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Patents in the 119th Congress: The Latest on Patent Settlements, Skinny Labeling, and Patent Thickets

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Panelists

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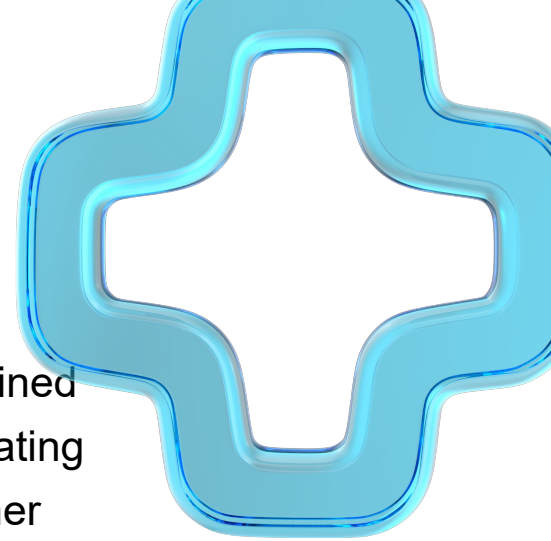
PTO Notice of Proposed Rulemaking (10/17)



- Comments due 11/17
- Proposed rules effectively remove IPR as an option for generic and biosimilar companies
  - **§ 42.108 Institution of *inter partes* review.**
    - **(d) *Required stipulation for efficiency.*** *Inter partes* review shall not be instituted or maintained unless each petitioner files a stipulation with the Board and any other tribunal where it is litigating or later litigates regarding the challenged patent, stating that if a trial is instituted, the petitioner and any real party in interest or privy of the petitioner will not raise grounds of invalidity or unpatentability with respect to the challenged patent under 35 U.S.C. 102 or 103 in any other proceeding.
    - **(f) *Parallel Litigation –*** *Inter partes* review shall not be instituted or maintained if, more likely than not, any of the following will occur, with respect to a challenged claim or an independent claim from which a challenged claim depends, before the due date for the final written decision pursuant to 35 U.S.C. 316(a)(11):

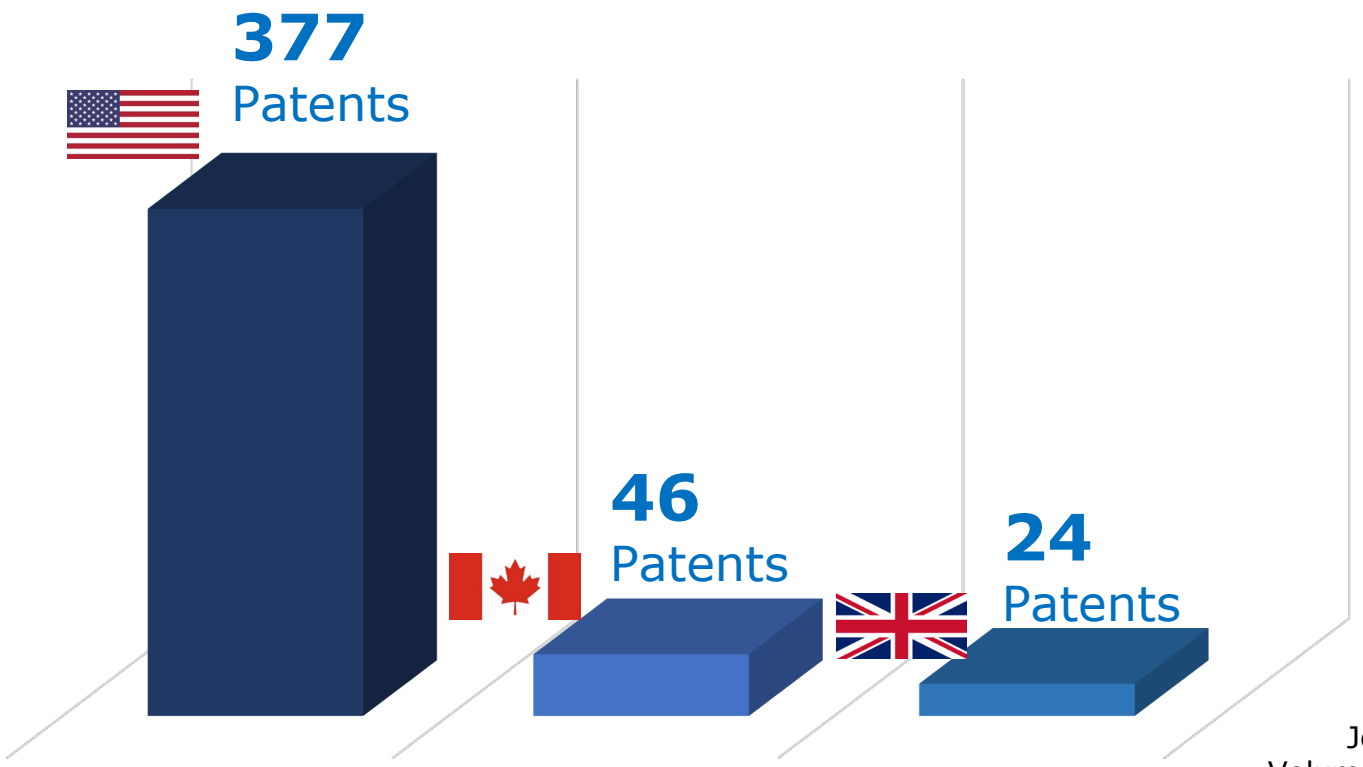
      (1) *U.S. District Court* – A district court trial in which a party challenges the patent under 35 U.S.C. 102 or 103;
      (2) *U.S. International Trade Commission* – an initial or final determination of the U.S. International Trade Commission with respect to 35 U.S.C. 102 or 103; or
      (3) *PTAB Final Written Decision* – issuance of a final written decision by the Board under 35 U.S.C. 318(a) or 328(a).

