Litigation Webinar Series

Hatch-Waxman 201

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FISH & RICHARDSON

Overview

- Hatch-Waxman Series
- Housekeeping
  - CLE Contact: Jane Lundberg
    - lundberg@fr.com
  - Questions
  - Materials: www.fr.com/webinars
- #fishwebinar

Hatch-Waxman 201

- Value proposition of drug exclusivities.
- Orange Book strategies and hidden dangers.
- Citizen petitions as an adjunct to Hatch-Waxman litigation.
- Preparing for Hatch-Waxman litigation.

Value Proposition of Drug Exclusivities

Exclusivities protect various “markets” from competition:

- Drugs
- Uses
- Patient populations

Designed to incentivize pharmaceutical R&D by offering brand protections for reasonable periods.

Can be leveraged against competitive entry.

Can be monetized – sold, waived, encumbered.

In some cases they can combine; in others they overlap; are complementary to patent protections; can even “extend” patent protections.

Exclusivities and patents are integral to pharmaceutical IP strategies and investment decision making.

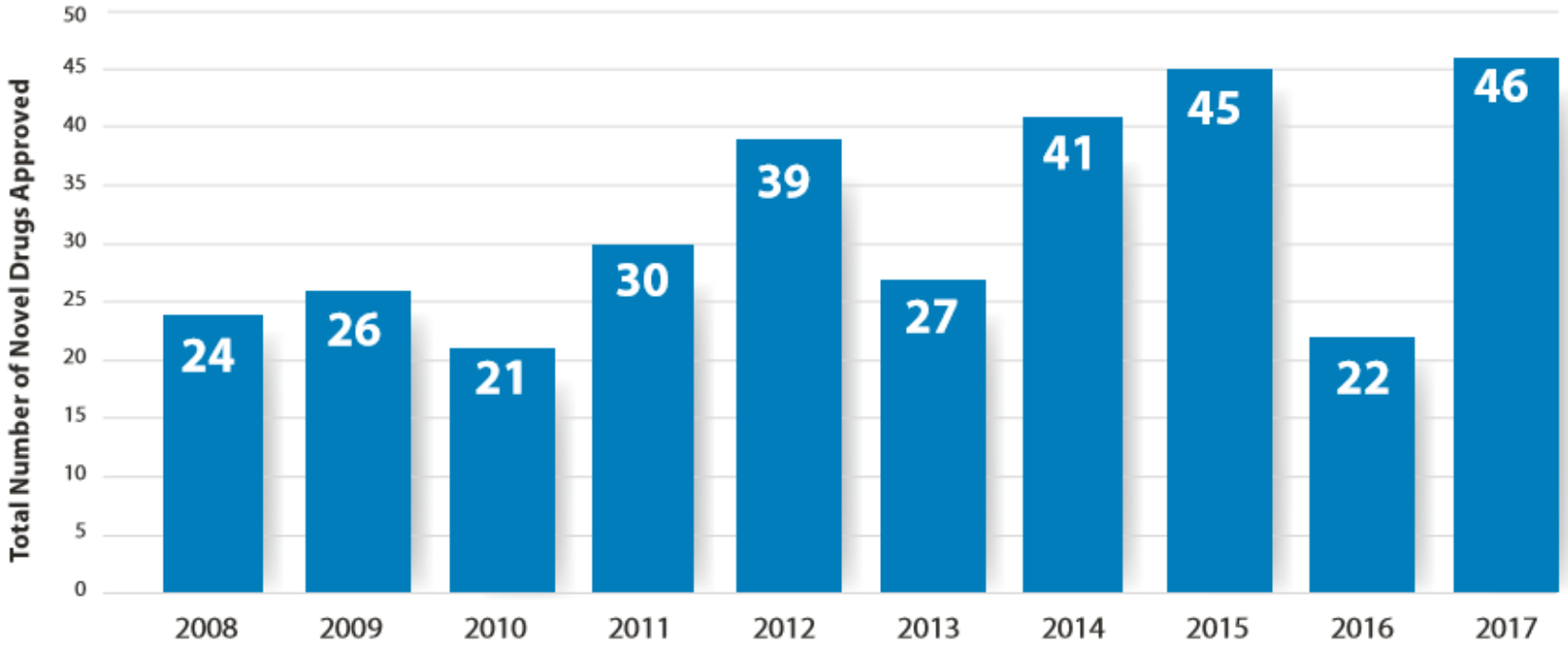
Major Exclusivities

Five year Data (New Chemical Entity) – prevents the submission of ANDAs and 505b2s for the same active moiety.

- Four year filing option if an Orange Book patent is challenged – Paragraph IV certification.
- If brand timely files suit, FDA prevented from approving for 30 months.
- For NCE, 30 month stay runs from end of 5 year exclusivity.
- Patent term extension may also be available for NCE approvals.
- If NCE approved for “orphan” pediatric population, sponsor may be eligible for Rare Pediatric Disease Priority Review voucher.

CDER's Annual Novel Drug Approvals: 2008 - 2017

In 2017, CDER approved 46 novel drugs. The ten-year graph below shows that from 2008 through 2016, CDER has averaged about 31 novel drug approvals per year.



Major Exclusivities

Three year Marketing – prevents ANDAs and 505b2s from being approved for same "conditions of approval" for same active moiety.

