Hatch-Waxman: Positioning Your Company For Success Against Generic Challenges

Life Sciences Webinar Series

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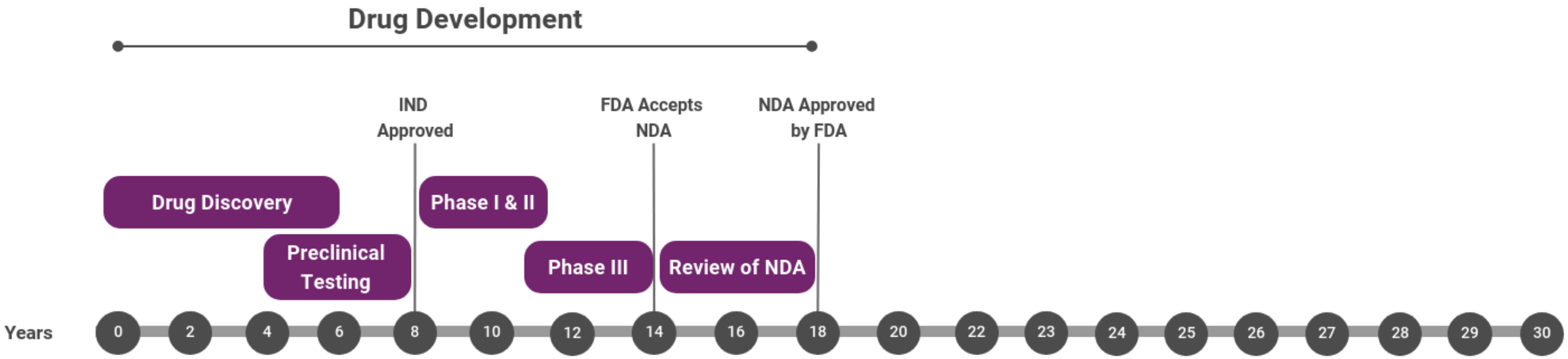
Drug Development Timeline



Hatch-Waxman Timing

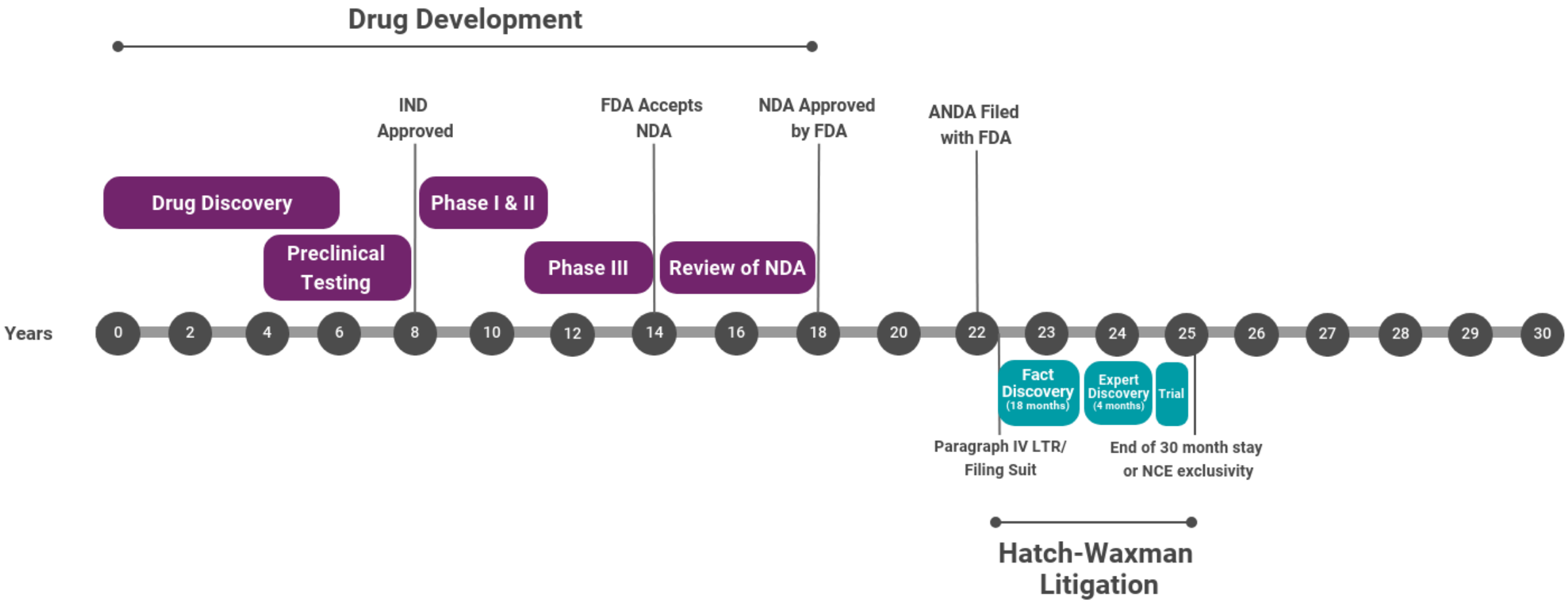
- **Exclusivities**
  - New Chemical Entity (“NCE”) – 5 years
  - Marketing – 3 years
  - Pediatric
  - Orphan Drug