Patent Thickets

Study Results:

The U.S. is an outlier in terms of the high number of patents litigated against the same 30 biosimilars around the world

Results: total number of patents asserted against 30 biosimilars

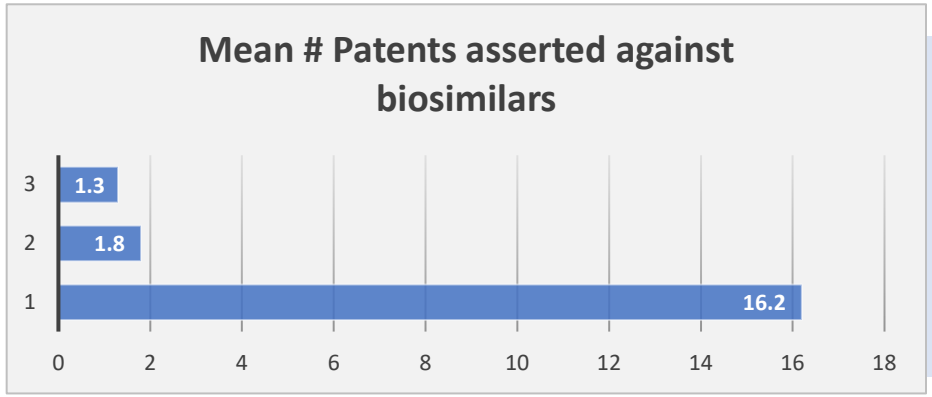


Data collected in November 2021

Journal of Law and the Biosciences,
Volume 9, Issue 2, July-December 2022,
https://doi.org/10.1093/jlb/lsac022

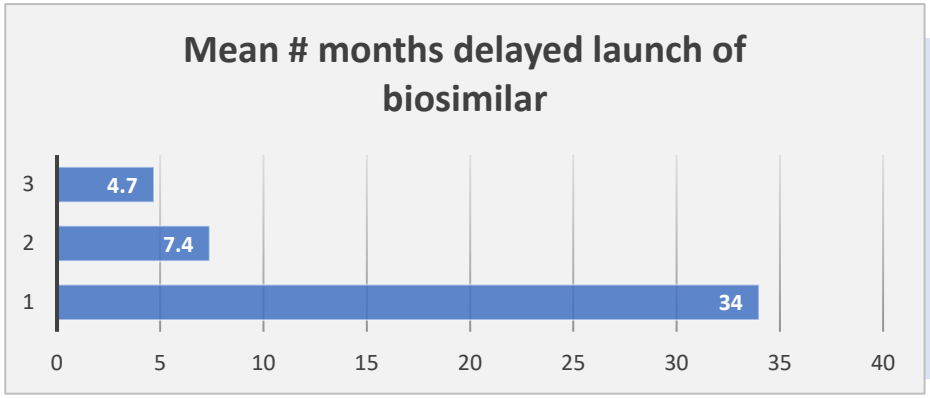
Study Results:

Large patent estates correlate with delayed biosimilar market entry in the U.S.



Footnote: data derived from the **first launched** biosimilar for each branded drug

On average, **9x more patents** are asserted against the "first launched" biosimilars in the US compared to Canada and **12x more patents** compared to the UK.



