The Evolving Jurisprudence of Patent Thickets:
Decisions, Legislation and Future Considerations

Fangli Chen, Partner
Baldassare (Baldo) Vinti, Partner

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Proskauer Speakers

Fangli Chen, Ph.D.
Partner and Vice Chair, Life Sciences Patent Practice
+1.617.526.9633
fchen@proskauer.com

Baldassare (Baldo) Vinti
Partner and co-Head, Intellectual Property Group
+1.212.969.3249
bvinti@proskauer.com

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Overview

- What Is a Patent Thicket?
  - Why Does a Patent Thicket Exist?
  - Patent Thickets vs. Life Cycle Management
- Patent Thicket Examples
  - AbbVie's Patent Thickets for Humira®
  - Patent Thickets for Other Products
- Are Patent Thickets Legal?
  - Humira Antitrust Litigation
  - Possibilities for Future Patent Thicket Challenges
  - Pending Legislation to Address Patent Thickets
- Key Takeaways
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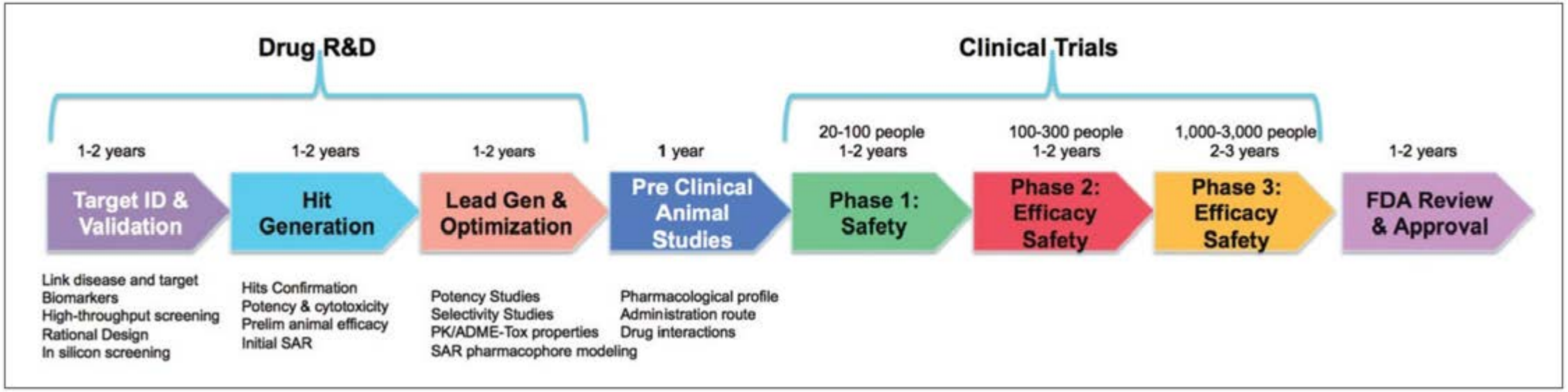
What Is a Patent Thicket?

- A patent thicket is "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology."
  - Or more simply put: "multiple patents that cover a single product or technology."
- The term first came up in the 1970s regarding an antitrust lawsuit against Xerox, in which the plaintiff, SCM Corporation, claims that Xerox had "created a 'patent thicket' strong enough to prevent SCM and others from making plain-paper office copiers."
- A patent thicket is also known as a "wall of patents."

Why Does a Patent Thicket Exist?

- To extend market exclusivity
  - Pharmaceutical companies have effectively used patent thickets to extend market exclusivity, block out competitors, and maximize the return on the investment in the drug development.