- **Timing of ANDAs**
  - Marketing exclusivity – ANDAs can be filed any time after NDA approval
  - NCE exclusivity – ANDAs can be filed four years after NDA approval if ANDA includes a Paragraph IV certification

- **Filing of ANDA is an “artificial act” of infringement**
  - NDA sponsor can sue when it receives paragraph IV notice

- **Stay of FDA Approval**
  - If suit brought within 45 days of notice, FDA cannot finally approve ANDA for 30 months from filing of the lawsuit
  - OR, for drugs with NCE exclusivity, 30 months from 5 year exclusivity date

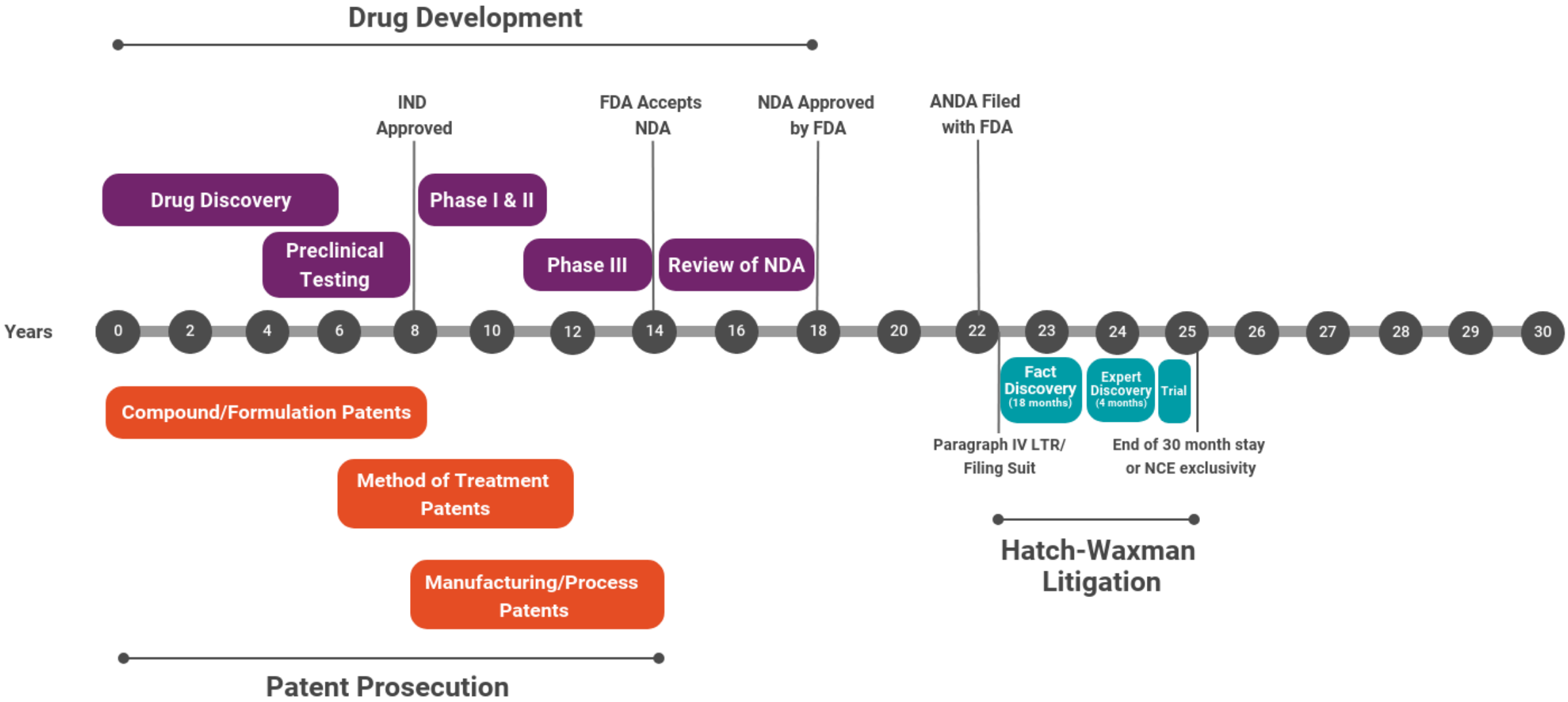
Hatch-Waxman Timeline



Hatch-Waxman Trial

- **Types of Patents**
  - Orange Book-Listed Patents
    - Compound
    - Formulation
    - Methods of treatment
    - Polymorph
  - Devices
  - Process patents
  - Metabolite patents