Footnote: delayed launch calculated as the time difference between regulatory approval of the biosimilar and launch of the biosimilar in each respective country

Time lapse between regulatory approval and launch compared between the US, Canada and the UK. **US sees 7x longer delayed biosimilar launch** compared to the UK.

We hypothesize that increased patent numbers in the US is one cause of delayed biosimilar launches, which leads to increased drug prices in the US.

How the U.S. manages double patenting challenges is the difference

Double-patenting and is generally prohibited by patent offices around the world.

The USPTO, however, **will allow a patentee to overcome an "obviousness-type double patenting**" challenge by filing a terminal disclaimer, which aligns the expiry date of the two, or more patents. This is supposed to ensure that patents claiming the same invention could not inappropriately extend the life of the original, or "parent patent".

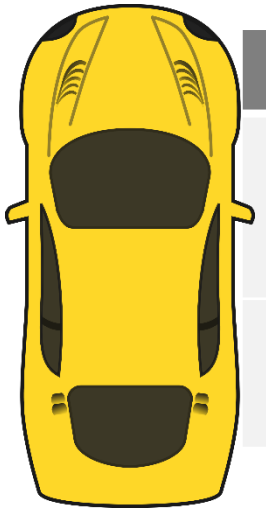
In other words, **a patent owner may obtain multiple patents with non-patentably distinct claims**. This results in a cluster of patents, tied together by terminal disclaimers.

INCREMENTALLY DIFFERENT INVENTIONS

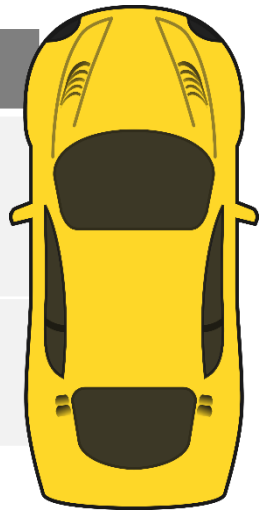
NON-PATENTABLY DISTINCT INVENTIONS

Finding: Patent thickets are comprised mostly of non-patentably distinct inventions.

Examples:



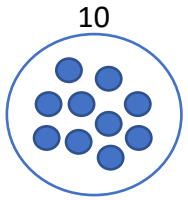
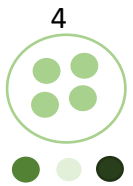
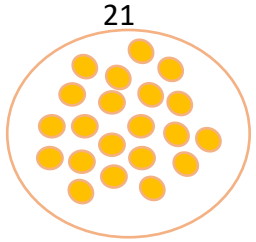
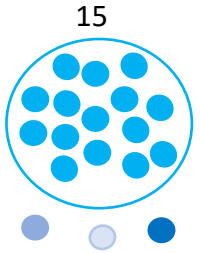
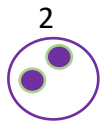
Patent	Summary of Claims
Patent 1	A method for treating rheumatoid arthritis in a human subject, administering subcutaneously a total body dose of 40 mg of [drug A] once every 13 - 15 days for a time period sufficient to treat the rheumatoid arthritis
Patent 2	A method of reducing signs and symptoms in a patient with moderately to severely active rheumatoid arthritis, administering subcutaneously a total body dose of 40 mg of [drug A], once every 13-15 days



Patent	Summary of Claims
Patent 1	Method of treating Crohn's disease with [drug b] Administer a first dose of 160mg Two weeks later administer a second dose of 80mg
Patent 2	Method of treating Crohn's disease with [drug b] Administer a first dose of 160mg (as 4 sets of 40mg injections) Two weeks later administer a second dose of 80mg (as 2 sets of 40mg injections)

How do originators get 73 patents from 14 inventions?

Case study: US patent portfolio of Drug X

Filed in 1996	Filed in 2001	Filed in 2002	Filed in 2002	Filed in 2006	Filed in 2010	Filed in 2007	Filed in 2007
							
Product	**Primary indications**	**Formulation**	**Secondary indications**	**Purity level**	**Tertiary indications**	**Juvenile indications**	**Follow-on formulation**
1 invention	**4 inventions**	**1 invention**	**4 inventions**	**1 invention**	**1 invention**	**1 invention**	**1 invention**
10 patent cluster	4 patent cluster + 3 distinct patents	21 patent cluster	15 patent cluster + 3 distinct patents	8 patent cluster	2 patent cluster	3 patent cluster	4 patent cluster

80% of patents within this portfolio are non-patentably distinct from one another

= one patent

= a cluster of patents linked through terminal disclaimers (non patentably-distinct inventions)

