Hatch-Waxman: How to Prepare for the Paragraph IV Letter

June 3, 2021

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Meet the Speakers

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Agenda

- When to Prepare for Hatch-Waxman Litigation
- Preparing Your Patent Portfolio
- Anticipating ANDA Filers
- Where To Sue
- Preparing a Complaint

When to Prepare for Hatch-Waxman Litigation

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Hatch-Waxman Exclusivities

- **5 year "data" exclusivity**
  - New chemical entities ("NCEs") only
  - No ANDA or 505(b)(2) applications can be filed for five years
  - But, if Orange Book-listed patent challenged,can be filed after four years

- **3 year "marketing" exclusivity**
  - Protects drug label information based on clinical studies essential to approval
  - No approval of ANDAs and 505(b)(2) applications for three years
  - But, ANDA can be filed anytime after NDA approval

- **Pediatric exclusivity**

- **Orphan drug exclusivity**

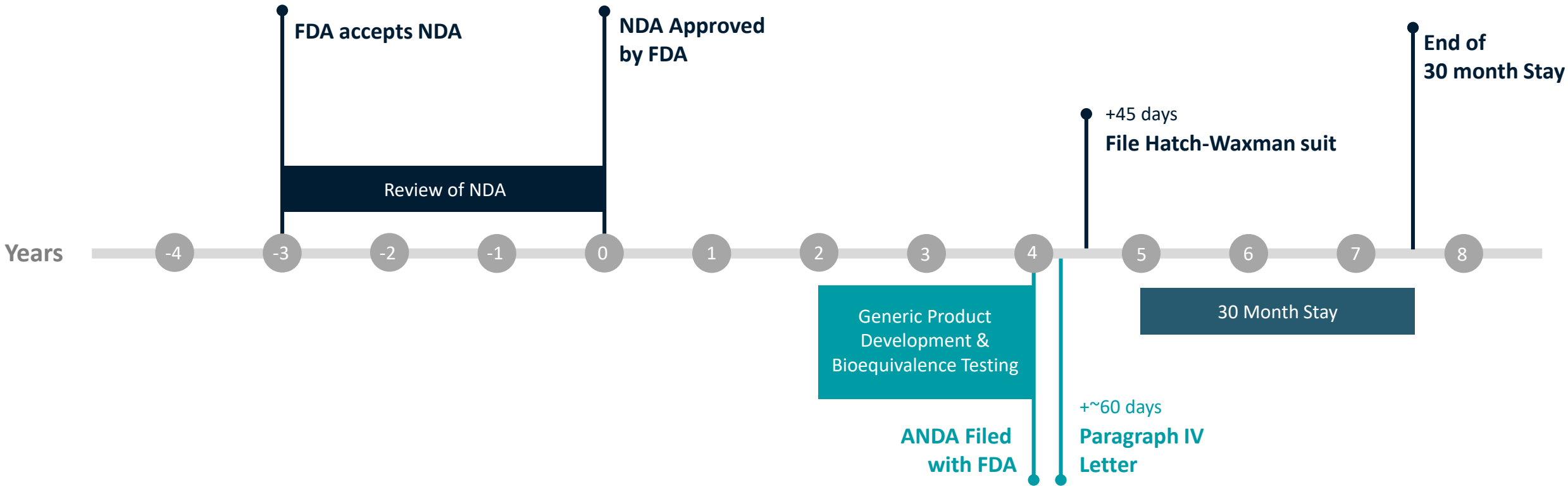
Timing of Litigation

- **PIV notice letter**
  - Generic must notify NDA holder of filing of an ANDA with a Paragraph IV certification
  - Generic may not send notice until receiving ANDA acknowledgement letter from FDA, then must send within 20 days
  - Typically, Paragraph IV notice letters received 60-90 days after ANDA filed

- **Filing of lawsuit**
  - 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



When to Prepare for Hatch-Waxman Litigation?