Hatch-Waxman Timeline



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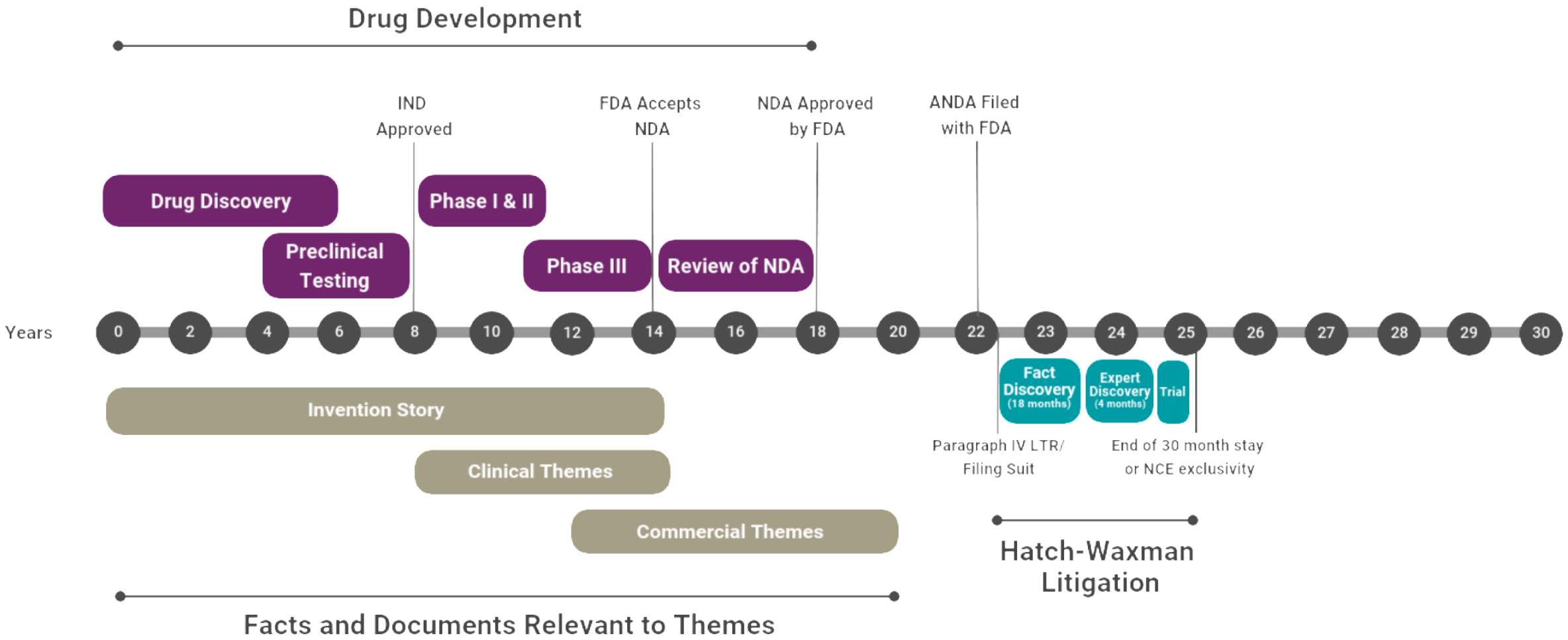
Hatch-Waxman Trial

- **Themes**
  - Invention story
  - Clinical benefits
  - Commercial impact

- **Fact Witnesses**
  - Inventor(s)
  - Face of the company/clinician
  - Commercial witness

Hatch-Waxman Timeline



Invention Story – Why Is It Important?

Finally, the process engaged by the inventors' demonstrates the highly unpredictable nature of the prodrug development approach. The inventors prepared 20 prodrug candidates and evaluated their conversion rates and absorption rates. Pfizer submitted evidence that their **[*40]** experiments yielded unpredictable results. (Tr. 435:10-18, 436:18-19, 437:1-12 (Maag).) The inventors' results, and Dr. Janero's ultimate admission that prodrugs are complicated, are powerful evidence of the unpredictability inherent in prodrug design, a factor that weighs strongly against an obviousness finding. *Procter & Gamble Co. v. Teva Pharm USA, Inc., 566 F.3d 989, 996 (Fed. Cir. 2009)* (highlighting unpredictability seen with a class of compounds in finding nonobviousness). This

Pfizer Inc. v. Mylan Pharms. Inc., 2017 U.S. Dist. LEXIS 125634, *39-40 (D. Del. Aug. 9, 2017)

[20] I find even stronger support for the non-obviousness of claim 16 of the '456 patent in the struggles of the inventors to arrive at rivaroxaban. The plaintiffs describe the fortuitous path the inventors took to arrive at rivaroxaban,

Bayer Intellectual Prop. GmbH v. Aurobindo Pharma Ltd., 2018 US. Dist. LEXIS 116931 *39, n. 20 (D. Del. July 13, 2018)

Develop Invention Story Early

- **Talk to inventors early and understand the story they will tell at trial**
  - What was the problem?
  - Inventors' unique appreciation of the problem
  - Eureka moment(s)
  - Failures and hurdles along the way
  - Benefit of invention compared to previous treatments

- **Tell the invention story in the specification**
  - Highlight the problem, hurdles, and benefits of the invention consistent with the inventor's story
  - Can support inventor's testimony at trial

- **Make sure patent claims are consistent with the invention story**
  - Do the claims require and focus on the key features of the invention?
  - Are the patent claims commensurate in scope with what the inventors say they invented?