= a patent family (Inpadoc standard definition)

Summary: 73 patents; 14 distinct inventions; 59 patents are non-patentably distinct

Comparison case study:
Patent portfolio of the same drug in Europe

Case study: US patent portfolio of Drug X

Filed in 1996	Filed in 2001	Filed in 2002	Filed in 2002	Filed in 2006	Filed in 2010	Filed in 2007	Filed in 2007
2	2	2	1	Patent not granted	1	Patent not granted	Patent not granted
Product	**Primary indications**	**Formulation single conc**	**Secondary indications**	**Purity level**	**Tertiary indications**	**Juvenile indications**	**Formulation double conc**
2 inventions	**2 inventions**	**2 inventions**	**1 invention**	**-**	**1 invention**	**-**	**-**
2 distinct patents	2 distinct patents	2 distinct patents	1 distinct patent	-	1 distinct patent	-	-

= one patent

= a cluster of patents linked through terminal disclaimers (non patentably-distinct inventions)

= a patent family (Inpadoc standard definition)

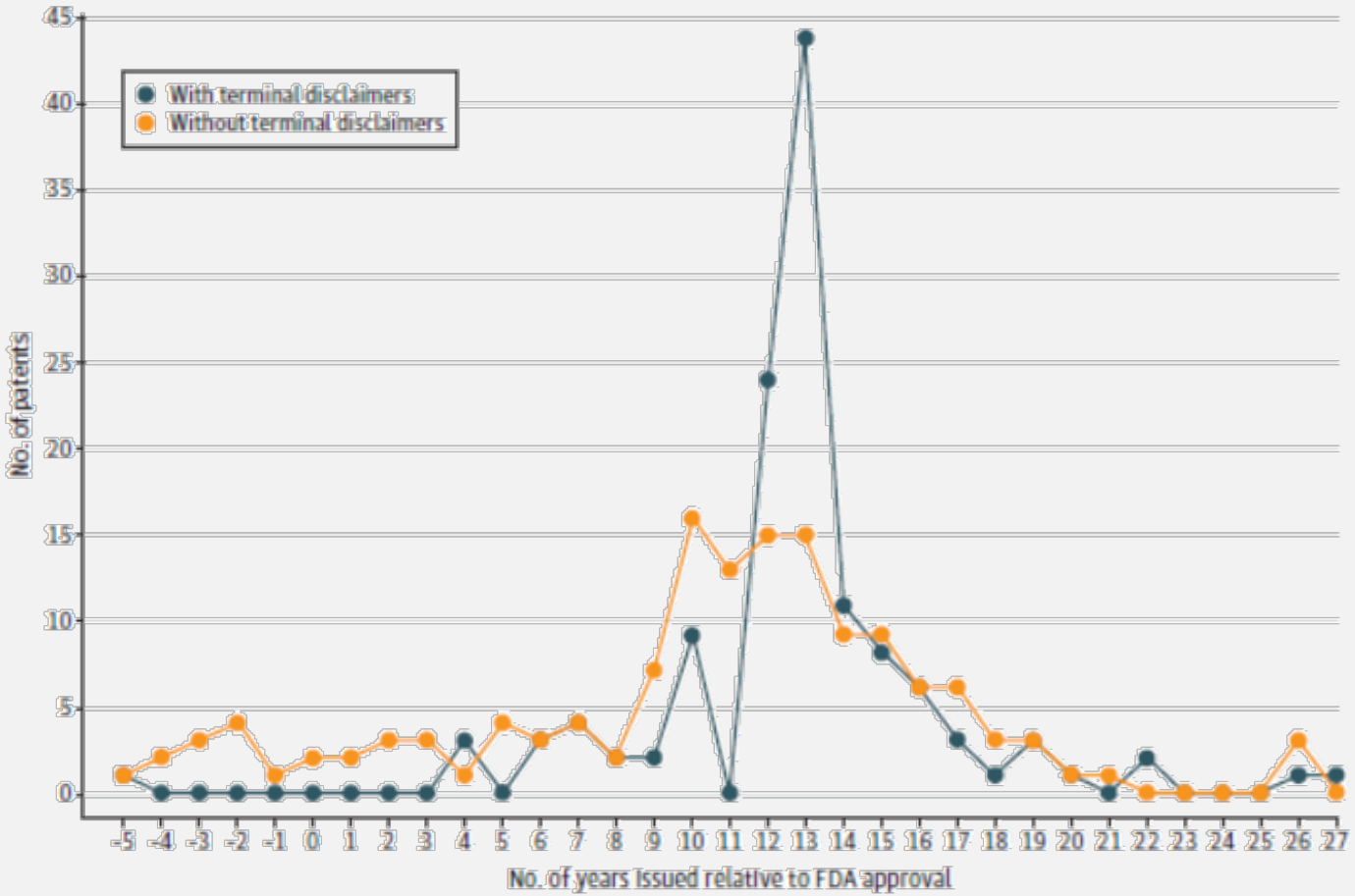
Summary:

8 patents; 8 inventions; 0 patents are non-distinct; 0% of the portfolio is duplicative

Why do we think this is a calculated strategy to slow down biosimilar entry?

