Waves of Patent Litigation

- The patent dance process requires:
  - Prompt disclosure of biosimilar application (and potentially other information regarding manufacturing processes)
  - Prompt disclosure of all infringed patents by RPS
  - Prompt initiation of suit for infringement
- Two waves of patent litigation:
  - Allows biosimilar applicant to restrict scope of 1st wave patent litigation to a single patent only
  - 2nd wave patent litigation after 180 day notice of commercial launch may involve numerous additional patents
- Does not preclude biosimilar launch prior to adjudication or require court to decide infringement claims prior to launch

# Patent Dance Provides for Two Waves of Patent Litigation

- A "1st wave" infringement suit may be brought on any patent included on the first list served by the RPS and included on the final list of patents negotiated between the parties to be litigated in the 1st wave
- RPS may not bring suit on other patents on initial list until after biosimilar applicant provides 180-day notice of commercial launch
- A "2nd wave" infringement suit may be brought on any patent included on the first list served by the RPS but not included on the final 1st wave list
- Biosimilar applicant must provide notice 180 days before commercial launch; preliminary injunction on 2nd wave patents may not be sought until such notice

# If the Dance is Optional, Why Dance?

**Why dance?**

- Gain some control over scope of issues, number of patents, and timing of lawsuit
- RPS precluded from suing on patents not on 3A list

**Why skip?**

- Delay disclosure of manufacturing information and licensing agreement, including third-party information
- Accelerate litigation (brand may sue immediately if patent dance declined)
- Avoid disputes over compliance with various dance steps

# Phases of U.S. Litigation in Federal District Court

- Pleadings: complaint filed and answered
- Fact discovery
  - Documents (including electronic documents)
  - Depositions of fact witnesses
- Expert discovery
  - Expert reports
  - Depositions of expert witnesses
- Summary judgment (sometimes permitted)
- Trial
- Appeal

# Discovery in U.S. Litigation

- Broad scope of discovery: the other side entitled to virtually all documents and information concerning the aBLA product
- Documents that may be discovered include:
  - Lab notebooks, data, analytical results
  - Manufacturing processes and batch records
  - Emails and personal notes
  - Memos, reports, and spreadsheets, including drafts
- Depositions of individuals with knowledge of the aBLA product
- Even if not aBLA filer, if involved in process of developing or making the aBLA product, can be subject to discovery

# Preliminary Injunctions

- No automatic regulatory stay of approval of the biological application during the course of the patent litigation; an RPS must move for preliminary injunction (PI) to prevent an "at risk" launch of the biologic
- Applicant must notify RPS at least 180 days' of notice of commercial marketing (NCM), which triggers RPS's right to bring an infringement action/seek a PI
- Why are PIs likely?
  - FDA approval can be as fast as 10 months after acceptance of aBLA but patent dance takes 6-8 months to complete
  - Regulatory and patent dance timelines usually mean that FDA approval will happen soon after first-wave complaint is filed
  - If applicant wants to market upon approval, then first and second waves will likely collapse into one; upon NCM, RPS can sue on all remaining 3(A)-listed patents

# Safe Harbor Statute

It shall **not** be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention … **solely for uses reasonably related to the development and submission of information** under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1)

**$70 Million Damages Award to Amgen**

- In September 2017, a Delaware federal jury found that Hospira infringed one of Amgen's Epogen/epoetin alfa (EPO) patents and awarded Amgen
- $70 million in damages
- Some portion of each of the batches accused of infringement were used for testing for purposes of submitting an aBLA to FDA
- Jury agreed with Amgen in finding that 21 of Hospira's biosimilar *EPO batches were produced to create a stockpile of commercial product, and not protected by the safe harbor of § 271(e)(1)*

# Induced Infringement

- Induced infringement where:
  - (1) there's an act of direct infringement, and
  - (2) alleged inducer knowingly induced that act, and
  - (3) alleged inducer possessed specific intent to encourage another's infringement.
- Need intent: Must show that inducer knew that the induced acts would constitute patent infringement.
- Intent shown where inducer has actual knowledge that acts infringe or willful blindness (taking deliberate actions to avoid confirming a high probability of wrongdoing).
- Intent difficult to show where product has substantial non-infringing uses, e.g., there is an unpatented, approved indication.