Documents Supporting the Invention Story

- **Lab Notebooks**
  - Help prove that a particular event happened on a particular date, and show the inventor appreciated the importance
  - Record failures as well as successes
  - Countersign for corroboration
  - Do not include privileged information (e.g., other companies' patents, discussions of prior art, notes of meetings with lawyers, or efforts to design around a patent)

- **Regular Project Reports and Gating Documents**
  - Often present the bigger picture of the inventors' and team's work
  - Can show the scope of the work, hurdles overcome by the team, and how the team learned of things that were (or were not) working
  - Gating documents often show why this particular drug candidate was selected, often among multitudes of other candidates, for clinical studies

- **Make Sure These Documents Are Preserved and Easy to Find!!**
  - Don't just stick them in a filing cabinet and assume the litigation team will later find them

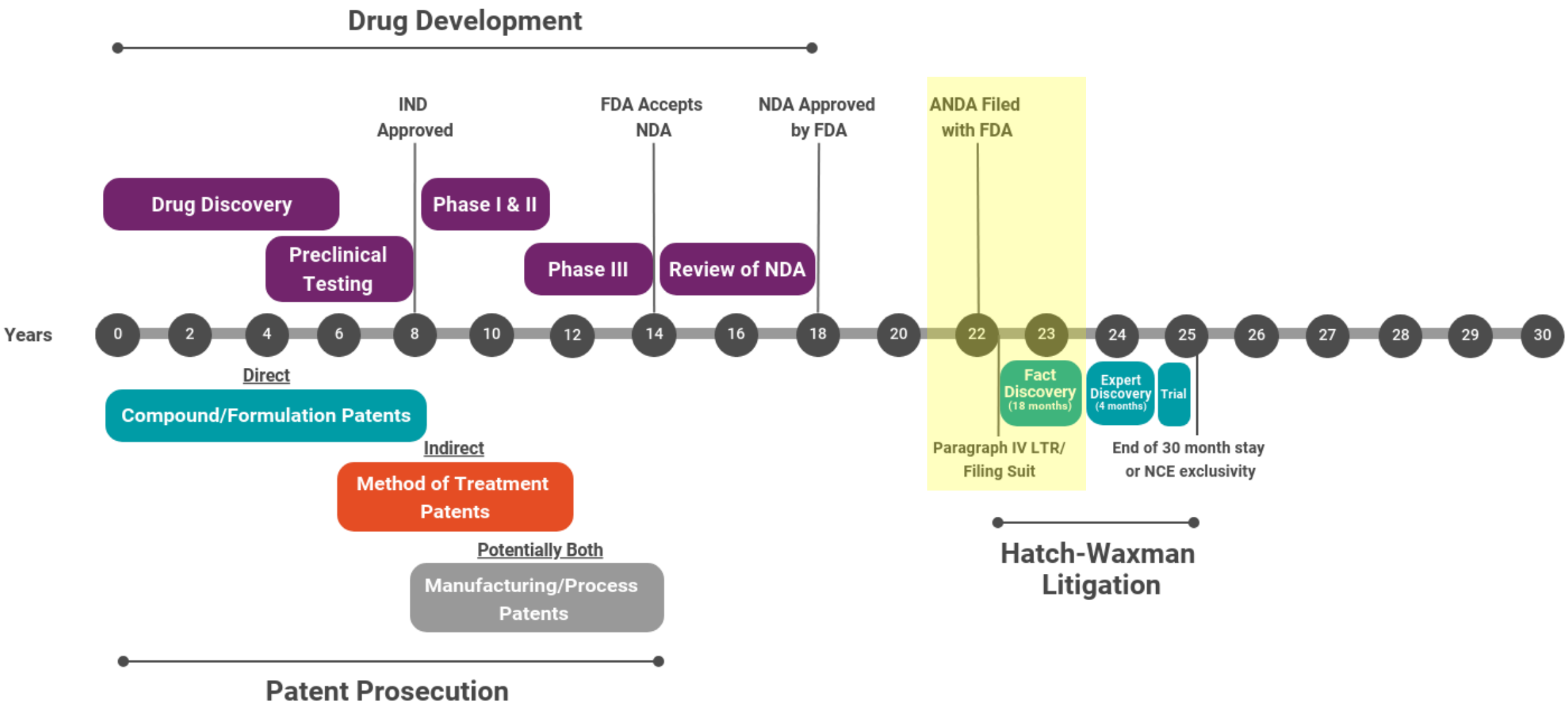
Preparing for Clinical and Commercial Themes

- **IP group needs to coordinate with clinical, commercial and regulatory teams from development through marketing to ensure consistent messaging**
- **Avoid creating bad documents that can later be spun by an opponent in litigation**
- **Commercial documents**
  - "Evergreening"/line extensions
  - Informal pricing discussions
- **Clinical documents**
  - Make sure that regulatory documents are consistent with patents and the invention story
    - State of the art/standard of care
    - Indications

Hatch-Waxman Trial

- **Types of Infringement**
  - Direct
  - Indirect
    - Inducement
    - Contributory

Hatch-Waxman Timeline



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Preparing to Prove Direct Infringement

- **Investigate what information will likely be submitted with the ANDA**
  - Look at NDA documents for branded product
  - FDA Guidance documents for particular type of ANDA product
  - Examples: pharmacokinetic data, XRPD measurements, stability, etc.
  - What process steps will need to be described in the DMF?