By adding patents with terminal disclaimers beginning in year 12, biologic manufacturers introduce uncertainty precisely when biosimilar challenges begin and as the product patent PTE typically expires. Biologic exclusivity expires at year 12. Biosimilar manufacturers must then contest, settle, or design around a wave of new patents that become enforceable just as statutory exclusivity periods end. This effectively shields secondary patents from scrutiny.

Figure. Number of Patents With vs Without Terminal Disclaimers Involved in Litigation Relative to Drug Approval From the US Food and Drug Administration (FDA)



The pronounced peak for patents with terminal disclaimers in the study group occurred in years 12 and 13, coinciding with the end of FDA-granted statutory exclusivity and shortly before the typical expiration of product patent PTEs.

The Eliminating Thickets to Increase Competition (ETHIC) Act (S. 2276/H.R.3269)

Rep. Arrington (TX), Rep. Doggett (TX), Sen. Hawley (MT), Sen. Welch (VT)

Under the bill, a branded drug company can assert only one patent for each patentably-distinct improvement made on the drug. The more the drug is innovated, the more patents the innovator can assert against a generic or biosimilar manufacturer.

The bill applies only to patents asserted against generic and biosimilar drug manufacturers and does not impact other industries.

Rewards innovation by ensuring that every improvement to a drug gets the intellectual property protection it deserves.

Allows a drug company to assert one patent per 'terminally disclaimed group' against a generic or biosimilar competitor, meaning if one patent in a family of duplicates is struck down by the courts, then all of its duplicates will also be invalidated.

Numbers Game

A biosimilar company must invalidate every single patent for freedom to launch, and cannot use the invalidation of one non-patentably distinct patent as a ground to dismiss another in the same cluster.

Patent owners need only prove that one of the patents in a cluster is valid and infringed in order to block a biosimilar form the market.

+

This is a numbers game that brands know generics and biosimilars can't win. It is much cheaper to obtain a patent than to challenge a patent:

- Approximately, $25,000 to obtain and maintain a patent.
- Approximately $1 million to challenge a biological patent via an IPR/PGR.

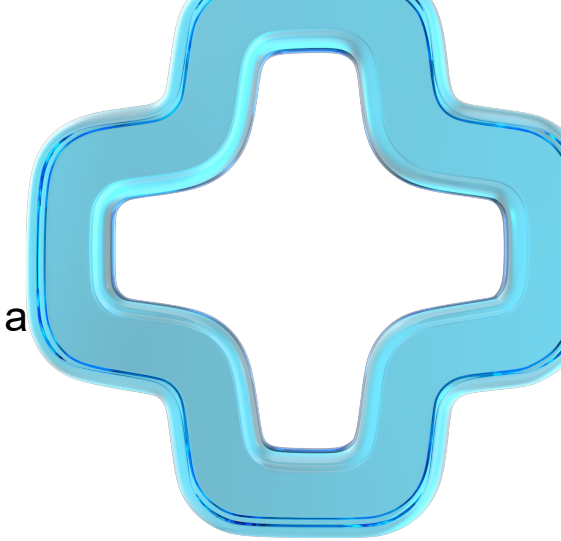
=

Challenging a mountain of patents is unfeasible both for competitors and federal courts, allowing innovators to shield secondary inventions from scrutiny.

Unchallenged, the most expensive drugs on the market maintain monopolies long after originators have recouped their investments and been rewarded for their inventions, and after lower cost alternatives have come to market in allied countries.

