On Sale Bar

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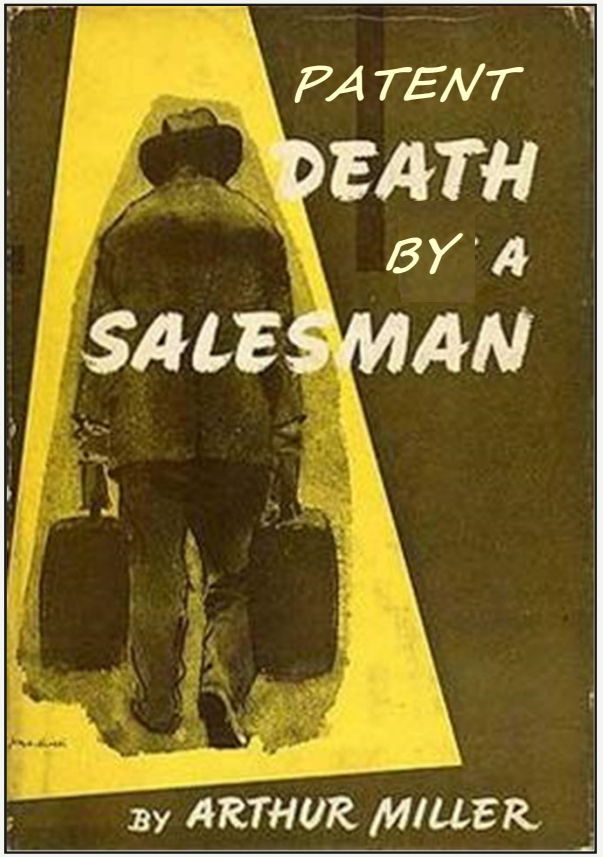
wolf greenfield
INTELLECTUAL PROPERTY LAW

Overview

On Sale Bar

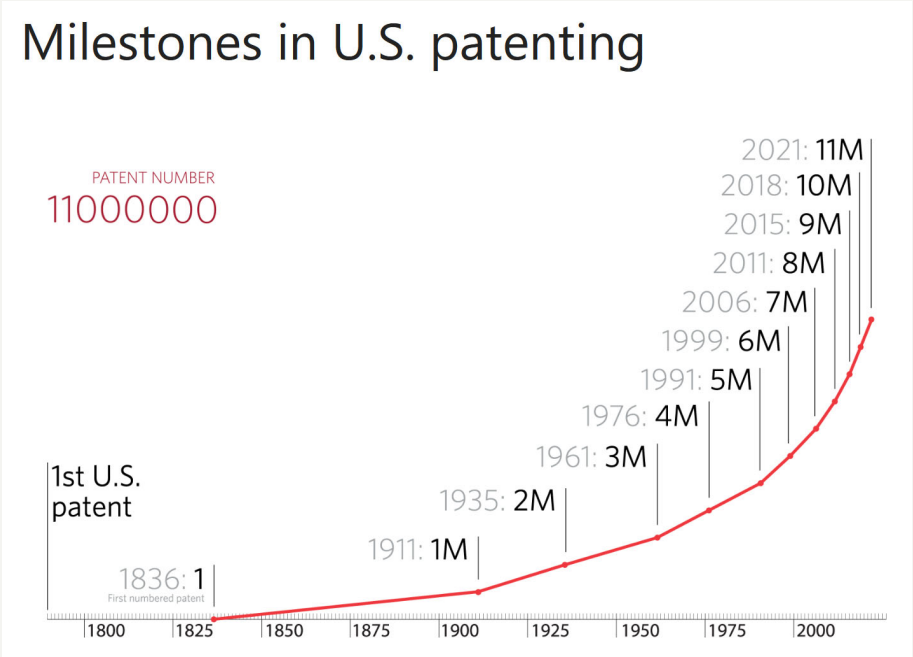
- Introduction
- Legal Framework
- Examples
- Considerations and Recommendations



Introduction

https://www.uspto.gov/patents/milestones

- Sales - a bar to patentability since the establishment of the patent office.
- "[T]here shall be established … an office to be denominated the Patent Office"
- The Commissioner on due proceedings may grant a patent to any person for inventions "not, at the time of his application for a patent, … **on sale**"
- Patent Act of 1836, Ch. 357, 5 Stat. 117 (July 4, 1836)



35 U.S.C. § 102 (AIA)

On Sale Bar

(a) **Novelty; Prior Art.**

A person shall be entitled to a patent unless—

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention

(b) **Exceptions.**

(1)Disclosures made 1 year or less before the effective filing date of the claimed invention.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—

(A)the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor

What triggers the On Sale Bar?