- **If relevant, draft claims that focus on information you know will be on the label, ANDA, or DMF**
  - May be easier to prove infringement
  - May lessen need for potential testing of product samples

Preparing to Prove Indirect Infringement

- **Proving Acts of Inducement**
  - Starts with the ANDA Label
  - Labels that instruct infringement = evidence of a specific intent to induce

- **What Parts of the Label**
  - The label as a whole may be considered.
  - Stronger case for inducement when indication refers to other sections of the label.
    - Dosage/Administration; Clinical Studies; Contraindications; Warnings; Etc.
  - Avoid claims that depend on statements that may describe an infringing use, but do not affirmatively encourage or promote the use.

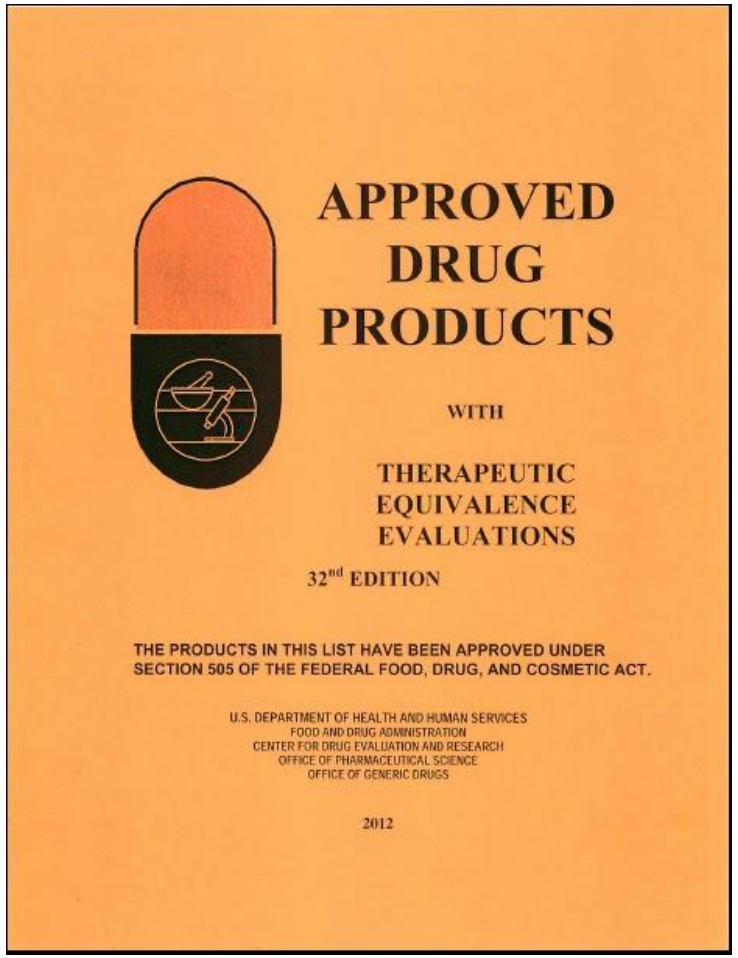
Preparing to Prove Indirect Infringement

- **Compare the patent claims with the draft NDA product label**
  - Claiming the label
  - Do the claims align closely with the label?

- **Ensure you have spoken to key clinical stakeholders**
  - Have you spoken with clinicians about how treatment occurs?

- **Use the right types of treatment terms (administering, providing, supplying, taking)**

Listing Patents in The Orange Book



Listing Patents in The Orange Book

- **Eligibility**
  - Patent must claim a drug or method of using a drug for which a claim of patent infringement could reasonably be asserted
  - 2003 Orange Book Reforms – no packaging patents, metabolites or intermediates

- **FDA Form 3542 – Patent Information**
  - Use patents must be identified on label
  - Patent “use code” provided for each method patent
  - Signed under “penalty of perjury”

- **Timing**
  - NDA Sponsor must submit within 30 days of approval of NDA or supplement and patent issuance
  - If submitted after 30 days, pending ANDAs do NOT have to certify
  - New patents (after NDA approved) must be filed within 30 days to perfect issue date in OB

Orange Book Listing - Use Codes and Carve Outs

- **Tool for FDA – identifies language on label protected by method patents**
  - Drafted by pioneer based on reasonable claim construction
  - 240 Character Max
  - Caraco v. Novo Nordisk (Supreme Court 2012) – use code cannot prevent generic from marketing a drug for an approved use not claimed by the patent

- **“Section viii” Carve Out – 505(j)(2)(A)(viii)**
  - Permits a generic to “carve out” of label approved uses that it is not seeking approval for
  - Generic product must still be safe and effective for remaining approved uses
  - Impact: ANDA with carved out label can be approved absent another PIV (i.e. no First to File blocking approval)