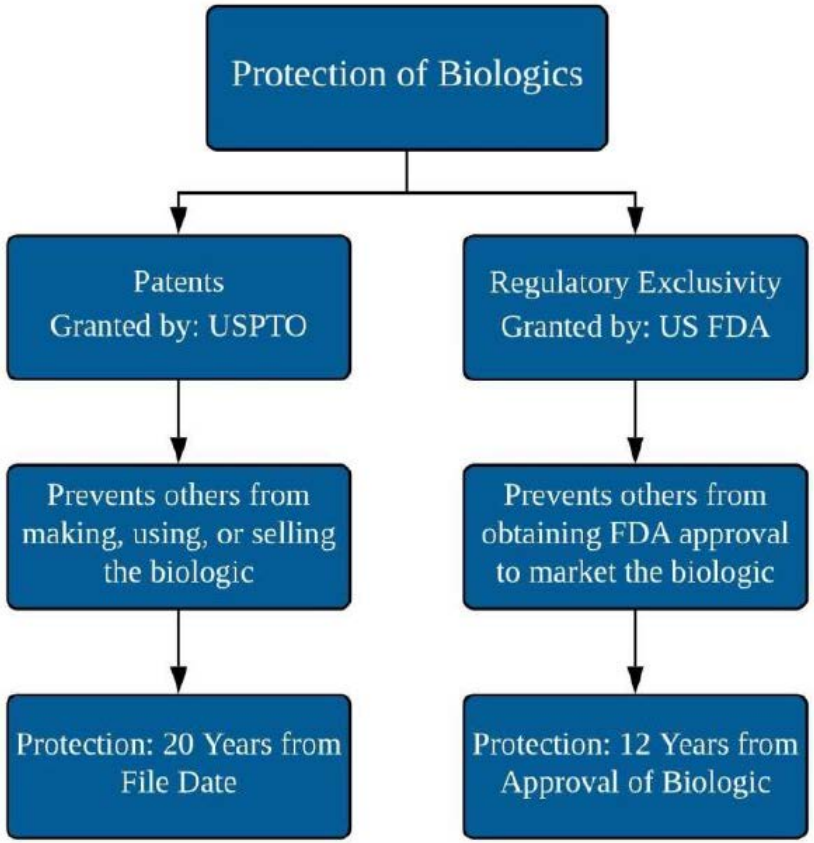
Drug Development Timeline



- It typically takes 10-15 years and millions of dollars to bring a drug to market.
- The original composition patent typically expires within 5-10 years after the launch of the product.

How do you protect the enormous investment and secure a fair return?

Patents vs. Regulatory Exclusivity for Biologics



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Life Cycle Management of Patents: Evergreen

To provide effective patent protection, drugmakers extend the market exclusivity of a drug beyond the life of its original patent by obtaining multiple patents that cover different aspects of that drug, including:

- Compositions (e.g., structures, antibody CDRs and variable regions, etc.)
- Method of use (e.g., specific indications)
- Formulations
- Methods of manufacturing
- Expression systems
- Mechanisms of actions

- Dosing
- Mode of administration
- Biomarkers
- Patient stratification
- Efficacy
- Combination therapy

Patent Thickets vs. Life Cycle Management

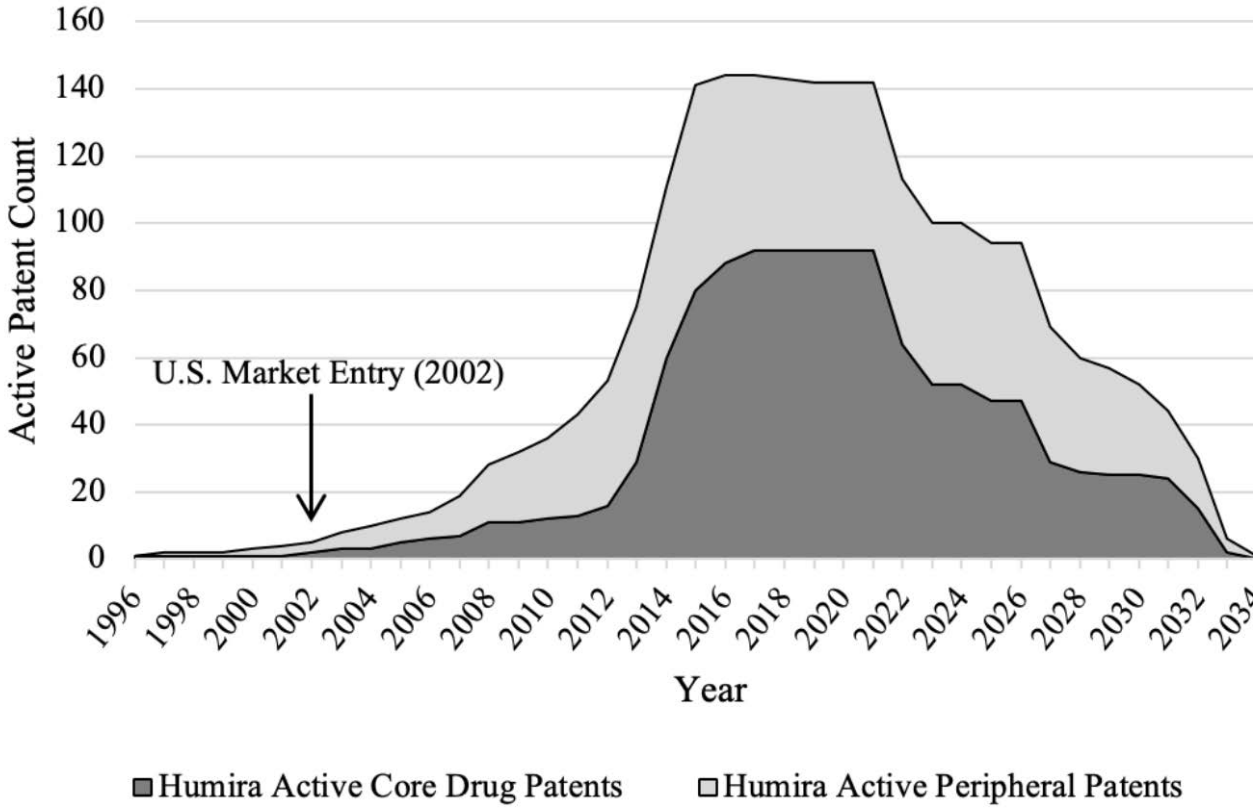
- The difference between patent thickets and life cycle management is that the primary concern of the former is the number of patents while that of the latter is the increased year span of the collective patent term.
- However, patent thickets and life cycle management interplay with one another, with the former having the inherent capability to achieve the latter.