Pfaff v. Wells Elecs., Inc. 525 U.S. 55 (1998)

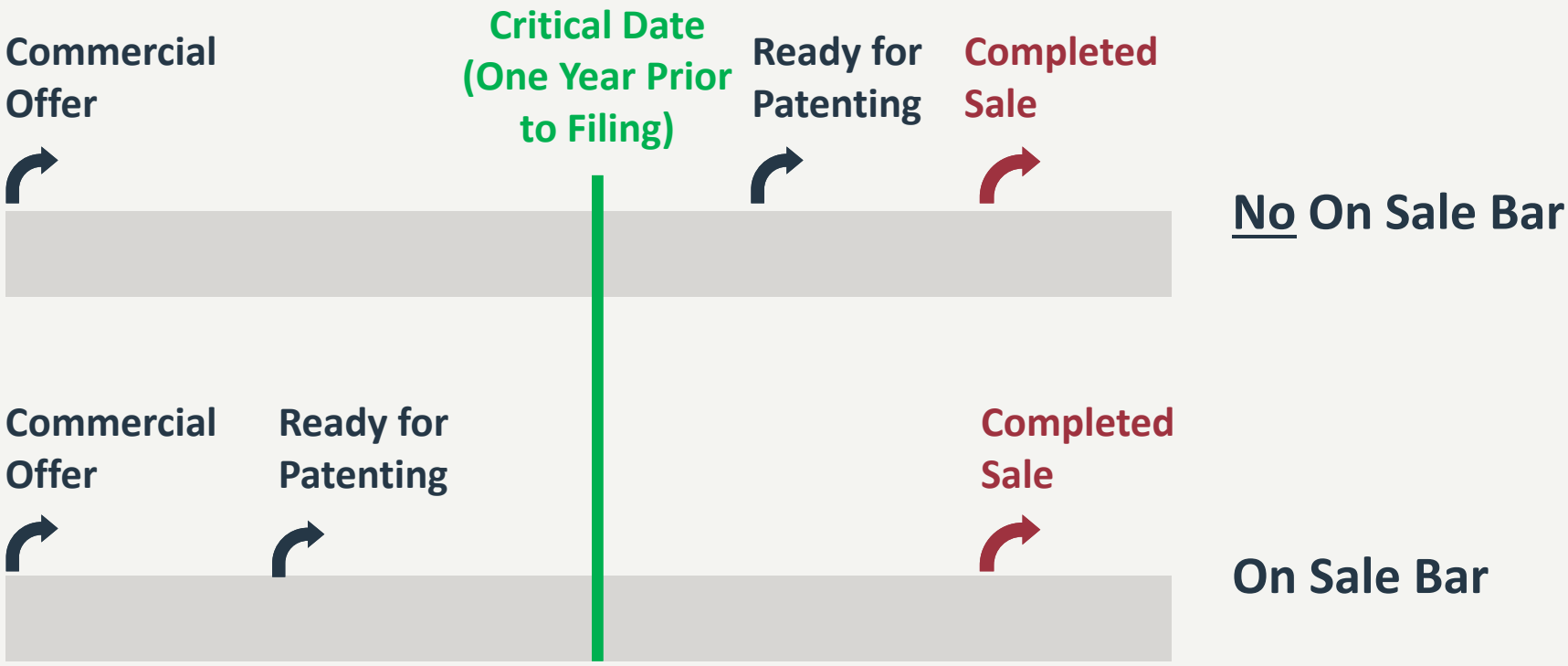
Policy Rationale for the On Sale Bar

On Sale Bar

1. avoiding removing inventions from the public domain which the public justifiably comes to believe are freely available due to commercialization — Public
2. favoring prompt and widespread disclosure of inventions to the public — Public
3. giving inventors a reasonable amount of time following sales activity to determine whether a patent is worthwhile — Inventor

Timing Considerations

Hypothetical scenario where patent application is filed (critical date/one year prior to filing shown)



What is a Commercial Sale?