Patent Settlements

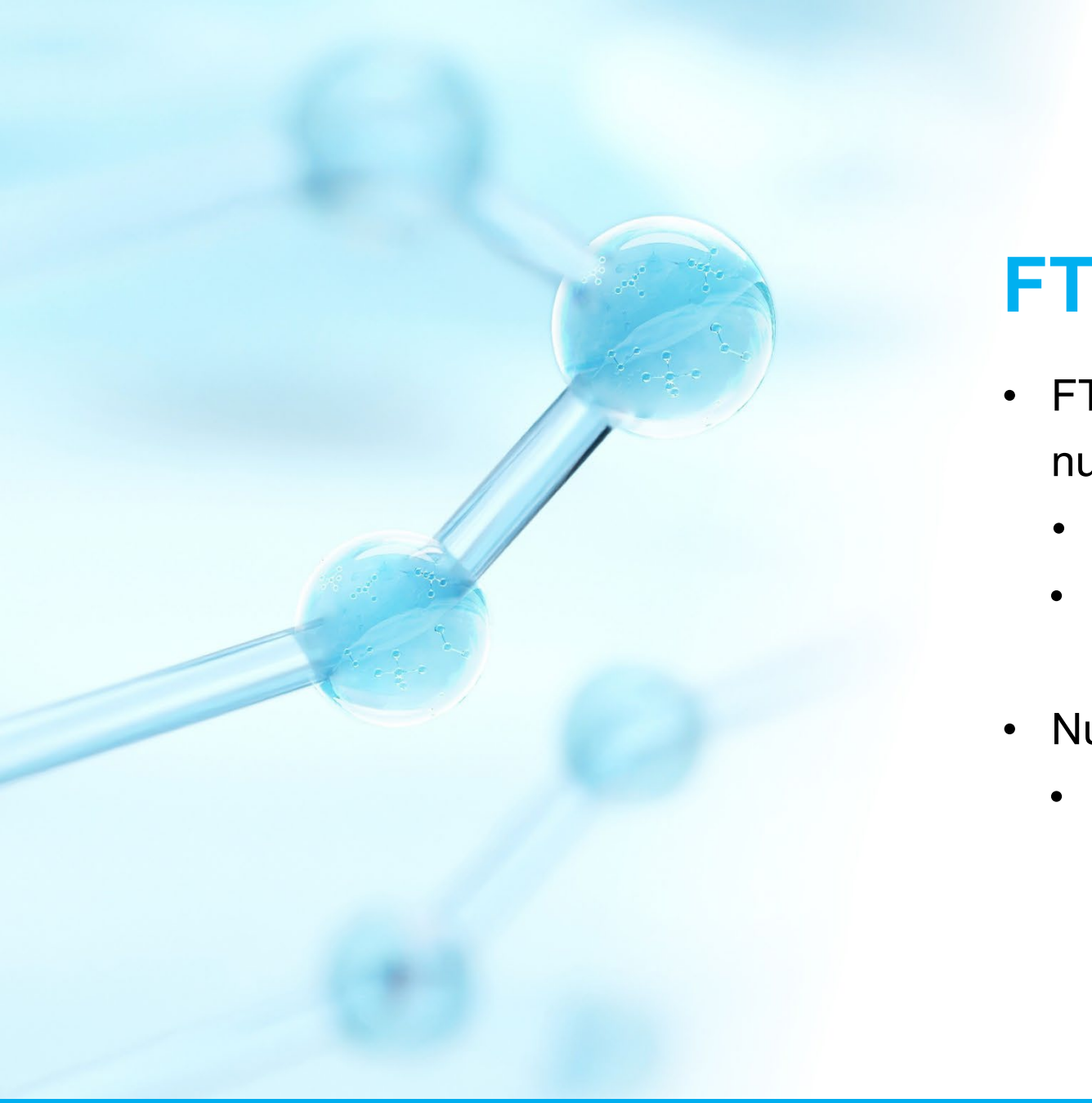
S. 1096: Preserving Access to Affordable Generics and Biosimilars Act



- Bill prohibits brand sponsors from compensating generic/biosimilar sponsors to delay market entry of a substitutable drug
  - Precludes "anticompetitive agreements" in patent settlements
    - ***Presumes*** anticompetitive effect of patent settlement if:
      - Generic/biosimilar sponsor receives "anything of value," including an exclusive license, in exchange for agreement to limit or forego development of ANDA/biosimilar for any period of time
    - Exception if:
      - Parties can demonstrate by preponderance of the evidence that the value is compensation solely for goods or services the follow-on sponsor has promised to provide; or
      - Procompetitive benefits outweigh anticompetitive effects
    - Shifts burden of proof to companies to demonstrate agreement is pro-competitive or legitimate
- Civil Penalties: Commission may bring a civil action for remedies of civil penalty, mandatory injunctions, and further equitable relief
  - Penalties include forfeiture of "anything of value" and potential treble damages