# Label Carve Outs

- Carving out an approved indication from the biosimilar label may be an effective strategy for avoiding patents claiming the indication
- But even with a carve-out, there is the potential for the RPS to claim that biosimilar label or marketing materials will "induce" doctors or patients to practice the carved-out indication
- For example, RPS may allege that label encourages "off-label" prescriptions of biosimilar for carved-out indication
- RPS may also alleged that sales force or ad encourages "off-label" prescriptions of biosimilar for carved-out indication

# Label Carve Outs – *Immunex v. Sandoz* (etanercept)

- Sandoz submitted an aBLA seeking approval for indications for psoriatic arthritis and plaque psoriasis, but later withdrew those indications
- FDA ultimately approved a label that **did not** contain indications for psoriatic arthritis and plaque psoriasis
- In litigation, Immunex asserted a patent covering the carved-out methods of use and moved for summary judgment of infringement, arguing:
  - The original act of submitting an aBLA seeking approval of the psoriatic arthritis and plaque psoriasis indications (including with clinical trial data for plaque psoriasis) constitutes infringement under § 271(e)(2)(C)
  - Irrelevant whether Sandoz subsequently withdrew those indications from review because infringement has already occurred
- The court issued a sealed order on August 21, which is likely a decision on Immunex's motion
- Trial begin on September 11, 2018 and concluded on September 25, 2018
  - Neither of the patents asserted at trial were the psoriasis treatment patent that was the subject Immunex's motion
  - **This likely means that either the court denied Immunex's motion or granted summary judgment of non-infringement, such that Immunex did not assert the psoriasis patent at trial**

# Damages

- Damages: lost profits, reasonable royalty, enhanced damages, attorney fees
- Precludes remedies under U.S. patent statute for infringement of patents not disclosed on preliminary or final lists
- Reasonable royalty is only relief available if 1st wave infringement suit not timely filed or diligently prosecuted (e.g., not brought within 30-day window)
- Biosimilar applicants should consider the potential risk of losing the benefit of the damages limitation under § 271(e)(6) when considering their patent dance strategies

# BPCIA Litigation Statistics

22 cases filed under the BPCIA to date:

- 3 decided on summary judgment motions
- 1 motion to dismiss granted
- 13 still pending
- Several cases settled
- 2 preliminary injunctions granted

| Molecule | Cases |
|---|---|
| Pegfilgrastim/filgrastim | 9 |
| Infliximab | 2 |
| Epoetin alfa | 1 |
| Etanercept | 1 |
| Bevacizumab | 1 |
| Trastuzumab | 4 |
| Rituximab | 2 |
| Adalimumab | 3 |

# Settlements

- When to fight and when to settle?
- Laddered entry for biosimilars
- Federal Trade Commission scrutiny of “pay for delay”
- Private antitrust suits to combat aggressive anticompetitive tactics

# When to Fight and When to Settle

- By settling patent lawsuits and other disputes, biologics manufacturers can orchestrate launch timing for biosimilar competition
- As one example, AbbVie has settled claims regarding its Humira/adalimumab patents with multiple parties, resulting in different launch dates for adalimumab biosimilars in the U.S.:

| Biosimilar Manufacturer | Launch Date Pursuant to Agreement |
|---|---|
| Amgen | January 31, 2023 |
| Samsung Bioepis | June 30, 2023 |
| Mylan | July 31, 2023 |
| Sandoz | September 30, 2023 |
| Fresenius Kabi | September 30, 2023 |
| Pfizer | November 20, 2023 |
| Momenta | November 20, 2023 |