Grp. One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1047 (Fed. Cir. 2001)

- **Federal Circuit Law (not State law)**
  - Avoids inconsistent outcomes from state to state
  - Analyzed under the law of contracts as generally understood
  - Uniform Commercial Code is a helpful guide

- **Sale**: consists in the passing of title from the seller to the buyer for a price UCC § 2-106
  - The passage of title is a helpful indicator of whether a product is "on sale," as it suggests when the inventor gives up its interest and control over the product. Medicines Co. v. Hospira, Inc., 827 F.3d 1363, 1375 (Fed. Cir. 2016)

What is a Commercial Offer?

The UCC does not define "offer," so courts look to the common law.

- **Commercial offer happens when sale can be made by simple acceptance**:
  - "Only an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration)" triggers the On Sale bar. Medicines Co. v. Hospira, Inc., 827 F.3d 1363, 1378 (Fed. Cir. 2016)

- **Offer must be consistent with what would be understood as a sale in the commercial community:**
  - Commercial offer "must meet the level of an offer for sale in the contract sense, one that would be understood as such in the commercial community". Grp. One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1046 (Fed. Cir. 2001)

Indicators of a Commercial Sale / Offer for Sale

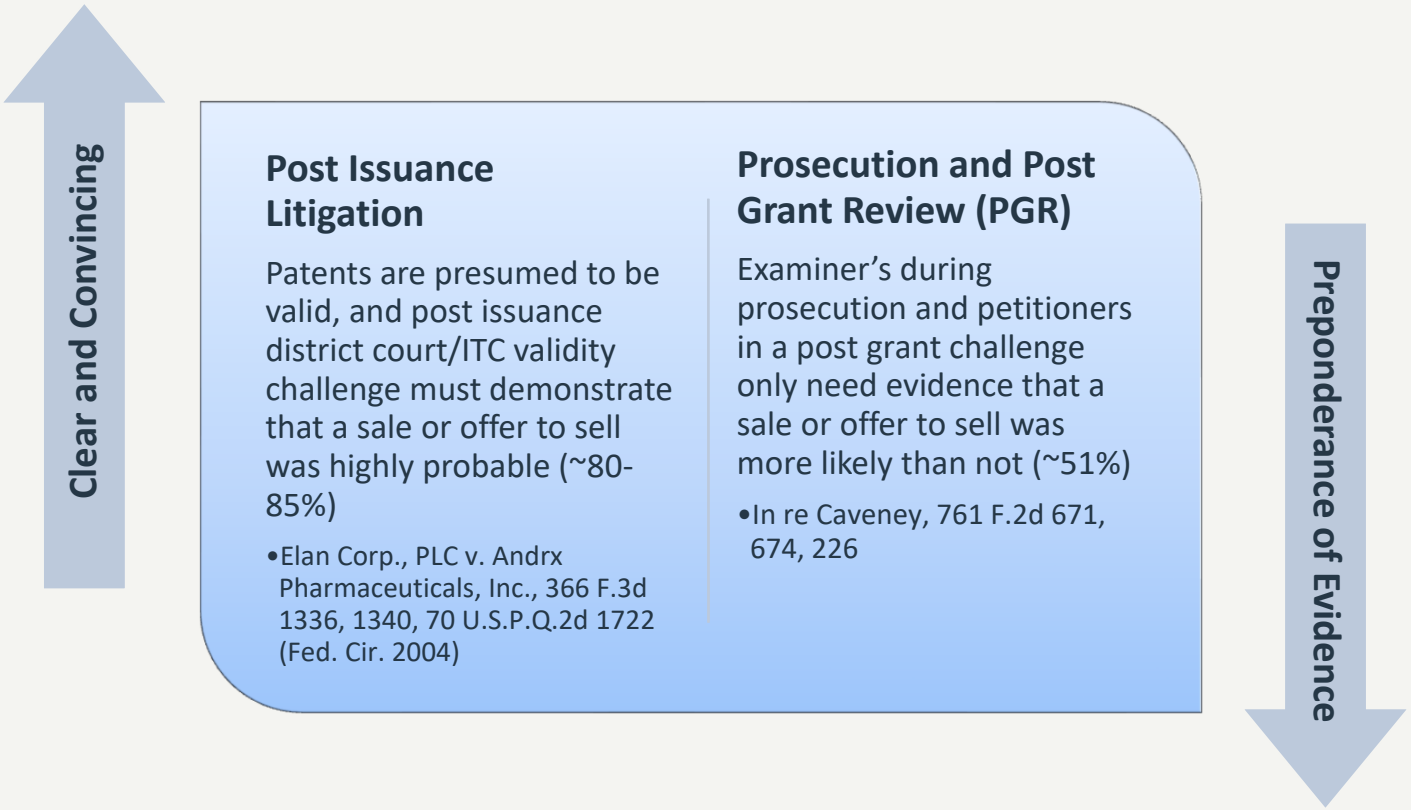
Fact Specific Inquiries

Commercial Sale / Offer for Sale	No Commercial Sale / Offer Sale
• Title Transfer • Invoicing • Pricing Terms • Delivery location/timing • Quantity • Product specifications • Marketing efforts	• Indefinite terms • No title transfer • No commercial marketing • No change of control • To some extent confidentiality

Additional Considerations:

- For there to have been a commercial offer: Inventor need not profit, sale doesn't need to be completed, sale can be conditional, delivery doesn't need to happen, etc.
- Custom and practice within a given industry can be used in determining whether activities constitute a commercial offer for sale – software license can be a sale

Evidentiary Requirements



On Sale Bar is Not Limited to Inventor Sales

Third party sales can trigger on sale bar with or without inventor's consent or knowledge

- Abbott Laboratories v. Geneva Pharmaceuticals, Inc., 182 F.3d 1315, 1318, 51 U.S.P.Q.2d 1307, 1309 (Fed. Cir. 1999) ("[T]he statutory **on-sale bar is not subject to exceptions for sales made by third parties** either innocently or fraudulently."—affirming summary judgment of invalidity based on sales by a non-party)