FTC Settlement Authority

- Medicare Modernization Act requires manufacturers to file certain types of patent settlements (and agreements entered within 30 days of an initial agreement) with the FTC
  - Generic-Brand Agreements
  - Biological Product Agreements
  - Generic-Generic Agreements
  - Biosimilar-Biosimilar Agreements
- Review focuses on substance of agreements
  - Intended to identify “reverse payments” that include “large and unjustified” payments from the brand to generic



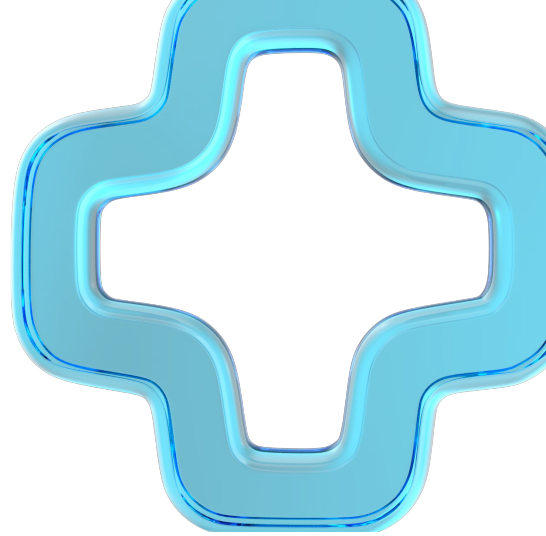
FTC Data

- FTC releases reports each fiscal year with number of patent settlements reviewed
  - Latest data from 2021
  - Shows 199 patent settlements reviewed for 86 distinct products
- Number of problematic settlements low
  - While patent settlement agreements have grown increasingly complex, explicit reverse payments have become less common.

FTC Data

	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Final Settlements	14	11	28	33	66	68	113	156	140	145	160	170	232	226	245	194	205	199
w/ Restriction on Generic Entry and Compensation	0	3	14	14	16	19	31	28	40	29	21	14	30	20	38	24	20	33
w/ Restriction on Generic Entry and Compensation (excluding Solely Litigation Fees ≤ $7 million)	0	3	13	14	15	11	17	25	33	15	11	5	1	3	2	3	1	0
w/ Restriction on Generic Entry and Compensation Involving First Filers	0	2	9	11	13	15	26	18	23	13	11	7	16	6	18	14	11	14

IQIVIA Data on Patent Settlements



- Report, titled "Assessment of the Impact of Settlements," examines effects of patent litigation settlements on patient savings and access
- Assessed 288 molecules for settlement information and found 84 involved patent settlements with early or timely generic/biosimilar entry
  - Product launches averaged ***64 months*** before patent expiry
  - 17% of the cases accelerate generic or biosimilar entry by more than a decade prior to patent expiry
- Average savings to the healthcare system per molecule are ***$5 billion***.

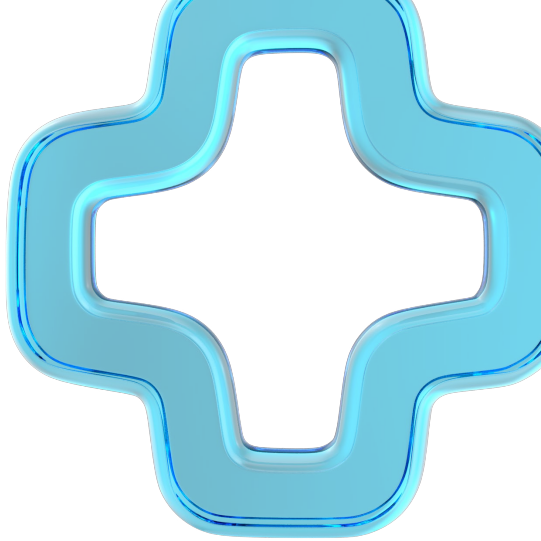
Median Savings	$516.4 M
Mean Savings	$5.0B
Total Savings	$422.9B
Median Months Prior to Patent Expiry	56
Mean Months Prior to Patent Expiry	64
Total Months Prior to Patent Expiry	5,365

SEC v. Jarkesy

Supreme Court ruled that the SEC could not use its administrative authority to impose civil penalties for securities fraud through ALJs without violating 7th Amendment right to a jury trial. In other words, right to jury trial extends to actions by federal government.