- Protects drug label information based on clinical studies (other than BA studies) essential to approval for which the sponsor has the right of reference.
- But not all clinical label information is necessarily protected; must be "essential to approval."
- And information that comes off of label to conform to new clinical language is not protected (Vanda/FANAPT case).
- Further, use exclusivities can be carved out of label by ANDA applicants without impacting AB-rating (automatic substitution by pharmacies).
- So what does 3 year exclusivity really protect?
    - Labeling/marketing of a generic drug for the "conditions of approval."
    - Subsequent 505b2 approvals for same active moiety for the same "conditions of approval" (Veloxis/Envarsus XR and Otsuka/Aristada cases).

Major Exclusivities

Six month Pediatric – add 6 months to all existing exclusivities (5-year, 3-year, orphan) for all dosages/strengths/formulations for same active moiety.

- Adds 6 months to OB patent expiration dates for studied drug product.
- Follows the OB patents if listed for other drugs/combos with same active moiety.
- Requires a “written request” from FDA for studies in a pediatric population/sub-population.
- Requires studies to be conducted and submitted in accordance with WR; does not require positive results or labeling approval.
- PREA requires pediatric studies for most NDA approvals so requesting exclusivity via WR should be “no brainer” for most NDAs.
- PREA exemption if pediatric sub-population is designated as an “orphan subset” – can save time and $ and not hold up adult population approvals.

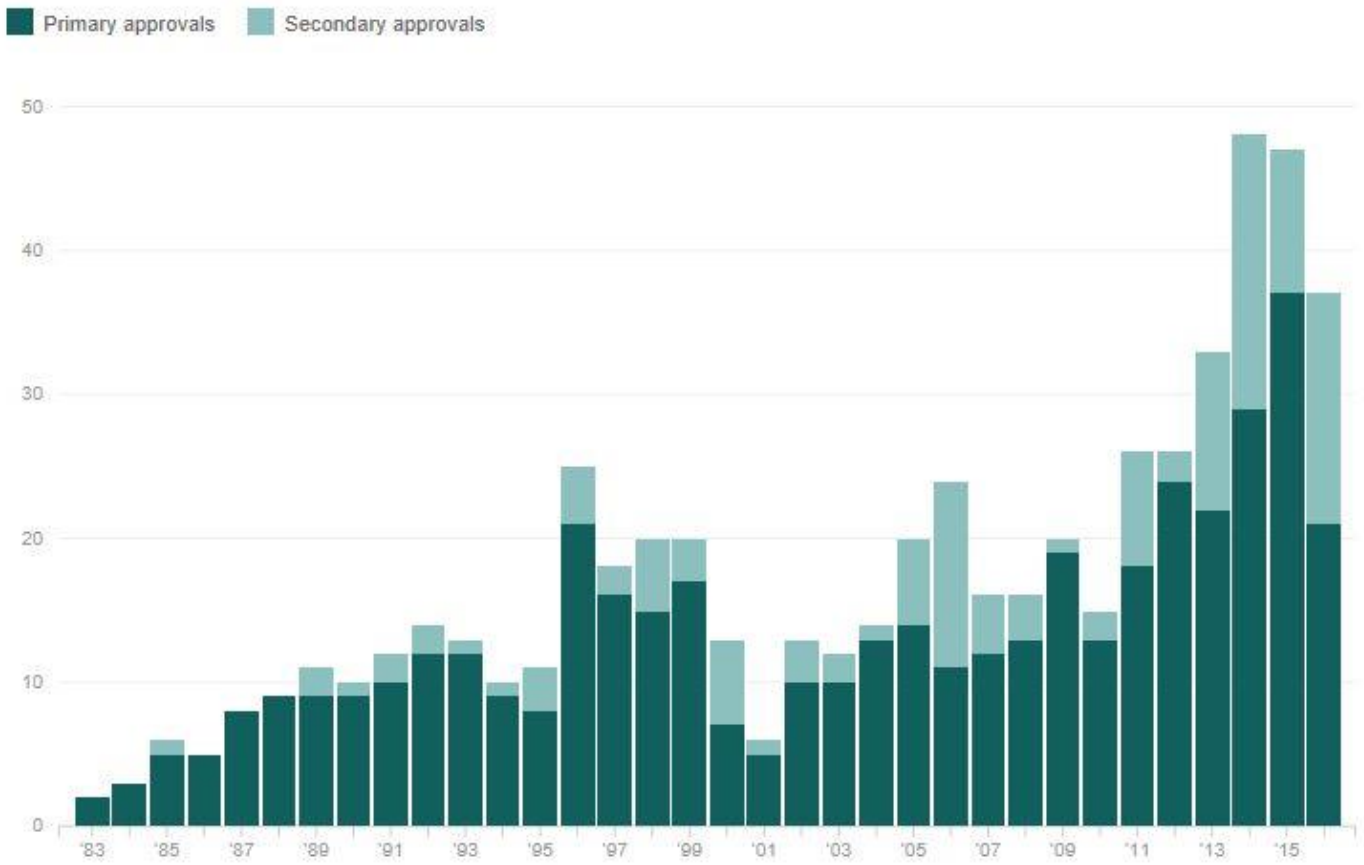
Major Exclusivities

Seven year Orphan – protects against approval of any drug with the same active moiety for the same approved “rare disease or condition.”