- In re Epstein, 32 F.3d 1559, 1564, 31 U.S.P.Q.2d 1817, 40 Fed. R. Evid. Serv. 773 (Fed. Cir. 1994) 'public use' and 'on sale' bars are not limited to sales or uses by the inventor or one under the inventor's control, but **may result from activities of a third party** which anticipate the invention, or render it obvious."—using abstracts showing software product sold by third party to affirm rejection of claims)

- Pennwalt Corp. v. Akzona Inc., 740 F.2d 1573, 1580 n.14, 222 U.S.P.Q. 833 (Fed. Cir. 1984) ("Although Pennwalt [the licensee] rather than Armark [the patentee] made the subject sales, it is well settled that the **'on sale' bar applies to sales made by the inventor or another**, with or without the inventor's consent."—affirming finding of invalidity)

America Invents Act (AIA)

Expanded geographic scope; did not limit prior art to public sales

§ 102 (pre-AIA)	§ 102 (post-AIA)
A person shall be entitled to a patent unless — … (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or **on sale in this country**, more than one year prior to the date of the application for patent in the United States	(a) Novelty; Prior Art.—A person shall be entitled to a patent unless— (1) the claimed invention was patented, described in a printed publication, or in public use, **on sale**, or otherwise available to the public before the effective filing date of the claimed invention *No Geographic Limitations*

Secret Sales Can Trigger the On Sale Bar: "[A]n inventor's sale of an invention to a third party who is obligated to keep the invention confidential can qualify as prior art under § 102(a)" - holding that AIA changes did not limit the On Sale bar to public sales. Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., 202 L. Ed. 2d 551, 139 S. Ct. 628, 634 (2019)

Relationship to Claimed Invention

The product/service sold must "embody" the claimed invention

- Subject matter of the sale or offer to sell **must anticipate the claimed invention, or render it obvious**
  - "Section 102(b) may create a bar to patentability either alone, if the device placed on sale is an anticipation of the later claimed invention or, in conjunction with 35 U.S.C.A. § 103, if the claimed invention would have been obvious from the on-sale device in conjunction with the prior art." LaBounty Mfg., Inc. v. U.S. Intern. Trade Com'n, 958 F.2d 1066, 1071, 13Int'l Trade Rep. (BNA) 2281, 22 U.S.P.Q.2d 1025 (Fed. Cir. 1992).
- **Product v. process claims**
  - **Product claims** – have to actually sell the product or use of the product to trigger on sale bar
  - **Process claims** – sale of product produced by process or sale of performance of process triggers on sale bar
- Sales of IP/patent rights in the invention do not trigger on sale bar
- Contracting for services not embodying the claimed invention do not trigger on sale bar