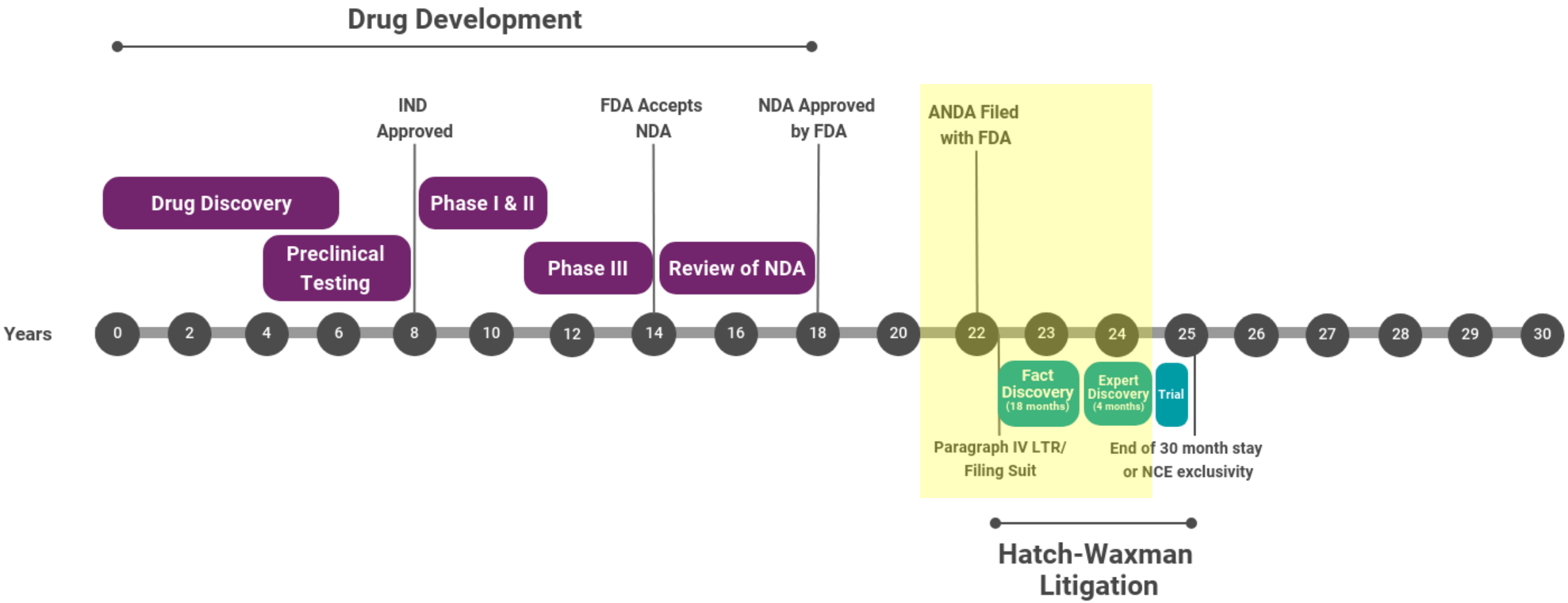
Considerations in Drafting Use Codes

- **Consider patent claims, label, and use codes together**
- **Makes sure they are harmonized**

Hatch-Waxman Trial

- **Defenses**
  - Anticipation
  - Obviousness
  - Section 112
  - Equitable defenses