- Protects against NDAs as well as ANDA and 505b2s.
- Rare disease or condition means one that affects less than 200,000 persons in the US; or affects more than 200K and for which there is no reasonable expectation of cost recovery.
- “Disease or condition” can be sub-divided into medically distinct patient populations; e.g. some biologics have received as many as 7 OD approvals for a single macro-molecule.

Major Exclusivities

- Chart below shows surge in OD primary and secondary approvals



Source: FDA's Orphan Drug Database, Kaiser Health News

Credit: Eunice Esomonu and Brittany Mayes/NPR

Major Exclusivities

- Pediatric orphan population for an NCE can lead to fully transferrable Priority Review voucher ($ MM).
- OD exclusivity does not protect same drug for same use found to be "clinically superior."
    - Means safer or more effective than the approved use; flexible standard (dosage change from injectable to oral found superior in one drug; whereas change from oral to injectable found superior in another); or
    - Means "major contribution to patient care" – for severe or life threatening diseases MC2PC can involve convenient treatment location; duration of treatment; patient comfort; improvements in drug efficiency; advances in the ease and comfort of drug administration; longer periods between doses; and potential for self-administration.

Orange Book Patent Strategies and Hidden Dangers

The Orange Book is FDA's official compilation of approved drugs and therapeutic equivalents:

- NDA holders required to list patents that claim the drug product or approved "conditions of use" for which a claim for infringement could reasonably be asserted.
- OB listing provides opportunity to litigate patents prior to generic launch.
- OB listing is powerful weapon for drug protection but carries certain risks.

OB listing must be signed under "penalty of perjury."

Willful and false statements are criminal offenses under 18 USC 1001 (False Claims Act).

OB declaration can be evidentiary source in patent litigations; same with absence of listing.

Orange Book Patent Strategies and Hidden Dangers

FDA 2003 Rules (to prevent OB abuses like “evergreening”).

- No packaging patents.
- No intermediate or metabolite patents.
- MOU patents – approved uses only.
- OB patent litigation – only one 30 month stay per ANDA.

Recent study on OB patent listings 2005-2015 (evergreening still alive).

- 74% of patents were listed for previously approved drugs.
- Of 100 top selling drugs, 80% extended OB protection at least once; 50% more than once.
- 40% of all drugs added new OB protection; 80% of those more than once; some up to 20x.

Orange Book Patent Strategies and Hidden Dangers

FDA 2016 Rules implementing 2003 MMA – Use Patents:

- OB listing of MOU patents must be claim specific.
- Listing must specify drug label sections/sub-sections that correspond to patent claims.
- Use code cannot claim an approved condition of use unless patent claim reads on the approved use "in its entirety."
- FDA will allow section viii statement (1) if UC partially overlaps approved use; and (2) generic is no less S&E as brand for all remaining conditions of use.
- Partial overlap of use code allowed for regulatory purposes (*Caraco v. Novo Nordisk*, notwithstanding) even if "a claim for infringement could reasonably be asserted."
- Problem areas: is every claim element required to appear in the use code (250 characters max.); will FDA allow section viii carve out if any single claim element is removed from label?

Orange Book Patent Strategies and Hidden Dangers

Aggressive OB practices and dangers of misuse:

- FCA criminal cases (none yet).
- FCA civil cases (on the rise).
- Antitrust cases (well established).

Orange Book Patent Strategies and Hidden Dangers

FCA Civil Suits:

- FCA elements are: (1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, (4) causing the government to pay out money or forfeit moneys due. *Escobar* 136 S. Ct. 1989 (2016).
- Whistleblower suits (*qui tam*) permit sharing of government overpayments.
- Numerous successful FCA actions against brand manufacturers for knowingly marketing drugs for off-label uses.
- New FCA actions emerging against pharma manufactures:
    - GMP violations – case pending on remand from 9th Circuit on question of materiality (would government not have paid Medicare/Medicaid claims if it knew of the GMP violations).
    - OB listing violations (*Amphastar v. Aventis*, 9th Circuit May, 2017) – fraudulent act was listing of invalid patent in the OB; scienter was inequitable conduct before the PTO. Case dismissed on technicality (public disclosure bar prevented suit) but materiality of OB listing established.
    - What about valid patents falsely listed that are known not to infringe? Would reckless disregard constitute scienter? Sham litigation; baseless claim construction; overbroad use code?

Orange Book Patent Strategies and Hidden Dangers

Antitrust Suits

- "Pay for delay" antitrust cases (FTC and private causes of action):
  - Medicis (Solodyn) class action based on invalid/unenforceable OB patents; sham patent suits to force settlement with generics.
  - Novartis (Gleevec) – settlement/payment based on fraudulent follow-on patent listed in OB.
  - AbbVie (Androgel) – settlement/payment based on objectively baseless patents listed in OB.

Orange Book Patent Strategies and Hidden Dangers

- Conventional antitrust actions:
  - Improperly listing a patent in the Orange Book may subject the patent holder to antitrust liability. See *In re Buspirone Patent Litig*., 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002).
  - Listing is not a petitioning activity so outside of Noerr-Penington protections; sham law suits also outside N-P.
  - Class actions for monopolization based on wrongful OB listing and sham Par IV litigation of pen injection device patents. (Sanofi/Lantus recently dismissed – OB listing was reasonable and not objectively baseless.)