- **Disparities to consider**
  - Effort required prior to ANDA filing
  - Resources
  - Experience

- **No "safe" amount of sales**

- **When to start preparing? Early!!!!**

Preparing Your Patent Portfolio

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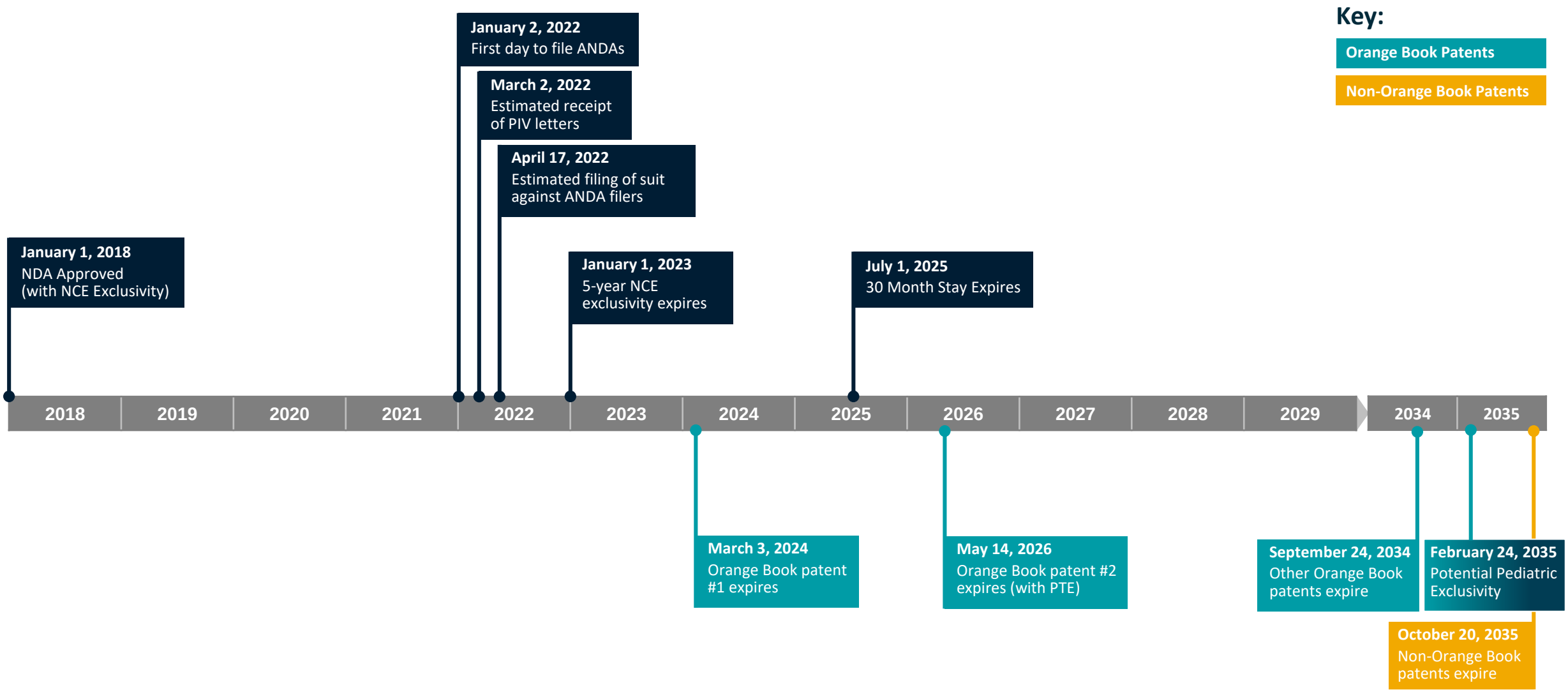
Types of Patents to Consider Asserting

- **Orange Book-Listed Patents**
  - Compound
  - Formulation
  - Methods of treatment
  - Polymorph

- **Non-Orange Book-Listed Patents**
  - Process patents
  - Metabolite patents
  - *Devices

- **Opportunity to add to portfolio?**

Understand Exclusivity Timeline



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Perfecting Your Patent Claims