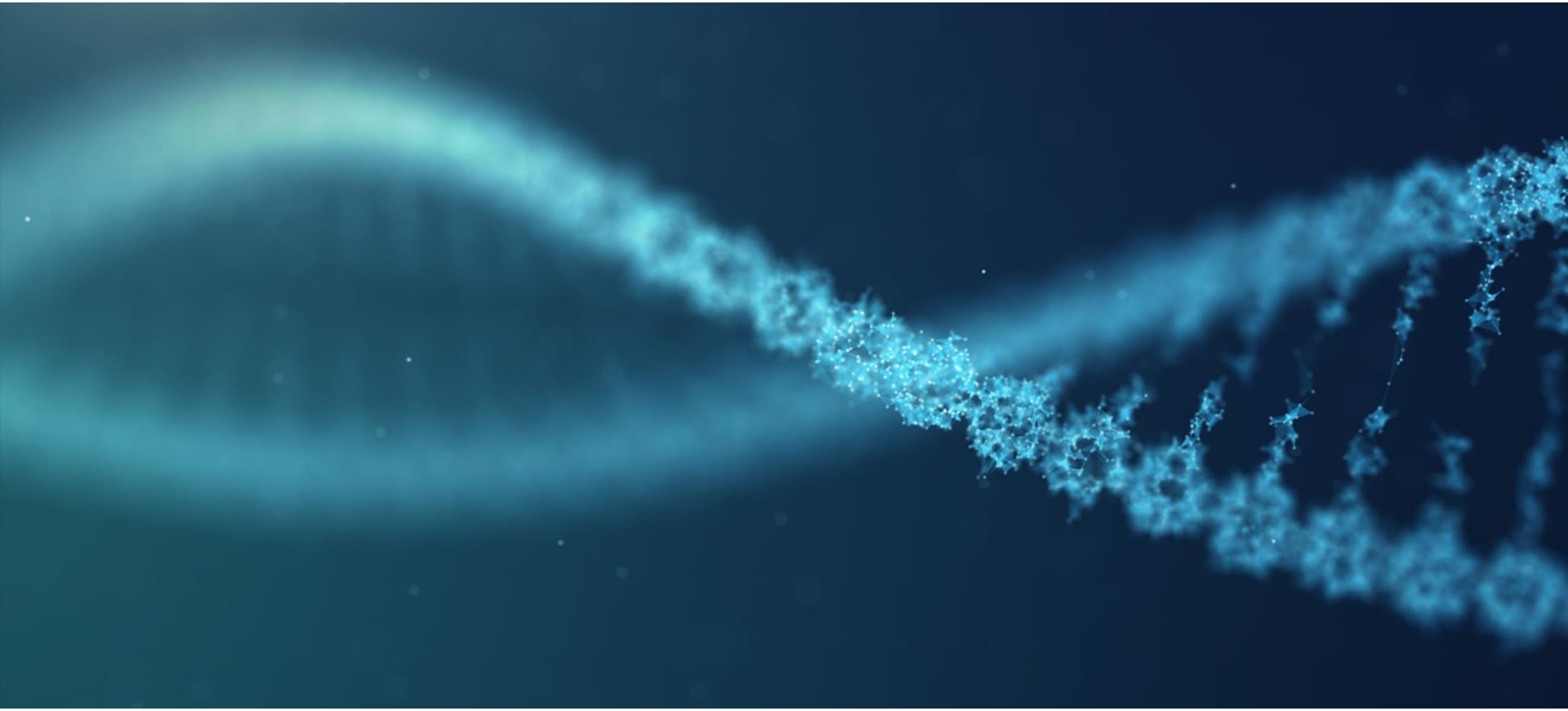
# FTC Scrutiny of "Pay For Delay"

- Under "Patent Right to Know Drug Prices Act" (S. 2554), Reference Product Sponsors and biosimilar applicants must file patent settlement agreements with the Federal Trade Commission ("FTC") and the U.S. Department of Justice ("DOJ") for review
  - Signed into law on October 10
  - Imposes the same FTC and DOJ disclosure requirements currently in place for ANDA litigation settlements

- "SUPPORT for Patients and Communities Act" (H.R. 6), a bill primarily focused on the opioid crisis, made certain changes to the FTC disclosure requirement
  - Closed loophole in prior bill that only required disclosure for biosimilar applicants that provided a statement under section § 262(l)(3)(B)(ii)(I) in the patent dance
  - Extended disclosure requirement to agreements between two biosimilar applicants regarding the exclusivity period for the first interchangeable biosimilar under § 262(k)(6)
  - Signed by President on October 25, 2018

# LITIGATION ISSUES TO CONSIDER WHEN LAUNCHING A BIOLOGIC

## Litigation in the USPTO



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# Litigation at the USPTO

- The America Invents Act (AIA) created new mechanisms for challenging patents at the Patent Trial and Appeal Board (PTAB), including: inter partes review (IPR) and post grant review (PGR)
- Combine with district court litigation strategy
- Early clearance of patent barriers
- Estoppel
- Limitations in PTAB for presenting evidence and expert testimony