In other words, patent thickets are an aggressive version of life cycle management.

AbbVie's Patent Thickets for Humira

- By one estimate, AbbVie filed 247 patent applications and obtained 132 patents by 2018, directed to uses, processes of manufacturing, and ingredients and formulations.
  - These >100 patents can be traced to 20 root patents, 15 of which are formulation or manufacturing patents (and account for 84 of the issued patents)
- These patents could have protected Humira for up to 39 years.
- The original core patents for Humira® expired in 2016.
- However, the price for Humira jumped 144% since 2012.

AbbVie's Patent Thickets for Humira



Jeffrey Wu & Claire W. Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 Chi.-Kent J. Intell. Prop. 93 (2020). Available at: https://scholarship.kentlaw.iit.edu/ckjip/vol19/iss1/12

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AbbVie Created Patent Thickets for Imbruvica

- AbbVie used the same strategy to protect its small molecule compound drug Imbruvica.
- AbbVie has filed 165 patent applications for Imbruvica and obtained 88 patents.
- AbbVie filed 55% of Imbruvica's patent applications after FDA approval.
- The company’s add-on patents have earned AbbVie another 9 years of patent protections for a total of 29 years of market exclusivity.

Other Companies also Use Patent Thickets

- **Rituxan (Biologic)**
  - > **80** patent applications have been filed
- **Revlimid (Small Molecule)**
  - > **73** patent applications have been filed
- **Enbrel (Biologic)**
  - > **47** patent applications have been filed

Are Patent Thickets Legal?

Humira Antitrust Litigation

- In March 2019, a proposed class filed in Illinois federal court accusing AbbVie of anti-competitive behavior.
- Plaintiffs allege that AbbVie abused its monopoly by "obtaining and asserting 'swaths of invalid, unenforceable, or non-infringed patents.'"
- Plaintiffs pointed to AbbVie's comments:
  - "the bulk of AbbVie's IP strategy was to 'make it more difficult for a biosimilar to follow behind.'"
  - "[AbbVie] CEO noted that market entry by biosimilars would be delayed because patent litigation takes more than four years and at-risk launches are rare."
  - "It simply is not feasible for biosimilar manufacturers to engage in time-consuming and expensive patent litigation against this mass of dubious patents**."**

Humira Antitrust Litigation

- AbbVie argued that there is no basis for limiting the number of patents a company can hold, in view of U.S. Supreme Court precedent, any such limit would be "arbitrary and unworkable line-drawing."
- "AbbVie's rate of success with its patent applications…compels the conclusion, as a matter of law, that more than half of AbbVie's patent applications were not objectively baseless."
- With respect to post-grant challenges in *inter partes review* [IPR] petitions, "AbbVie's success rate was even higher…while the Patent Trial and Appeal Board [PTAB] found invalid three of the five AbbVie patents that it reviewed…it declined to initiate *inter partes review* with regard to thirteen of AbbVie's other patents."