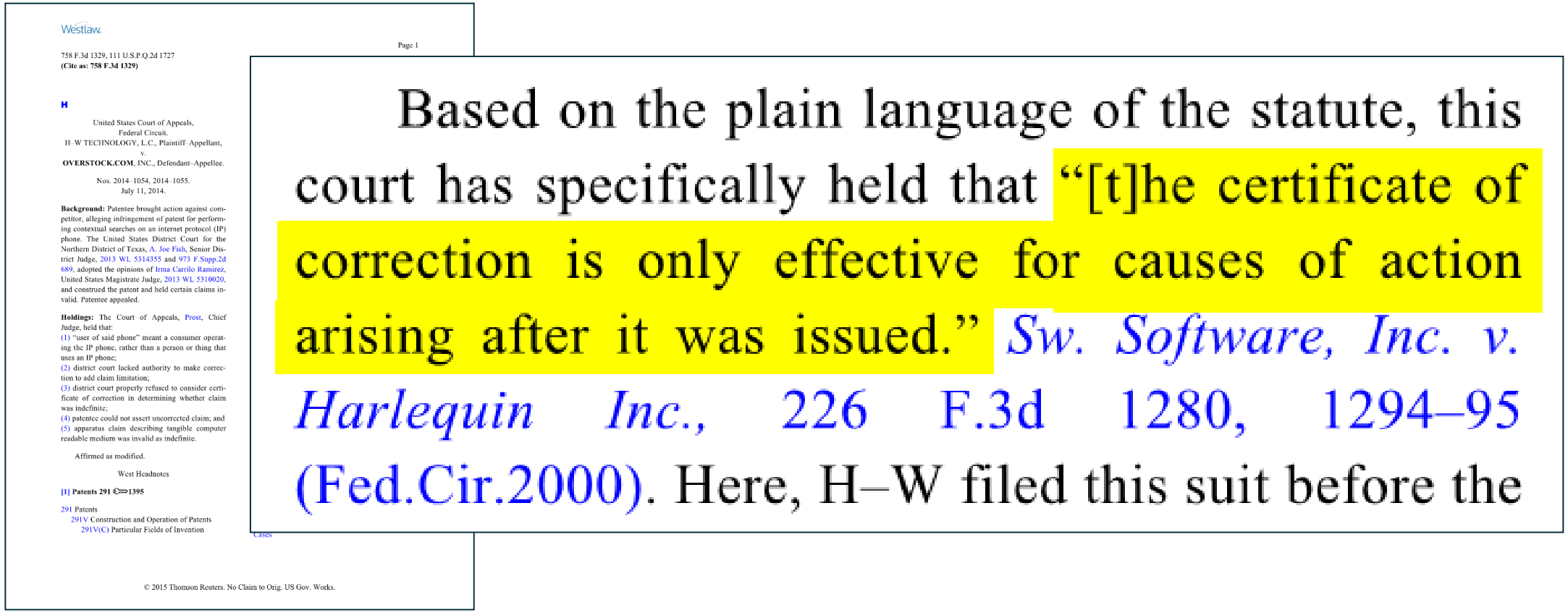
- **How will I prove infringement of each element of the claim?**
  - Proving infringement in a Hatch-Waxman case starts with the ANDA
  - Particular focus on the label, but other materials can be considered
  - Can I avoid testing?

- **Patent the label**
  - Compare the patent claims with the draft NDA product label
  - Do the claims align closely with the label, or are tweaks needed?

- **Patent other information that will be submitted with the ANDA**
  - Look to NDA documents for branded product
  - FDA Guidance documents for particular type of ANDA product
  - Examples: pharmacokinetic data, XRPD measurements, stability, process steps