# Post Grant Proceedings: Post-Grant Review (PGR)

- A trial proceeding conducted at the PTAB to review the patentability of one or more claims in a patent
- Begins with a third party (not patent owner) filing a petition on or prior to the date that is 9 months after the grant of the patent or issuance of a reissue patent
- May be instituted upon a showing that, it is more likely than not that at least one claim challenged is unpatentable
- If the proceeding is instituted and not dismissed, a final determination by the Board will be issued within 1 year

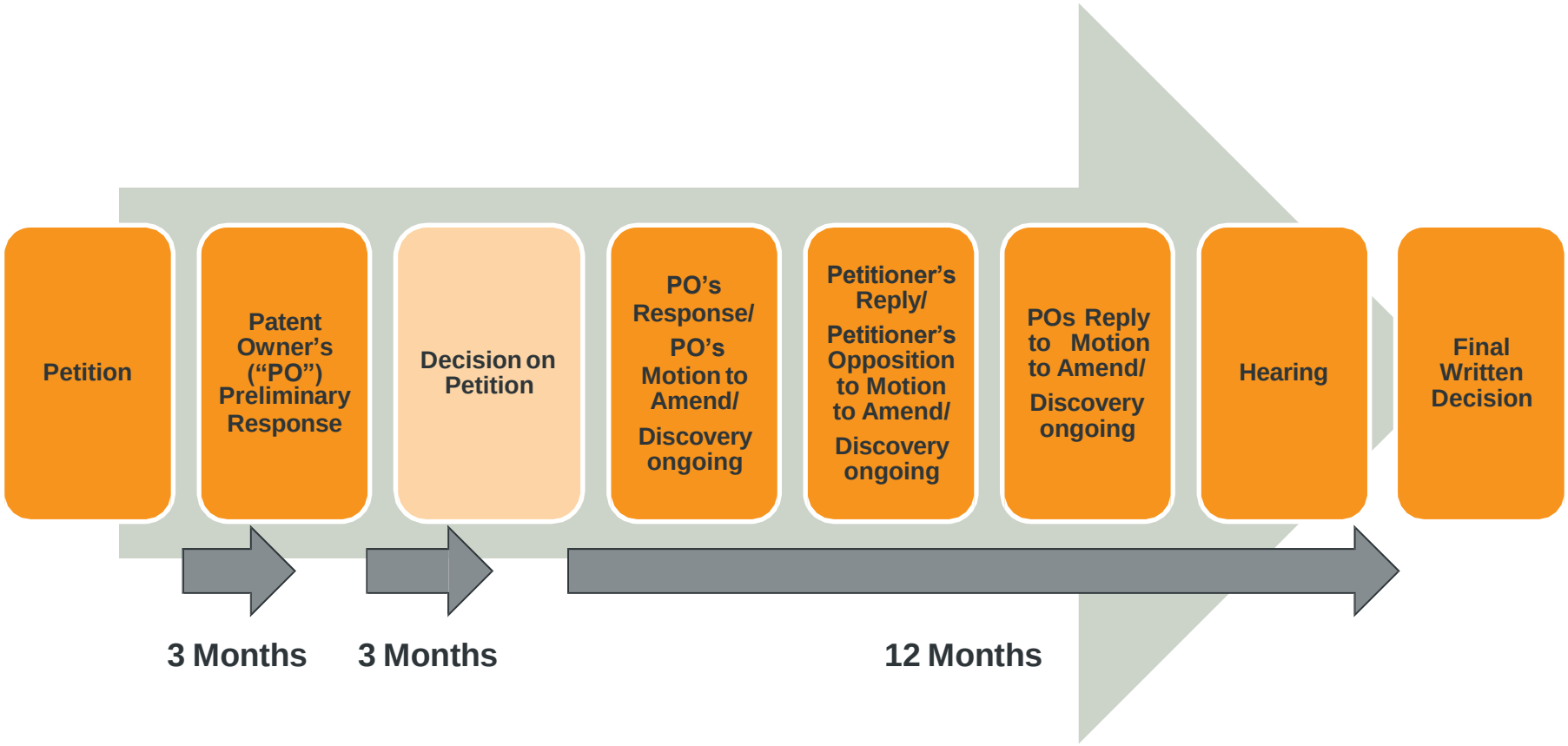
# Post Grant Proceedings: *Inter Partes* Review (IPR)