AbbVie Beats Antitrust Challenge to "Patent Thicket"

- **June 2020:** Lawsuit is dismissed, holding that plaintiffs have failed to allege either an antitrust violation or an antitrust injury.
  - "Abbvie has exploited advantages conferred on it through lawful practices and to the extent this has kept price high for Humira, existing antitrust doctrine does not prohibit it,"
- **July 2020:** Plaintiffs have filed an appeal of the decision with the Seventh Circuit Court of Appeals.
  - Legal experts predicted that odds of success of the appeal don't seem high

Possibilities for Future "Patent Thicket" Challenges

- **Focus on Non-Petitioning Activity**
  - The BPCIA information exchange does not involve petitioning activity.
    - *Humira* court noted that AbbVie's baseless patent assertions constituted a "kernel" of anticompetitive activity.
  - Future plaintiffs may embrace alternate theories:
    - Target patent dance: Natural extension of orange book cases. *See, e.g.*, *In Re: Lantus Direct Purchaser Antitrust Litigation*, 950 F.3d 1, 10-14 (1st Cir. 2020).
    - Bundling and rebates: See, e.g., *In re Remicade Antitrust Litigation*, No. 18-cv-2357-JCJ (E.D. Pa. 2017),

Pending Legislation to Address "Patent Thickets"

- **S.1416 – Affordable Prescriptions for Patients Act (Intr. 5/9/19)**
  - Would prohibit "product hopping"—defined as either a "hard switch" (ref. prod. withdrawn; follow-on product sold) or a "soft switch" (RPS "took actions" favoring its follow-on over its ref. prod.; such actions can be justified).
  - Would amend 35 USC § 271(e) to limit the number of patents that can be asserted in BPCIA litigation.
- **H.R.3991 – Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019 (Intr. 7/25/19)**
  - Would limit the number of patents that can be asserted in BPCIA litigation, absent good cause.

Pending Legislation to Address "Patent Thickets"

- **H.R.3199 – Terminating the Extension of Rights Misappropriated Act (Intr. 6/11/19)**
  - Would apply presumption of patent term disclaimer after the expiry of first-expiring patents asserted in Hatch-Waxman/BPCIA cases, absent a demonstration of "patentably distinct inventions" in later-expiring patents.
- **H.R.3379 – Price Relief, Innovation, and Competition for Essential Drugs Act (Intr. 6/20/19)**
  - Would limit FDA exclusivity for "brand name" biologics from 12 to 5 years.
- **H.R.1520 – Purple Book Continuity Act of 2019 (Passed House 5/8/19)**
  - Would amend the BPCIA to require RPS to publish list of patents disclosed in pre-suit exchange—akin to listing of patents in Orange Book.

Examples of Successful "Patent Thicket"

Teva/Ajovy (fremanezumab-vfrm)

- **Background:** Ajovy was approved in 2018, followed soon by Eli Lilly's Emgality. Teva hoped to use sales from Ajovy to help repay its debt from buying Allergan's generic drug business. Teva sued Lilly soon after Lilly launched, and Lilly filed IPRs against nine of Teva's patents.
- **Result:** In March 2020, the PTAB upheld the validity of three of Teva's patents (but found the remaining six invalid).
- **Impact:** The PTAB's decision was a success for Teva as it may continue assert its patents. Ajovy is expected to generate around $500 million in sales by 2022.

Examples of Successful "Patent Thicket"

Amgen/Enbrel (enterecept)

- **Background:** Amgen has filed over 47 patents covering Enbrel ® and methods of making it. Enbrel faced possible competition, including from Sandoz's Erelzi, which was approved in 2016. Amgen sued Sandoz for infringement.
- **Result:** In July 2020, the Federal Circuit affirmed a district court ruling upholding the validity of Amgen's patents.
- **Impact:** The ruling should fend off biosimilars until 2028-29, and puts Enbrel on track to become one of the biggest-selling blockbusters in history.

Key Takeaways

- Multiple patents covering various aspects of a product is an effective and crucial life cycle management tool.
- *Humira* decision validated the “Patent Thicket” strategy, at least for now.
- Future challenges might embrace alternate theories.
- Congress could intervene.

Questions?
Thank you.

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