Proofread

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

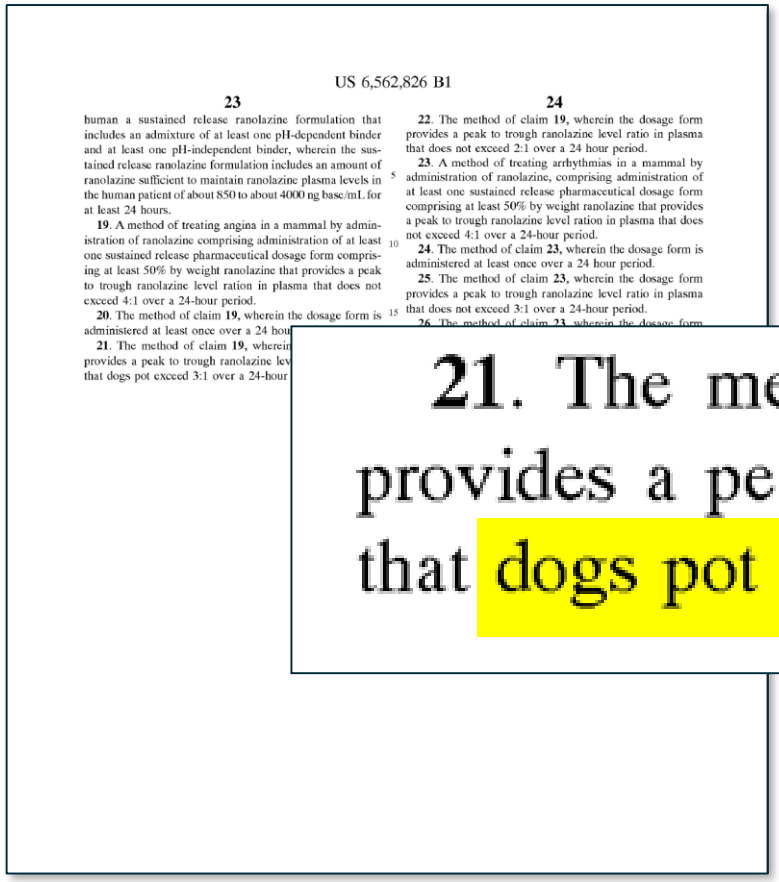
Cases

© 2015 Thomson Reuters. No Claim to Orig. US Gov. Works.

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).

Find the Errors



US 6,562,826 B1

23

human a sustained release ranolazine formulation that includes an admixture of at least one pH-dependent binder and at least one pH-independent binder, wherein the sustained release ranolazine formulation includes an amount of ranolazine sufficient to maintain ranolazine plasma levels in the human patient of about 850 to about 4000 ng base/mL for at least 24 hours.

19. A method of treating angina in a mammal by administration of ranolazine comprising administration of at least one sustained release pharmaceutical dosage form comprising at least 50% by weight ranolazine that provides a peak to trough ranolazine level ration in plasma that does not exceed 4:1 over a 24-hour period.

20. The method of claim **19**, wherein the dosage form is administered at least once over a 24 hou

21. The method of claim **19**, wherein

provides a peak to trough ranolazine lev

that dogs pot exceed 3:1 over a 24-hour

24

22. The method of claim **19**, wherein the dosage form provides a peak to trough ranolazine level ratio in plasma that does not exceed 2:1 over a 24 hour period.

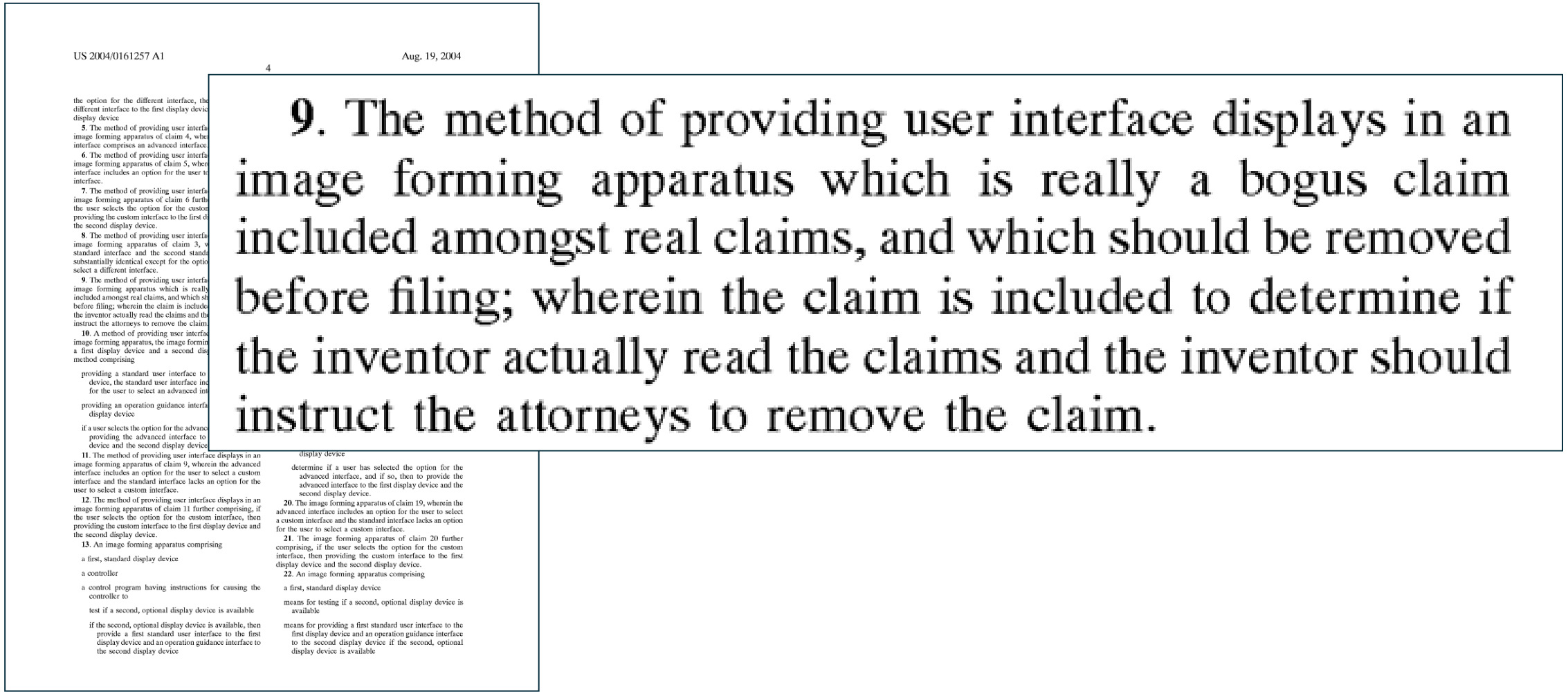
23. A method of treating arrhythmias in a mammal by administration of ranolazine, comprising administration of at least one sustained release pharmaceutical dosage form comprising at least 50% by weight ranolazine that provides a peak to trough ranolazine level ration in plasma that does not exceed 4:1 over a 24-hour period.