- A trial proceeding conducted at the PTAB to review the patentability of one or more claims in a patent only on a ground that could be raised under **§§ 102 or 103**, and only on the basis of prior art consisting of patents or printed publications
- Begins with a third party (not patent owner) filing a petition after the later of either:
  - (1) 9 months after the grant of the patent or issuance of a reissue patent (if priority date is on or after March 16, 2013); or (2) if a post grant review is instituted, the termination of the post grant review
- May be instituted upon a showing that there is a reasonable likelihood that the petitioner would prevail with respect to at least one claim challenged
- If the proceeding is instituted and not dismissed, a final determination by the Board will be issued within 1 year

# A Comparison of Post Grant Proceedings

| | ***Inter Partes* Review (IPR)** | **Post Grant Review (PGR)** |
|---|---|---|
| **Who may petition** | Non-owner | Non-owner |
| **What may be submitted** | Patents and printed publications | Invalidity arguments based on 101, 102, 103, and 112 |
| **Grounds for Granting Petition** | Reasonable likelihood of prevailing | More likely than not that at least one claim is unpatentable |
| **When** | For AIA patent, later of:<br>i. 9 months after issuance; or date of termination of a PGR<br>ii. Anytime for pre-AIA patent | No more than 9 months after issuance<br><br>Priority date of claims must be on or after March 16, 2013 (AIA patent) |
| **Limitations** | Cannot file if Petitioner has already filed civil action challenging validity.<br><br>Cannot file beyond one-year of being sued for infringement of challenged patent. | Cannot file if Petitioner has already filed civil action challenging validity of patent |

# A Timeline of Post Grant Proceedings



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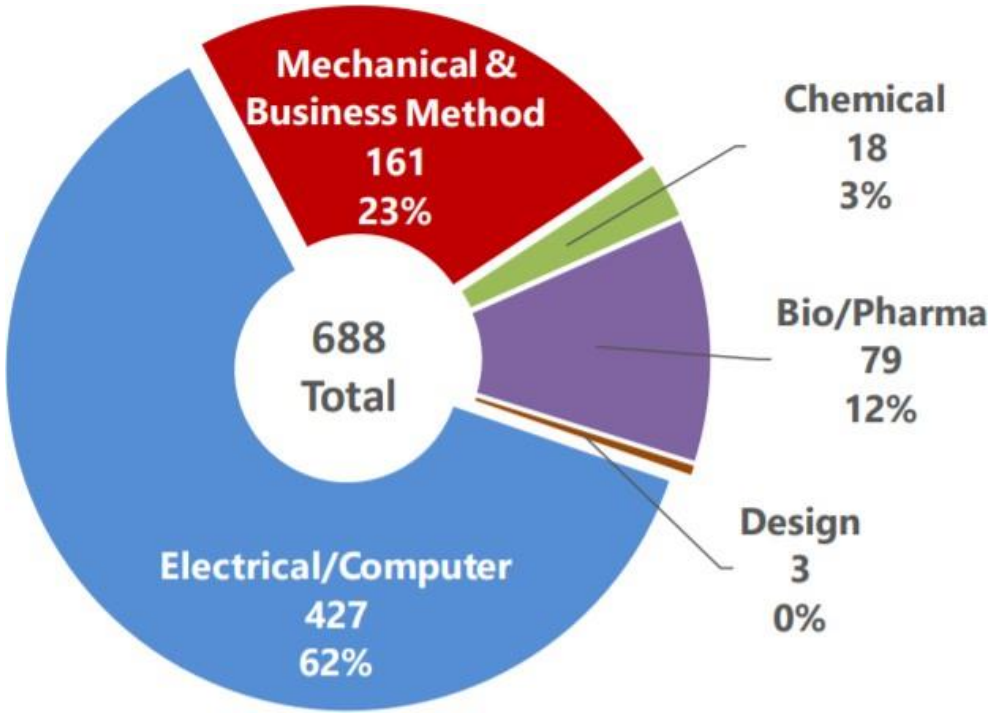
# Why Consider Filing Post Grant Proceedings?