Citizen Petition as an Adjunct to H-W Litigation

Citizen Petition and Petition for Stay are only private CoA to force FDA to act.

Both are public proceedings, allow public comment and required for "exhaustion."

Paragraph IV notice – may reveal defects in ANDA; proposed product or conditions of use:

- CPs typically filed to delay/stop generic approval; seek FDA rulings/interpretations/declarations; reveal unknown regulatory data/facts.
- Par IV notice is not confidential information.
- If a CP could delay ANDA/505(b)(2) approval Section 505(q) applies:
    - Requires disclosure of when cause for complaint first arose.
    - Approval cannot be delayed unless required to protect public health.
    - FDA must act within 150 days.
    - Leads to "cat and mouse" games with FDA dismissals.

Litigation PO blocks CP filings without court permission.

Preparing for Litigation

FISH.

Preparing for Litigation – When?

- Chemical entities
- Formulations
- Methods of treatment
- Some mixture of the above

Preparing for Litigation – When?

- 5 year "filing" exclusivity:
  - New active moieties only.
  - No generic or 505(b)(2) application can be filed for 5 years.
  - 4 year exclusivity if Orange Book listed patent is challenged
    - If drug approved on December 6, 2013, ANDA can be filed on December 7, 2017.

- 3 Year "Marketing" Exclusivity:
  - Clinicals required; must be essential to approval; change in dosage, new patient regulation, new indications, Rx to OTC.
  - No generic or 505(b)(2) can be approved for 3 years
    - ANDAs can be filed at any time.

No amount of sales are "safe."

Preparing for Litigation – When?

Things to Consider:

- Relative Disparities
- Portfolio
- Ownership
- Label

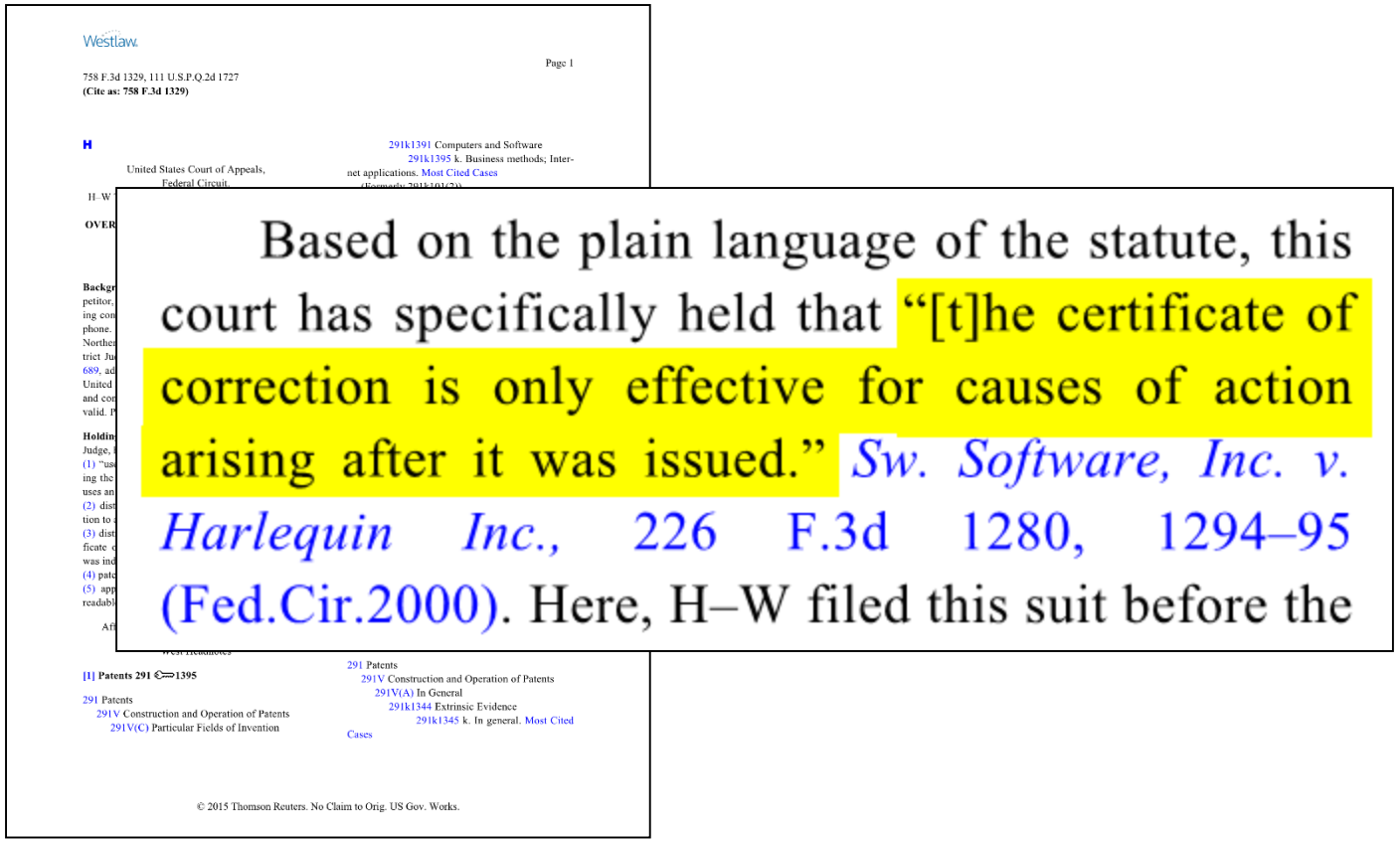
Preparing for Litigation

Relative Disparities:

- Time to prepare
- Resources
- Experience
  - Scientific
  - Litigation

Errors . . . everyone’s worst nightmare

Certificates of Correction



Westlaw.