Skinny Labeling

Skinny labels



- Section viii statement allows ANDA sponsor to “carve-out” patented method of use from product labeling
  - Section viii statements are supposed to allow ANDA applicants to avoid litigation by not infringing patent
  - But carve-outs need to be consistent to avoid incongruent IRs and may require FDA input to disentangle less obvious carve-outs
- Recent litigation, *GSK v. Teva*, raises risk of induced infringement claims for carve-outs
  - Fact-specific inquiry, looks to whether the ANDA applicant carved out all patented indications
  - Press releases, promotions, website, “AB-rated” claims, investor-related docs

GSK v. Teva

- Teva's approved ANDA for GSK's carvedilol carved-out congestive heart failure (CHF) indication
  - In 2014, GSK sued Teva for induced infringement of its CHF patent
    - Jury found Teva liable for induced infringement
    - But District Court granted Judgement as Matter of Law stating that GSK failed to show that Teva caused doctors to prescribe its generic
- GSK appealed to Federal Circuit
  - Federal Circuit held that induced infringement demonstrated by "ample record evidence" including promotional materials, product catalogs, and FDA labeling
    - Implied that labeling alone may have been enough to induce infringement due to insufficient carve-out
  - Reinstated $235 million jury verdict
  - Upheld after panel rehearing
- Supreme Court declined to hear → back to District Court

Amarin v. Hikma

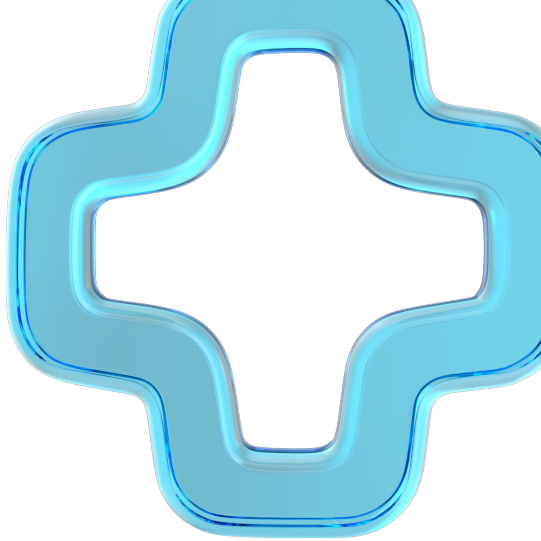
- Hikma received approval for generic of Amarin's Vascepa with 3 Amarin patents covering CV indication carved out
  - Amarin sued Hikma for induced infringement
    - Alleged that Hikma's approved label "is 'not skinny-enough'" and instructed CV indication due to side effect warning and no disclaimer
  - District Court found for Hikma, rejecting theory that warning is instruction
    - Other promotional statements not sufficient to support inducement
    - No affirmative steps to induce infringement – intent is not enough
- Federal Circuit reversed because Amarin's allegations against Hikma plausibly state a claim for induced infringement.
  - Appealed to SCOTUS – solicitor general invited to submit brief

Amarin v. Hikma

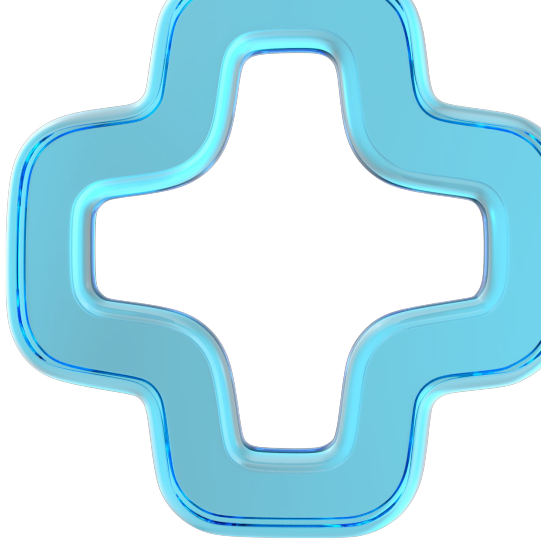
- Amarin also sued Health Net, an insurer that provides coverage for both Amarin's Vascepa and Hikma's generic
  - Amarin alleged that Health Net's placement of Hikma's generic on formulary induces substitution for CV indication, despite carve-out

    Health Net also listed generic for CV indication on Prior Authorization Form
- Claims against Health Net survived Motion to Dismiss
  - Court said that incentives in place to prescribe formulary raises factual questions
- Parties settled 1/3/2023

S. 43: The Skinny Label, Big Savings Act



- Response to *GSK v. Teva*
- Provides a statutory safe harbor from patent infringement claims based on skinny labels
- Actions not considered infringement of a method of use claim:
  - submitting or seeking approval of a skinny label;
  - promoting or commercially marketing a drug with skinny labeling;
  - describing a drug product approved by the FDA as a generic of, or therapeutically equivalent to, the branded drug.



Questions?