- Lower cost
- Quicker time to decision (subject to joinder or for good cause)
- Lower burden of proof compared to district court proceedings
- Avoids patent litigation
- Presumption of patent validity does not apply
- Technically-trained judges
- Estoppel only attaches if a final written decision is issued

# Petitions Filed by Technology Between Oct. 1, 2018 and Feb. 28, 2019




Bio/Pharma Institution Rate Sept. 16, 2012 to Feb. 28, 2019 59% (455 of 769)

Source: USPTO (3/28/2019)



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# Combined with District Court Litigation Strategy

- Deadline to file an IPR petition challenging a patent asserted in litigation is one year from the date the complaint was served
- Choosing when to file is a strategic decision

| | **"Pros"** | **"Cons"** |
|---|---|---|
| **Filing early (before litigation or soon after complaint)** | • Possible cost savings, if petition causes settlement or district court action is stayed<br>• Disclosure of Patent Owner's validity positions earlier | • Stay of district court action is not guaranteed<br>• Negative PTAB decision |
| **Filing later (close to 1 year bar)** | • Discovery from district court action can be helpful<br>• Can use the threat of IPR as leverage | • Parallel proceedings to manage |

# Combined with District Court Litigation Strategy

***Expect the unexpected***

- Institution decisions are unpredictable—even some "copy cat" petitions have been denied institution

- The claim construction standard has changed:
    - Old claim construction standard was "broadest reasonable interpretation"
    - For petitions filed on or after November 10, 2018, the PTAB will use the standard applied by District Courts: "*ordinary and customary meaning as understood by a POSA*"
    - PTAB constructions binding on District Courts?

- PTAB takes a conservative approach on discovery and will occasionally grant a request for additional or supplemental discovery

- Depositions should be treated as if they were cross examination

# Estoppel

## Petitioner Estoppel

- **35 U.S.C. § 315(e):** in an IPR "that results in a final written decision" on a patent claim:
- the petitioner (and any real parties in interest or privies of the petitioner) may not assert a claim of invalidity in a district court or ITC proceeding
- against that patent claim "on any ground that the petitioner raised **or reasonably could have raised during** that *inter partes* review"

Federal Circuit guidance on the scope of 35 U.S.C. 315(e):

- No estoppel for any claim for which PTAB did not institute IPR
  - See Synopsis, Inc. v. Mentor Graphics Corp., 814 F.3d 1309 (Feb. 2016)
- No estoppel for any ground that was not instituted in the IPR
  - See *Shaw Indus. Grp., Inc. v. Automated Creel Sys.*, 817 F.3d 1293 (Mar. 2016) and *HP Inc. V. MPHJ Tech. Investments, LLC*, 817 F.3D 1339 (April 2016)

# Estoppel

## Patent Owner Estoppel

An unfavorable PTAB ruling can impact a patent family

"A patent applicant or owner is precluded from taking action inconsistent with the adverse judgment, including obtaining in any patent:

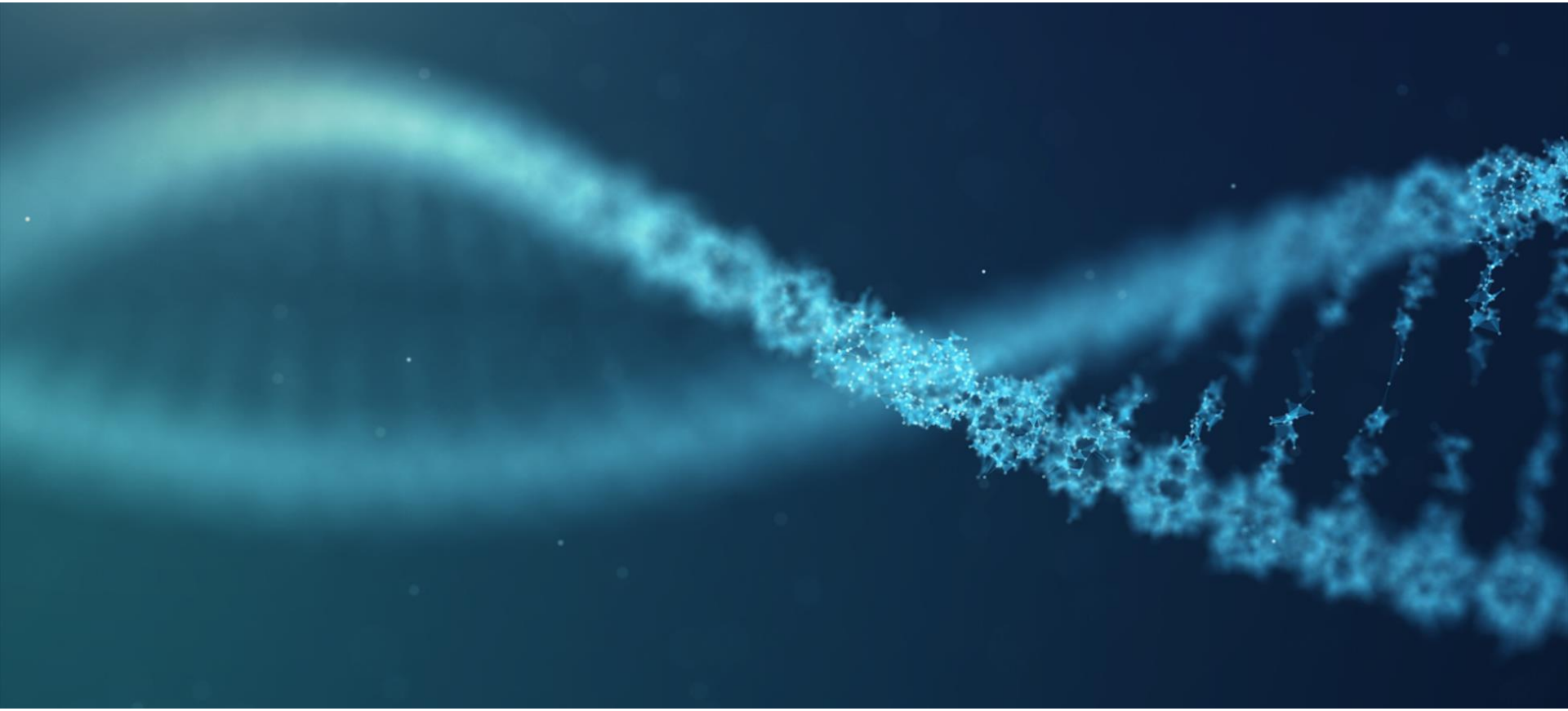
(i) A claim that is not patentably distinct from a finally refused or canceled claim…"

37 C.F.R. § 42.73(d)(3)(i)

# Limitations in PTAB for Presenting Evidence and Expert Testimony

- The PTAB has historically applied a high standard for what qualifies as a "printed publication," often requiring a showing that:
  - The publication was widely accessible in the art; and
  - A person of ordinary skill in the art looked at that source
- Example of the PTAB's "printed publication" determination:
  - Abstract added to IEEE library in November 2006 stating that an article by author was published with the proceedings of a conference in July 2006 and testimony that an article by author was included in a CD-ROM handed out at the end of the conference insufficient, Hamamatsu Photonics K.K. v. Semicaps PTE, Ltd., IPR2017-02110, Paper 35
- Choosing a good testifying expert is important even though there is no trial and no trial testimony
  - Experts will be deposed; often more than once
  - No live testimony at hearing, so depositions serve as cross examination. There is limited opportunity to "explain away" unfavorable testimony
  - PTAB rules require depositions to take place in the U.S.

# LITIGATION ISSUES TO CONSIDER WHEN LAUNCHING A BIOLOGIC
## Citizens Petitions in the FDA



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# Citizens Petitions in the FDA

- An FDA citizen petition is a process provided by the FDA for individuals and community organizations to make requests to the FDA for changes to health policy described in Title 21 of the Code of Federal Regulations (21 CFR Part 10)
- Citizen petitions are part of the basic law governing everything the FDA does - at any time, any "interested person" can request that the FDA "issue, amend, or revoke a regulation or order," or "take or refrain from taking any other form of administrative action"
- Pharmaceutical companies routinely use FDA citizen petitions to delay the entry of generic drugs into the United States marketplace
- Most citizen petitions are filed by drug companies against other drug companies
- FDA needs to respond to a petition within 150 days

# Thank You

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