Page 1

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

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United States Court of Appeals,
Federal Circuit.

291k1391 Computers and Software
291k1395 k. Business methods; Internet applications. Most Cited Cases

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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

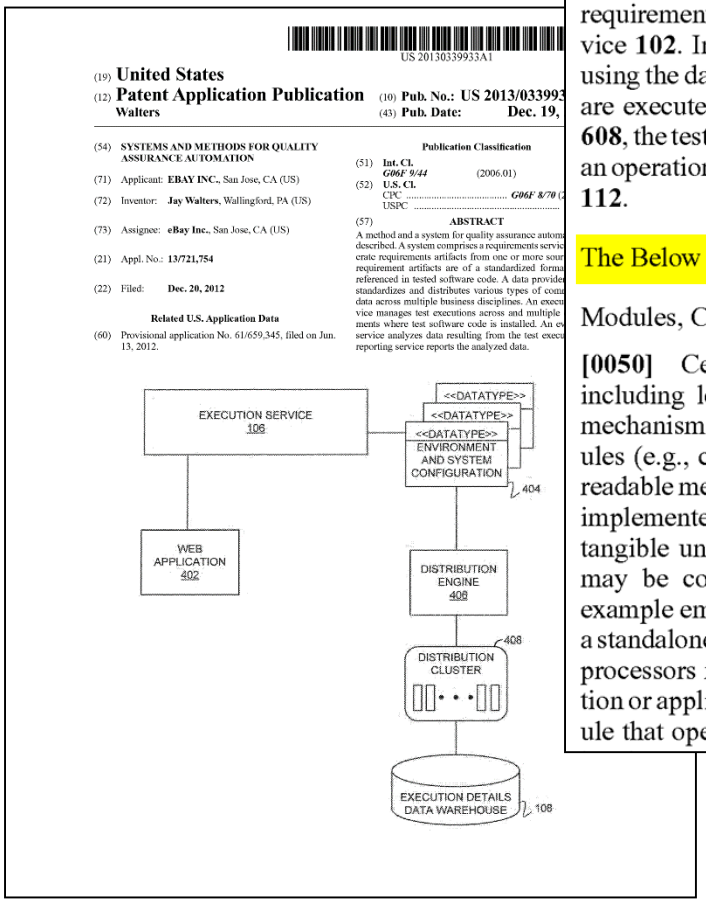
[1] Patents 291 ⇐1395

291 Patents
291V Construction and Operation of Patents
291V(C) Particular Fields of Invention

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

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

Find the Errors



US 20130339933A1

(19) **United States**

(12) **Patent Application Publication**

Walters

(10) **Pub. No.: US 2013/033993**

(43) **Pub. Date: Dec. 19,**

(54) **SYSTEMS AND METHODS FOR QUALITY ASSURANCE AUTOMATION**

(71) Applicant: **EBAY INC.**, San Jose, CA (US)

(72) Inventor: **Jay Walters**, Wallingford, PA (US)

(73) Assignee: **eBay Inc.**, San Jose, CA (US)

(21) Appl. No.: **13/721,754**

(22) Filed: **Dec. 20, 2012**

Related U.S. Application Data

(60) Provisional application No. 61/659,345, filed on Jun. 13, 2012.

Publication Classification

(51) **Int. Cl.**
G06F 9/44 (2006.01)

(52) **U.S. Cl.**
CPC *G06F 8/70*
USPC .....

(57) **ABSTRACT**

A method and a system for quality assurance autom
described. A system comprises a requirements servic
erate requirements artifacts from one or more sour
requirement artifacts are of a standardized forma
referenced in tested software code. A data provide
standardizes and distributes various types of conte
data across multiple business disciplines. An execu
vice manages test executions across and multiple
ments where test software code is installed. An ev
service analyzes data resulting from the test execu
reporting service reports the analyzed data.