24. The method of claim **23**, wherein the dosage form is administered at least once over a 24 hour period.

25. The method of claim **23**, wherein the dosage form provides a peak to trough ranolazine level ratio in plasma that does not exceed 3:1 over a 24-hour period.

21. The method of claim **19**, wherein the dosage form provides a peak to trough ranolazine level ratio in plasma that dogs pot exceed 3:1 over a 24-hour period.

Find the Errors



US 2004/0161257 A1 Aug. 19, 2004
4

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.

Double Patenting

- **Vetting includes looking for obviousness-type double patenting issues**

- **Judicially created doctrine that invalidates claims that are not "patentably distinct" from the claims of an earlier expiring patent to the same inventors**
  - Can be obviated by terminal disclaimer if commonly owned

- ***Gilead v. Natco* (Fed. Cir. 2014)**
  - OTDP extended. Later-filed, earlier issued patent invalidated by earlier filed, later issued patent
  - Previously, because second patent was later issued earlier, it would not have been an OTDP reference.
  - Based on rationale that public should be able to use any subject matter of an expired patent

Double Patenting

- **Terminal disclaimers available?**
  - Have to align ownership exactly
  - Complication with joint ventures

- **Patent Term Extension**
  - OTDP cannot take away Patent Term Extension. *See Novartis AG v. Ezra Ventures LLC, 909 F. 3d 1367* (Fed. Cir. 2018).

- **Patent Term Adjustment**
  - The Federal Circuit has not yet said if OTDP can take away PTA.
  - One district court has ruled that it can pre-Novartis. *See Magna Elecs., Inc. v. TRW Auto. Holdings Corp.,* 2015 WL 11430786 (W.D. Mich. 2015)
  - A more recent decision ruled that it cannot. *See Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.*, No. 3:17-cv-05319-FLW-DEA, 2021 (D.N.J. Mar. 22, 2021)

Develop Case Strategies

- Develop legal strategy
  - Analyze file histories, infringement, validity
  - Retain experts
  - Think like the generic

- Develop themes
  - Interview key witnesses, including inventors, other scientists, business person(s), prosecuting attorney
  - Work up invention timeline and story, history of technology
  - Collect and review documents from key custodians

Anticipating ANDA Filers

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Anticipating ANDA Filers

- **# of ANDA Cases Filed Since 2017: 1450**
- **What are Branded Sales?**
- **Specialty Drug?**
  - E.g., ophthalmics

Anticipating ANDA Filers

- Paragraph IV Certification List
  - https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions#List
- List of Drug Master Files
  - https://www.fda.gov/drugs/drug-master-files-dmfs/list-drug-master-files-dmfs
  - Updated quarterly

Where Can I Sue?