Products and Undisclosed Processes of Making Them

Celanese Int'l Corp. v. Int'l Trade Comm'n, 111 F.4th 1338 (Fed. Cir. 2024)
TorPharm, Inc. v. Ranbaxy Pharmaceuticals, Inc., 336 F.3d 1322 (2003)
In re Caveney, 761 F.2d 671, 675, 226 U.S.P.Q. 1, 3–4 (Fed. Cir. 1985)

Patentee sale of product to a buyer	• Bar as to product • Bar as to undisclosed process
Third party sale of product to a buyer	• Bar as to product • No Bar as to undisclosed process

Ready for Patenting

- **Reductions to practice**, e.g., demonstrations at a trade show, making/testing working prototypes or samples – where the embodiment meets every limitation of the claim and/or works for its intended purposes
- **Descriptions and depictions of the claimed invention** sufficient to enable a person of ordinary skill to make/use the invention (e.g., description of molecular structure, physical arrangements, flow charts, etc.)
- **For pharmaceuticals/biologics**, there is no requirement that a drug pass all testing required for FDA/Regulatory approval for it to be ready for patenting

Experimental Use Exception

City of Elizabeth v. American Nicholson Pavement Co., 97 U.S. 126 (1877)

- "Experimental use" of an invention is an exception to the on sale bar
  - Very narrow exception
  - Multi-factoral analysis of circumstances
  - More often implicated in public use cases rather than on sale cases
  - Extends to sales made solely for purposes of testing the product for suitability for a particular functional purpose – i.e., sales clearly incidential to an experimental use
  - Does not include market testing

Ex parte CONNECTYOURCARE, LLC

PTAB Ex parte reexamination appeal 2022-000108

- US Patent 10,032,217 relates to a management database system for employee contribution funded accounts

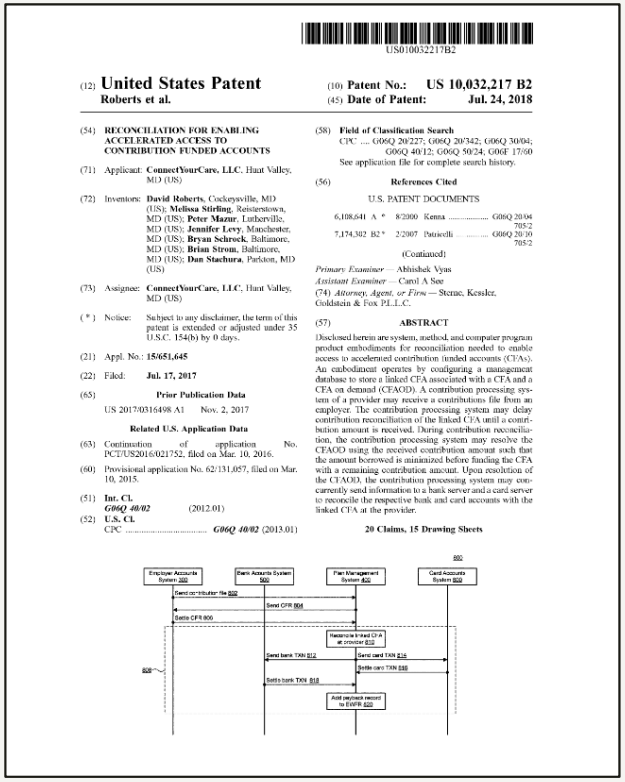
2013 Version of product had system errors

Critical Date: March 2014

Reduction to practice: July 2014

Earliest Filing Date: March 2015

- Examiner rejected the claims for § 103 obviousness over a § 1.132 Declaration and second reference
- The Examiner argued that the combination disclosed every element of independent claim 1, and the contents described in the Stirling Declaration were on sale before critical date.
- Appellant argued that the Declaration contents did not constitute an on sale bar because the invention was not ready for patenting until less than one year before the effective filing date.
- The Board found that the invention was only “ready for patenting” (through reduction to practice) on July 8, 2014, when the software had all of the claimed elements and the inventors fixed the software to work for its intended purpose – no on sale bar



US010032217B2

(12) **United States Patent**
Roberts et al.