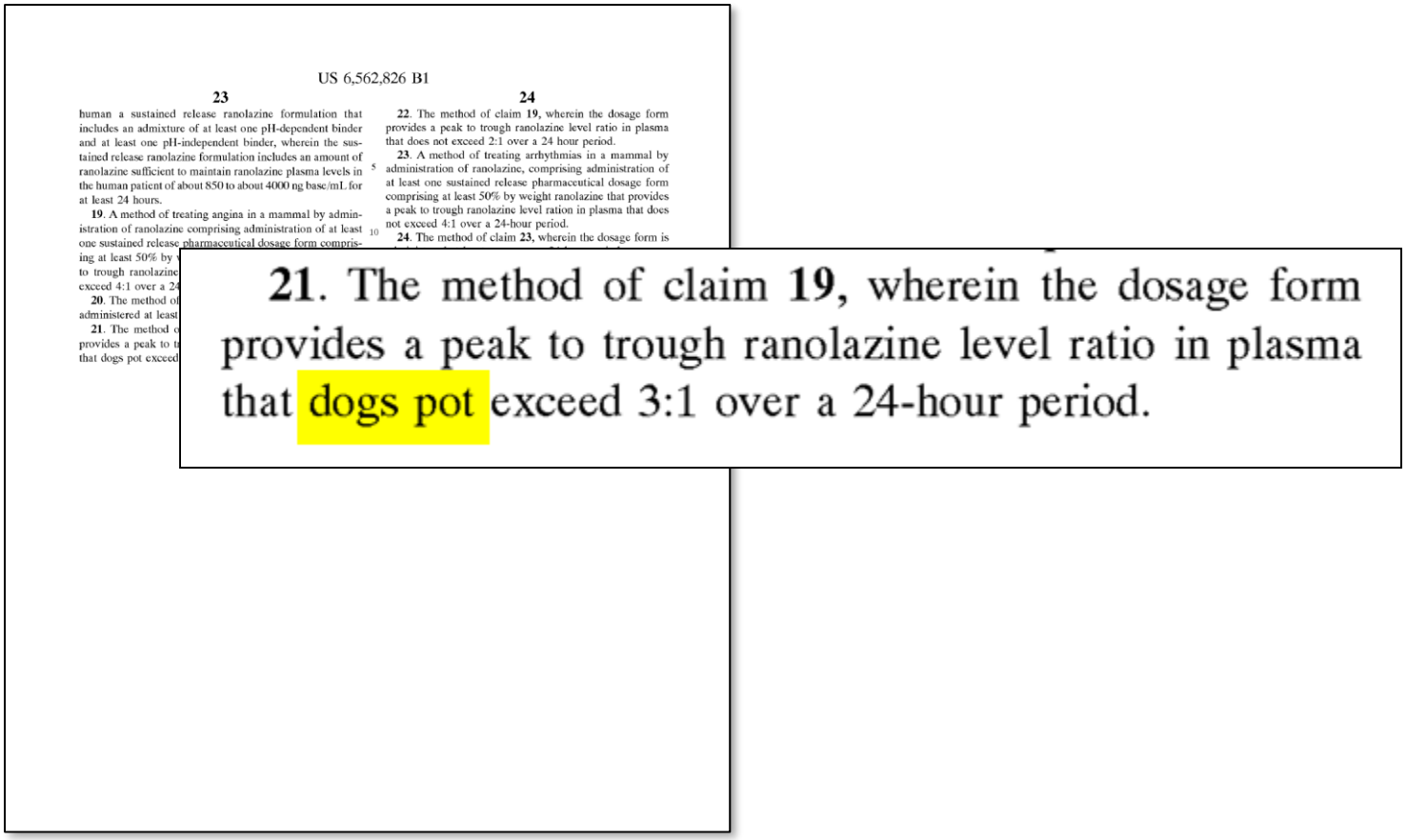
[0049] FIG. **6** is a flowchart illustrating an example method **600**, according to various embodiments. In an operation **602**, requirement artifacts are generated by the requirements service **102**. In an operation **604**, the test data is implemented using the data provider service **104**. In an operation **606**, tests are executed by the execution service **106**. In an operation **608**, the test data is evaluated by the evaluation service **110**. In an operation **610**, the test data is reported by the report service **112**.

The Below is Boilerplate.

Modules, Components and Logic

[0050] Certain embodiments are described herein as including logic or a number of components, modules, or mechanisms. Modules may constitute either software modules (e.g., code embodied (1) on a non-transitory machine-readable medium or (2) in a transmission signal) or hardware-implemented modules. A hardware-implemented module is tangible unit capable of performing certain operations and may be configured or arranged in a certain manner. In example embodiments, one or more computer systems (e.g., a standalone, client or server computer system) or one or more processors may be configured by software (e.g., an application or application portion) as a hardware-implemented module that operates to perform certain operations as described

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 compris-

ing at least 50% by
to trough ranolazine
exceed 4:1 over a 24
20. The method of
administered at least
21. The method o
provides a peak to t
that dogs pot exceed