Hatch-Waxman Timeline



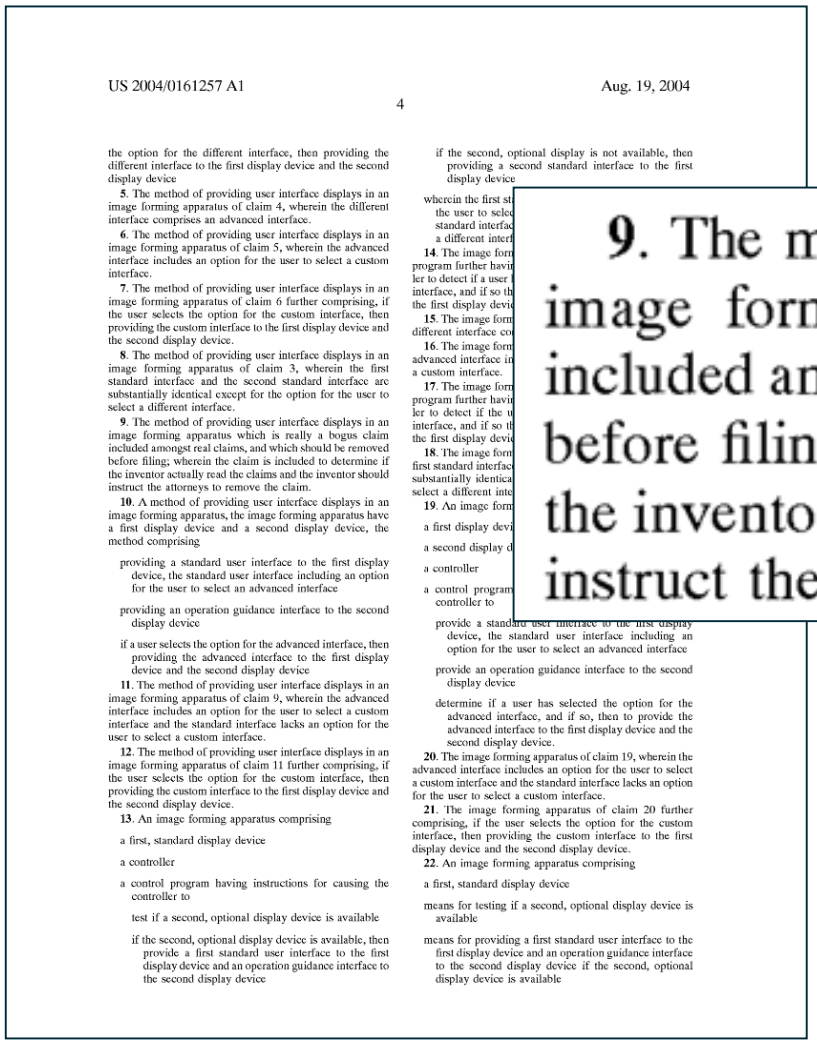
Preparing for Defenses

- **Obviousness**
  - Claims v. Invention Story

- **Section 112 and Claim Scope**
  - Does the patent include “picture” claims for the drug product or formulation?
  - Genus claims
    - Are they of a reasonable scope that is commensurate with the scope of the disclosure?
    - Can they successfully be defended against Section 112 challenges?
    - Does their scope matchup with what the inventor will testify that they invented?

- **Equitable Defenses**
  - Consider if there is any additional prior art that can/should be submitted to the Patent Office in continuation applications

Find and Correct Important Errors



US 2004/0161257 A1 Aug. 19, 2004
4

the option for the different interface, then providing the different interface to the first display device and the second display device

5. The method of providing user interface displays in an image forming apparatus of claim 4, wherein the different interface comprises an advanced interface.

6. The method of providing user interface displays in an image forming apparatus of claim 5, wherein the advanced interface includes an option for the user to select a custom interface.

7. The method of providing user interface displays in an image forming apparatus of claim 6 further comprising, if the user selects the option for the custom interface, then providing the custom interface to the first display device and the second display device.

8. The method of providing user interface displays in an image forming apparatus of claim 3, wherein the first standard interface and the second standard interface are substantially identical except for the option for the user to select a different interface.

9. The method of providing user interface displays in an image forming apparatus which is really a bogus claim included amongst real claims, and which should be removed before filing; wherein the claim is included to determine if the inventor actually read the claims and the inventor should instruct the attorneys to remove the claim.

10. A method of providing user interface displays in an image forming apparatus, the image forming apparatus have a first display device and a second display device, the method comprising

providing a standard user interface to the first display device, the standard user interface including an option for the user to select an advanced interface

providing an operation guidance interface to the second display device

if a user selects the option for the advanced interface, then providing the advanced interface to the first display device and the second display device

11. The method of providing user interface displays in an image forming apparatus of claim 9, wherein the advanced interface includes an option for the user to select a custom interface and the standard interface lacks an option for the user to select a custom interface.

12. The method of providing user interface displays in an image forming apparatus of claim 11 further comprising, if the user selects the option for the custom interface, then providing the custom interface to the first display device and the second display device.

13. An image forming apparatus comprising

a first, standard display device

a controller

a control program having instructions for causing the controller to

test if a second, optional display device is available

if the second, optional display device is available, then provide a first standard user interface to the first display device and an operation guidance interface to the second display device

if the second, optional display is not available, then providing a second standard interface to the first display device

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16. The image form
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first standard interfac
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19. An image form

a first display devi

a second display d

a controller

a control program
controller to

provide a standard user interface to the first display device, the standard user interface including an option for the user to select an advanced interface

provide an operation guidance interface to the second display device

determine if a user has selected the option for the advanced interface, and if so, then to provide the advanced interface to the first display device and the second display device.

20. The image forming apparatus of claim 19, wherein the advanced interface includes an option for the user to select a custom interface and the standard interface lacks an option for the user to select a custom interface.

21. The image forming apparatus of claim 20 further comprising, if the user selects the option for the custom interface, then providing the custom interface to the first display device and the second display device.

22. An image forming apparatus comprising

a first, standard display device

means for testing if a second, optional display device is available

means for providing a first standard user interface to the first display device and an operation guidance interface to the second display device if the second, optional display device is available

9. The method of providing user interface displays in an image forming apparatus which is really a bogus claim included amongst real claims, and which should be removed before filing; wherein the claim is included to determine if the inventor actually read the claims and the inventor should instruct the attorneys to remove the claim.