(10) **Patent No.: US 10,032,217 B2**
(45) **Date of Patent: Jul. 24, 2018**

(54) **RECONCILIATION FOR ENABLING ACCELERATED ACCESS TO CONTRIBUTION FUNDED ACCOUNTS**

(71) Applicant: **ConnectYourCare, LLC**, Hunt Valley, MD (US)

(72) Inventors: **David Roberts**, Cockeysville, MD (US); **Melissa Stirling**, Reisterstown, MD (US); **Peter Mazur**, Lutherville, MD (US); **Jennifer Levy**, Manchester, MD (US); **Bryan Schreck**, Baltimore, MD (US); **Brian Strom**, Baltimore, MD (US); **Dan Stachura**, Parkton, MD (US)

(73) Assignee: **ConnectYourCare, LLC**, Hunt Valley, MD (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/651,645**

(22) Filed: **Jul. 17, 2017**

(65) **Prior Publication Data**

US 2017/0316498 A1 Nov. 2, 2017

Related U.S. Application Data

(63) Continuation of application No. PCT/US2016/021752, filed on Mar. 10, 2016.

(60) Provisional application No. 62/131,057, filed on Mar. 10, 2015.

(51) **Int. Cl.**
G06Q 40/02 (2012.01)

(52) **U.S. Cl.**
CPC ***G06Q 40/02*** (2013.01)

(58) **Field of Classification Search**
CPC G06Q 20/227; G06Q 20/342; G06Q 30/04; G06Q 40/12; G06Q 50/24; G06F 17/60
See application file for complete search history.

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Primary Examiner — Abhishek Vyas
Assistant Examiner — Carol A See
(74) *Attorney, Agent, or Firm* — Sterne, Kessler, Goldstein & Fox P.L.L.C.

(57) **ABSTRACT**

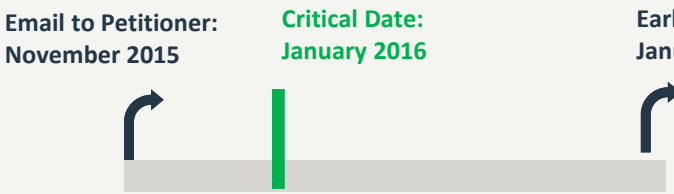
Disclosed herein are system, method, and computer program product embodiments for reconciliation needed to enable access to accelerated contribution funded accounts (CFAs). An embodiment operates by configuring a management database to store a linked CFA associated with a CFA and a CFA on demand (CFAOD). A contribution processing system of a provider may receive a contributions file from an employer. The contribution processing system may delay contribution reconciliation of the linked CFA until a contribution amount is received. During contribution reconciliation, the contribution processing system may resolve the CFAOD using the received contribution amount such that the amount borrowed is minimized before funding the CFA with a remaining contribution amount. Upon resolution of the CFAOD, the contribution processing system may concurrently send information to a bank server and a card server to reconcile the respective bank and card accounts with the linked CFA at the provider.

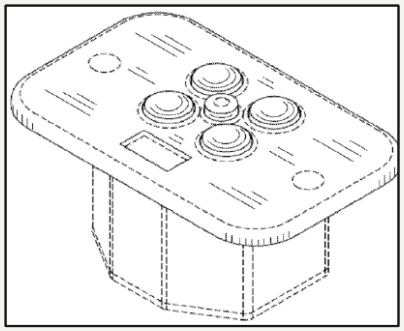
20 Claims, 15 Drawing Sheets

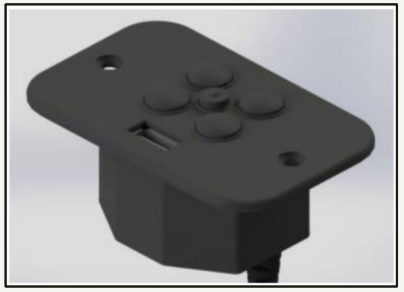
Man Wah Holdings Limited v. Raffel Systems, LLC

PTAB Post-grant review PGR2019-00029

- US Patent D821,986 relates to an ornamental design for a switch.







- Petitioner Man Wah argued that the D'986 patent was invalid for anticipation due to on sale bar over "Raffel_sample," which is an email dated November 17, 2015 from a representative of Patent Owner Raffel to representatives of Petitioner, providing images of a "ManWah – Power Recline and Headrest Controls," a product number, price, VAT tax rate, minimum quantity for purchase, and total price.
- The Board found that the email constituted a concrete offer for a product that was identical in design to the patented design.
- Accordingly, the patent claim was invalidated on grounds of anticipation by an on sale bar.

Quest Integrity USA, LLC v. Cokebusters USA Inc.