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Where Can I Sue?

- **Most Common Hatch-Waxman Jurisdictions**
  - Delaware (824 cases since 2017)
  - New Jersey (466 cases since 2017)

- **Two Procedural Hurdles**
  - Personal Jurisdiction
  - Venue

Personal Jurisdiction

- ***Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, 817 F.3d 755 (Fed. Cir. 2016)**
  - "The complaints in these cases allege that Mylan's generic drugs would be distributed and sold in Delaware and that Mylan intends to commercially manufacture, use, and sell the generics upon receiving FDA approval..."
  - "Such directing of sales into Delaware is sufficient for minimum contacts."

Patent Venue Statute - 28 U.S.C. § 1400(b)

- Any civil action for patent infringement may be brought in the judicial district where the defendant resides, or

- where the defendant has committed acts of infringement and has a regular and established place of business.

Venue Options after *TC Heartland*

- **Venue is proper in defendant's state of incorporation**

- **Venue is proper where acts of infringement have occurred *and* defendant has a <u>regular and established place of business</u>**
  - There must be a physical place in the district;
  - It must be the a regular and established place of business;
  - It must be the place of the defendant.

  In re Cray Inc., 871 F.3d 1355 (Fed. Cir. 2017)

Venue in Hatch-Waxman Cases

- ***Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.*, 978 F.3d 1374 (Fed. Cir. 2020)**
  - In a Hatch-Waxman case, what is an "act of infringement" under § 1400(b)?

Venue in Hatch-Waxman Cases

- ***Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.*, 978 F.3d 1374 (Fed. Cir. 2020)**
  - "[I]n cases brought under 35 U.S.C. § 271(e)(2)(A), infringement occurs for venue purposes only in districts where actions related to the submission of an Abbreviated New Drug Application ("ANDA") occur, not in all locations where future distribution of the generic products specified in the ANDA is contemplated."

Venue Options after *Valeant*

- **Venue "is proper only in those districts that are sufficiently related to the ANDA submission—in those districts where acts occurred that would suffice to categorize those taking them as a 'submitter under § 271(e)."**
  - Open question
    - D. Maryland where FDA received ANDA?
    - But, acts protected by 271(e)(1) safe harbor *not* relevant because non-infringing

Venue Options after *Valeant*

- **Consent**
- **Protective Suits**
- **Judicial Panel on Multidistrict litigation**
  - Consolidates 2 or more cases for pre-trial proceedings
  - Common questions of fact; convenience of parties/witness; efficiency

What about Foreign ANDA Filers?

- ***In re HTC Corp.*, 889 F.3d 1349, 1358 (Fed. Cir. 2018).**
  - Reaffirms § 1400(b) does not apply to aliens, § 1391(c)(3) does

- **28 U.S.C. § 1391(c)(3)**
  - a defendant not resident in the United States may be sued in any judicial district, and the joinder of such a defendant shall be disregarded in determining where the action may be brought with respect to other defendants.

Preparing the Complaint

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Preparing the Complaint

- **Who Can Sue?**
  - Principles of Standing Matter
    - **Patent Owner**
    - **Exclusive Licensee/Sublicensee**
    - **NDA holder / agent of NDA holder?**

- **Who Should Sue?**
  - Someone who can recover lost profits.
    - **A party (i.e. a party with an interest in the patent) to the suit *MUST* be the same party that is injured from the lost sales**
    - **Just being a parent may not be enough**

Preparing the Complaint

- **Who Can Be Sued?**
  - § 271(e)(2) defines the act of infringement as submitting the ANDA
  - § 271(e)(4) provides for relief against the § 271(e)(2) infringer
  - More than one "submitter" (e.g., foreign applicant and US subsidiary/agent)
    - **Allege active participation by all entities in preparing and submitting the ANDA, and a direct benefit from ultimately selling the drug upon approval (e.g., manufacturing or selling)**