24

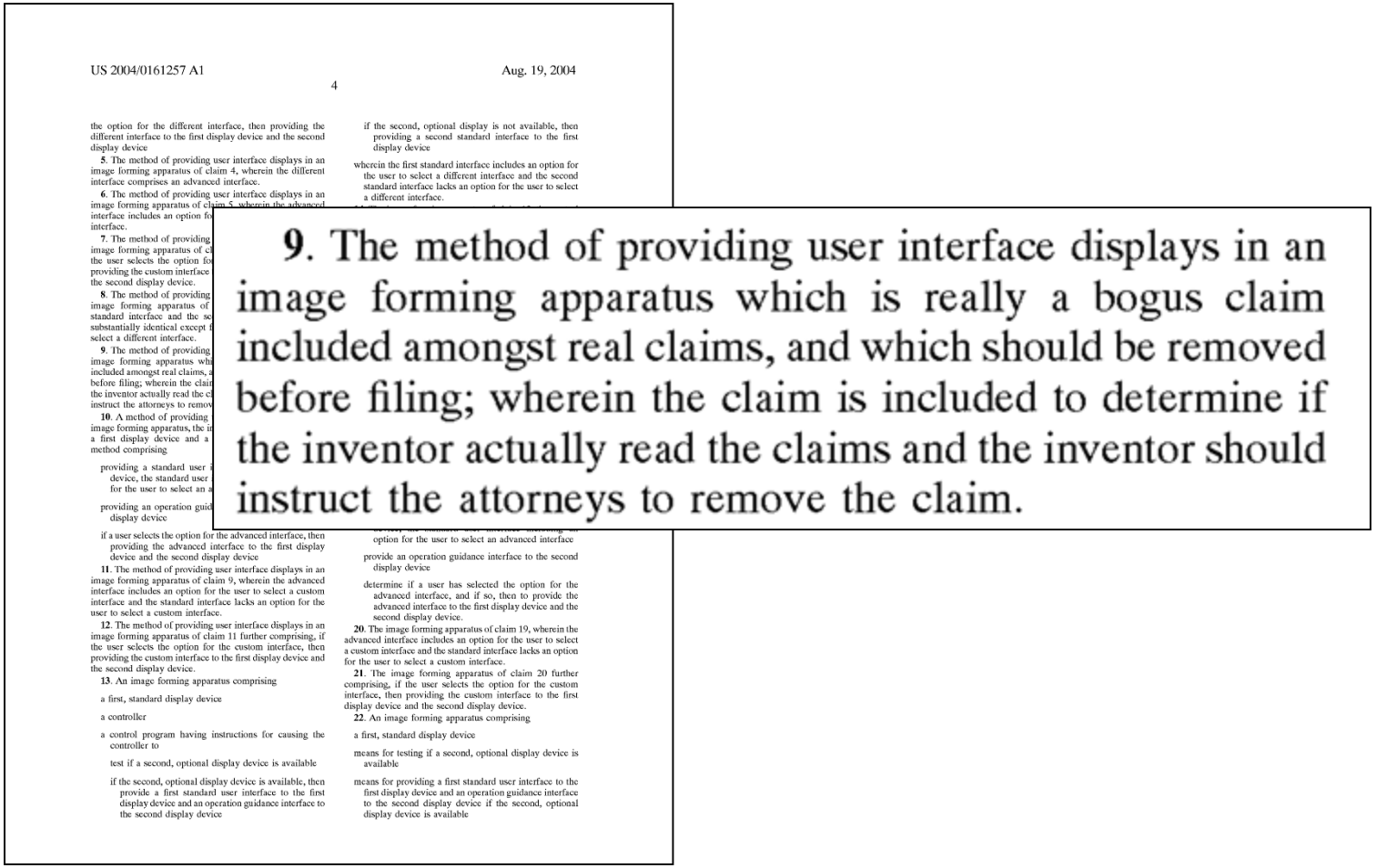
22. The method of claim **19**, wherein the dosage form provides a peak to trough ranolazine level ratio in plasma that does not exceed 2:1 over a 24 hour period.

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

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

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 fo
interface.

7. The method of providing
image forming apparatus of cl
the user selects the option fo
providing the custom interface
the second display device.

8. The method of providing
image forming apparatus of
standard interface and the se
substantially identical except f
select a different interface.

9. The method of providing
image forming apparatus wh
included amongst real claims, a
before filing; wherein the clai
the inventor actually read the cl
instruct the attorneys to remov

10. A method of providing
image forming apparatus, the i
a first display device and a
method comprising

providing a standard user i
device, the standard user
for the user to select an a

providing an operation guid
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

wherein the first standard interface includes an option for the user to select a different interface and the second standard interface lacks an option for the user to select a different interface.

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

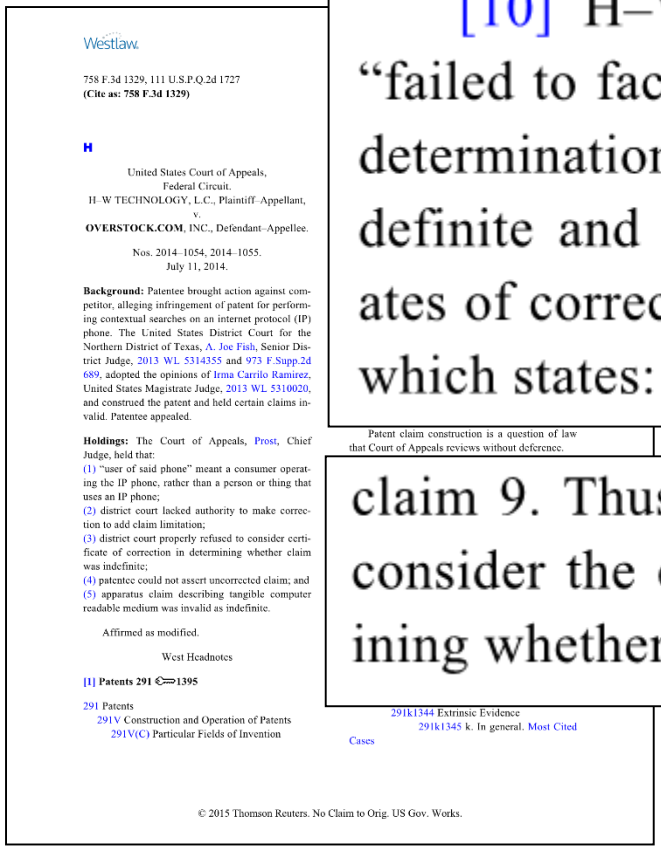
a first, standard display device

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.