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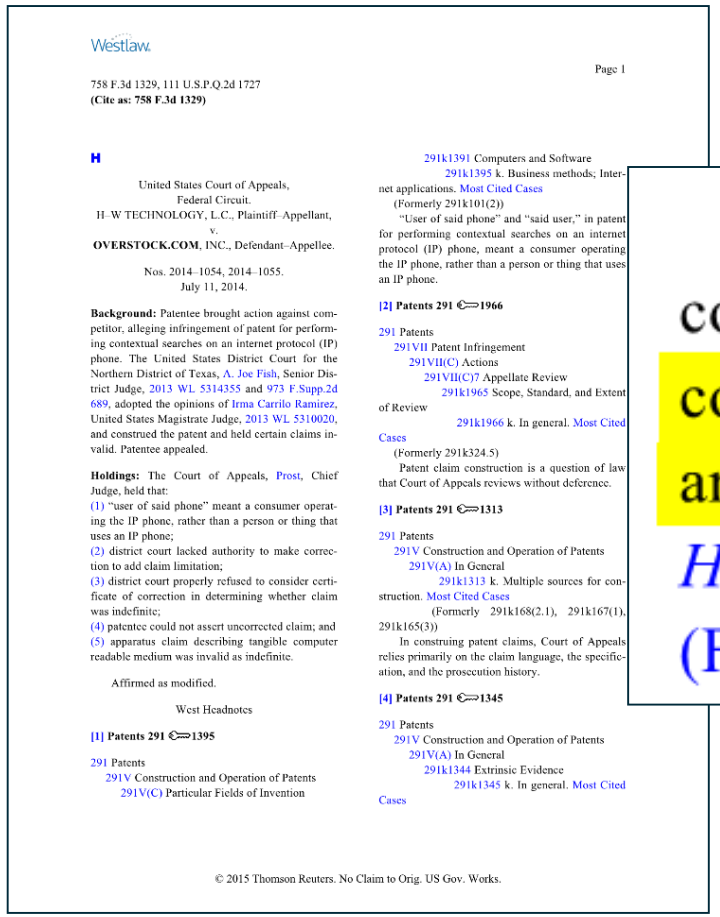
Certificates of Correction



Westlaw.

Page 1

758 F.3d 1329, 111 U.S.P.Q.2d 1727
(Cite as: 758 F.3d 1329)

H

United States Court of Appeals,
Federal Circuit.
H–W TECHNOLOGY, L.C., Plaintiff–Appellant,
v.
OVERSTOCK.COM, INC., Defendant–Appellee.

Nos. 2014–1054, 2014–1055.
July 11, 2014.

Background: Patentee brought action against competitor, alleging infringement of patent for performing contextual searches on an internet protocol (IP) phone. The United States District Court for the Northern District of Texas, A. Joe Fish, Senior District Judge, 2013 WL 5314355 and 973 F.Supp.2d 689, adopted the opinions of Irma Carrillo Ramirez, United States Magistrate Judge, 2013 WL 5310020, and construed the patent and held certain claims invalid. Patentee appealed.

Holdings: The Court of Appeals, Prost, Chief Judge, held that:
(1) "user of said phone" meant a consumer operating the IP phone, rather than a person or thing that uses an IP phone;
(2) district court lacked authority to make correction to add claim limitation;
(3) district court properly refused to consider certificate of correction in determining whether claim was indefinite;
(4) patentee could not assert uncorrected claim; and
(5) apparatus claim describing tangible computer readable medium was invalid as indefinite.

Affirmed as modified.

West Headnotes

[1] Patents 291 ⟸1395

291 Patents
291V Construction and Operation of Patents
291V(C) Particular Fields of Invention
291k1391 Computers and Software
291k1395 k. Business methods; Internet applications. Most Cited Cases
(Formerly 291k101(2))
"User of said phone" and "said user," in patent for performing contextual searches on an internet protocol (IP) phone, meant a consumer operating the IP phone, rather than a person or thing that uses an IP phone.

[2] Patents 291 ⟸1966

291 Patents
291VII Patent Infringement
291VII(C) Actions
291VII(C)7 Appellate Review
291k1965 Scope, Standard, and Extent of Review
291k1966 k. In general. Most Cited Cases
(Formerly 291k324.5)
Patent claim construction is a question of law that Court of Appeals reviews without deference.

[3] Patents 291 ⟸1313

291 Patents
291V Construction and Operation of Patents
291V(A) In General
291k1313 k. Multiple sources for construction. Most Cited Cases
(Formerly 291k168(2.1), 291k167(1), 291k165(3))
In construing patent claims, Court of Appeals relies primarily on the claim language, the specification, and the prosecution history.

[4] Patents 291 ⟸1345

291 Patents
291V Construction and Operation of Patents
291V(A) In General
291k1344 Extrinsic Evidence
291k1345 k. In general. Most Cited Cases

Based on the plain language of the statute, this court has specifically held that "[t]he certificate of correction is only effective for causes of action arising after it was issued." *Sw. Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280, 1294–95 (Fed.Cir.2000). Here, H–W filed this suit before the

H-W Tech., L.C. v. Overstock.com, Inc., 758 F.3d 1329, 1334 (Fed. Cir. 2014).

Thank You!

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