924 F.3d 1220 (Fed. Cir. 2019)

- Patent 7,542,874 relates to systems and methods for displaying inspection data collected from commercial furnaces.

- The parties agreed that the Norco Sale was a commercial offer for sale as applies to the on sale bar.
  - "Quest used its method, computer-readable medium, and system commercially to perform furnace inspection services and produce the Norco Reports for its customer."
- The court found that the Norco Sale met a particular "Display Limitation" recited in claims 12, 24, and 33 and therefore anticipated these claims due to on sale bar.

11. A computerized method for displaying inspection data collected from a furnace with a specified physical geometry, wherein said furnace comprises a plurality of tube segments interconnected by a plurality of bends so as to allow stacking of at least a portion of said tube segments, said method comprising:

partitioning said inspection data at a plurality of data markers each of which identifies a location of a physical feature of said furnace so as to correlate said inspection data to said physical geometry of said furnace;

generating a display of at least a portion of said partitioned inspection data arranged to represent said physical geometry of a plurality of said tube segments and enable visual detection of a problem area comprising one or more of said tube segments; and

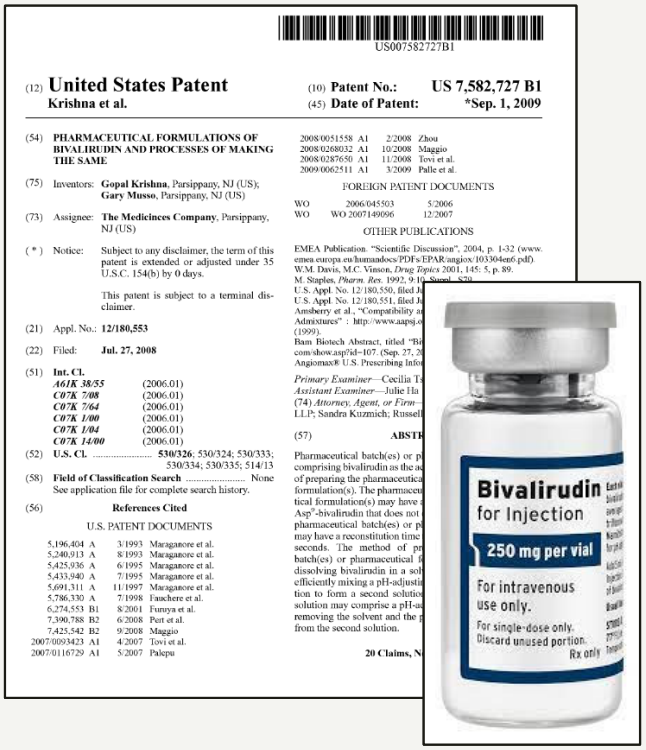
wherein said inspection data is collected by one or more devices selected from the following group: an ultrasonic transducer, a laser profilometer, and combinations thereof.

12. The computerized method of claim **11**, wherein said display is comprised of a two-dimensional or three-dimensional representation of one or more of said stacked tube segments of said furnace.

Medicines Co. Cases

Manufacturing services not an on sale bar as to product; marketing and distribution agreement concerning product was commercial sale

- U.S. Patents 7,582,727 and 7,598,343 covering the pharmaceutical drug bivalirudin held by Medicines
- Medicines engaged with Ben Venue Labs to manufacture batches of bivalirudin, work was performed more than one year before the filing of their patent applications.
- Later asserted patents against Hospira, Inc.
- Hospira argued that the manufacturing contracts constituted an on sale bar
- CAFC ruled that a confidential **manufacturing service contract did not constitute a commercial sale** (no transfer of title to product) – no on sale bar.
- Following remand and subsequent additional appeal, the CAFC found **separate marketing and distribution agreement *was* a commercial sale, as it involved the sale of product** rather than a manufacturing service



US007582727B1

(12) **United States Patent**
Krishna et al.

(10) **Patent No.: US 7,582,727 B1**
(45) **Date of Patent: *Sep. 1, 2009**

(54) **PHARMACEUTICAL FORMULATIONS OF BIVALIRUDIN AND PROCESSES OF MAKING THE SAME**

(75) Inventors: **Gopal Krishna**, Parsippany, NJ (US); **Gary Musso**, Parsippany, NJ (US)

(73) Assignee: **The Medicines Company**, Parsippany, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **12/180,553**

(22) Filed: **Jul. 27, 2008**

(51) **Int. Cl.**
A61K 38/55 (2006.01)
C07K 7/08 (2006.01)
C07K 7/64 (2006.01)
C07K 1/00 (2006.01)
C07K 1/04 (2006.01)
C07K 14/00 (2006.01)

(52) **U.S. Cl.** **530/326**; 530/324; 530/333; 530/334; 530/335; 514/13

(58) **Field of Classification Search** ..... None
See application file for complete search history.