Find the Errors



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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

Patent claim construction is a question of law that Court of Appeals reviews without deference.

291k1344 Extrinsic Evidence
291k1345 k. In general. Most Cited Cases

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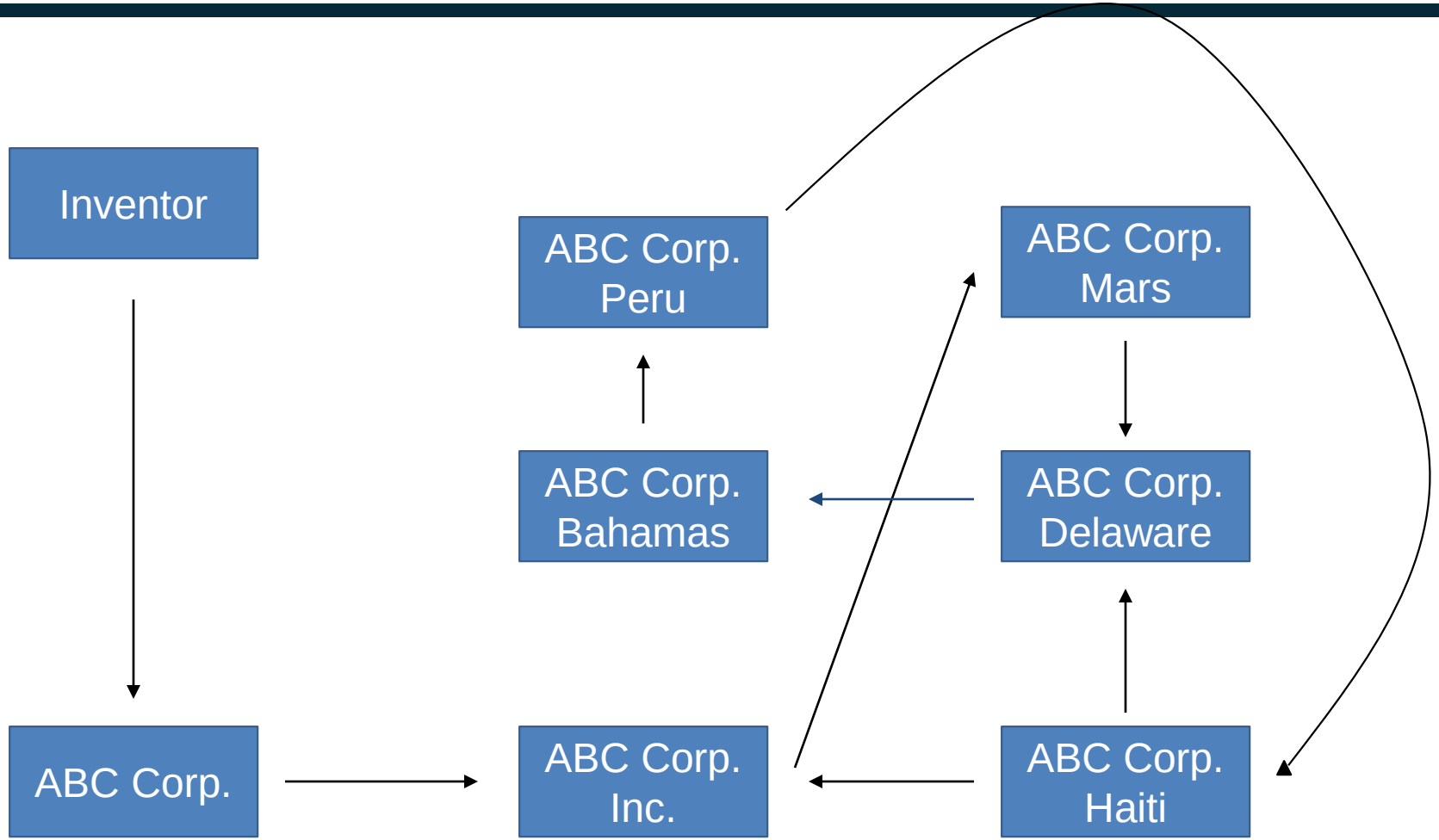
[10] H–W also argues that the district court "failed to factor the certificate of correction in [its] determination that claim 9 of the '955 Patent is indefinite and invalid." Appellant's Br. 21. Certificates of correction are governed by 35 U.S.C. § 254, which states:

claim 9. Thus, the district court was correct not to consider the certificate of correction when determining whether H–W could assert claim 9.

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

OWNERSHIP

Ownership


Inventor
ABC Corp.
ABC Corp. Peru
ABC Corp. Bahamas
ABC Corp. Inc.
ABC Corp. Mars
ABC Corp. Delaware
ABC Corp. Haiti

Ownership

For our purposes, two types of recovery:

- Reasonable Royalty
- Lost Profits

The only one that matters is *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 for Litigation – the Label

Proving Infringement is Based on the Label . . .

Listen in next time . . . .

Questions?

Thank you!

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