The Paragraph IV Letter Alleges Non-Infringement

- **Offers of Confidential Access; 21 U.S.C. § 355(j)(5)(C)(III)**
  - Contained in Paragraph IV Letter
  - Generic can impose restrictions on persons entitled to access, and use and disposition of information accessed “as would apply had a protective order been entered”
  - Purpose of access is limited to determining whether an action can be brought under 271(e)(2)

The Paragraph IV Letter Alleges Non-Infringement

- **Need Reasonable Basis, Based Upon Reasonable Investigation, to Allege Infringement of One Claim of Each Asserted Patent**

- **Rule 11(b).**
  - By presenting to the court a pleading . . . an attorney certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances: . . .
  - (2) the claims . . . are nonfrivolous . . .;
  - (3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery

Hoffman-LaRoche, 213 F.3d 1359 (Fed. Cir. 2001)

- **Background**
  - Pharma company filed suit, accusing generic manufacturers of infringing process claims
  - Pleading alleges:
    - **it put generics on notice of the patents and sought information to assist in assessing infringement, to no avail**
    - **inability to reverse engineering to assess infringement of patented process**
    - **resort to judicial process and the aid of discovery to confirm belief of infringement**
  - After suit was filed, and motion to dismiss was pending, the generic manufacturing process was provided under NDA
  - Thereafter, pharma co. dismisses suit
  - Generic manufacturer brings motion for Rule 11 sanctions and attorneys fees

Hoffman-LaRoche, 213 F.3d 1359 (Fed. Cir. 2001)

- 36. Roche, on behalf of Syntex, timely gave each defendant actual notice of the Syntex Patents and from that date has sought from each information that would assist Roche and Syntex in confirming whether each defendant's synthesis of ticlopidine hydrochloride is within the lawful scope of one or more claims of the Syntex Patents. No defendant has provided this information. No defendant has provided Roche or Syntex with sample quantities of the active ingredient ticlopidine hydrochloride used in their respective pharmaceutical preparation.

- 37. On information and belief, plaintiffs are presently not aware of any analytical technique which can be used to definitively establish that the ticlopidine hydrochloride manufactured by any of the defendants and used in their respective dosage form of pharmaceutical preparation was made by use of the invention of one or more claims of the Syntex Patents, and for that reason, has sought from each of them information as to its or its suppliers' process for the synthesis of that compound. In the absence of such information, **plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that each and every defendant infringes one or more claims of the Syntex Patents**.

Hoffman-LaRoche, 213 F.3d 1359 (Fed. Cir. 2001)

- **District Court Denies Attorneys Fees and Sanctions**
  - "[Although the] pre-filing inquiry with respect to defendant Torpharm was unsuccessful, it was reasonable. At the end of the plaintiffs' pre-suit investigation it had neither evidence of infringement nor non-infringement. Although plaintiffs could have assumed noninfringement at that point, that they chose to file suit and engage in discovery instead does not subject them to sanctions."
- **Federal Circuit Affirms**
  - "**It is difficult to imagine what else Roche and Syntex could have done to obtain facts relating to Torpharm's alleged infringement of their process patents. Torpharm has pointed to nothing else that it believes they could or should have done.** Its position apparently is that because they were unable to obtain and set forth in their complaint facts showing infringement, they should not have filed suit at all. The district court correctly rejected that theory."

Approved Approach in ANDA Cases

- ***In re Cyclobenzaprine Hydrochloride Extended-Releases Capsule Patent Litig.*, 693 F. Supp. 2d 409, 416-17 (D. Del. 2010)**
  - No Rule 11 violation where patentee requested manufacturing information, defendant demanded unreasonable restrictions and limitations, and plaintiff declined to accept offer of access

Preparing the Complaint

- **What Counts to Include?**
  - § 271(e)(2) Infringement
  - Declaratory Judgment of Infringement
    - **May provide broader relief, e.g., against "those acting in concert," etc… with the ANDA submitter**

- **How Much Detail to Include?**
  - Depends on Counts and Court
  - 271(e): ANDA submitted with PIV certification; sent PIV Letter; generally alleges infringement of a specific claim, and that submission constitutes an act of infringement under 271(e)(2)
    - **Belcher Pharms., LLC v. Int'l Medication Sys., 379 F. Supp. 3d 326 (D. Del. 2019)**

Thank You!

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