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U.S. Appl. No. 12/180,550, filed J
U.S. Appl. No. 12/180,551, filed J
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(1999).
Bam Biotech Abstract, titled "Bi
com/show.asp?id=107. (Sep. 27, 2
Angiomax® U.S. Prescribing Info

Primary Examiner—Cecilia T
Assistant Examiner—Julie Ha
(74) *Attorney, Agent, or Firm* –
LLP; Sandra Kuzmich; Russell

(57) **ABST**

Pharmaceutical batch(es) or p
comprising bivalirudin as the a
of preparing the pharmaceutica
formulation(s). The pharmaceu
tical formulation(s) may have
Asp^9-bivalirudin that does not
pharmaceutical batch(es) or p
may have a reconstitution time
seconds. The method of pr
batch(es) or pharmaceutical f
dissolving bivalirudin in a sol
efficiently mixing a pH-adjusti
tion to form a second solutio
solution may comprise a pH-a
removing the solvent and the p
from the second solution.

20 Claims, N

Medicines Co. v. Hospira, Inc., 791 F.3d 1368 (Fed. Cir.), *opinion vacated, appeal reinstated sub nom. The Medicines Co. v. Hospira, Inc.*, 805 F.3d 1357 (Fed. Cir. 2015), and *on reh'g en banc*, 827 F.3d 1363 (Fed. Cir. 2016) *The Medicines Co. v. Hospira, Inc.*, 881 F.3d 1347 (Fed. Cir. 2018)

Contract Manufacturing/Research Scenarios

Issues to keep in mind

- Contracts are not always set up as pure fee for service arrangements – may include transfer of title to materials/deliverables, e.g., products for evaluation

- Need to consider the overall nature of the agreement or intent of arrangement (not just the specific contractual language) when assessing risk of on sale bar
  - Look at issues relating to control over product under development and restrictions on manufacturing
  - Look at materials transfer arrangement
  - Consider extent to which relationship is confidential (press releases, regulatory filings)
  - Relative cost of work versus market value of product discovered or produced
  - Look at payment terms and how they relate to products produced and control over the same

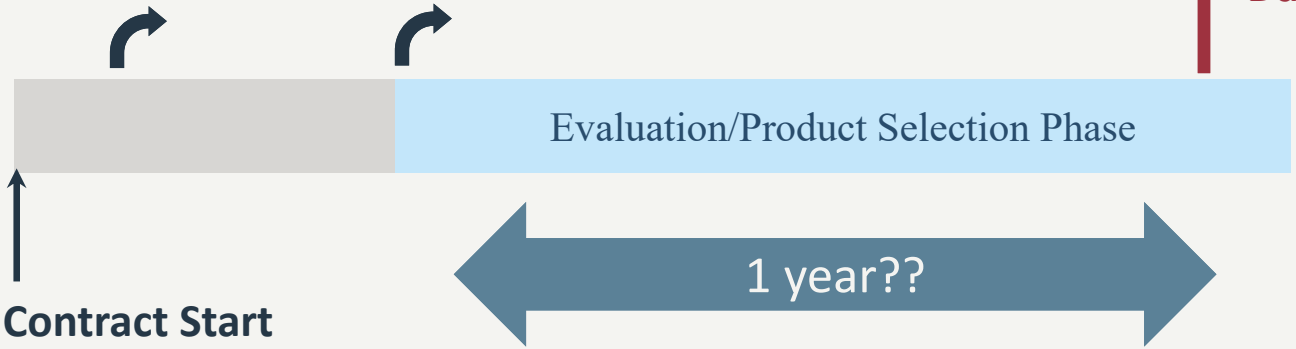
Hypothetical Scenario

Therapeutic Compound Discovery/Development

Discovery/screening phase; scope may be defined by SOW

Identification of active compounds (ready for patenting?)

Patent App. Filing Date



Contract Start potential including ongoing or later option to acquire title to discovered compounds

- Consider when a potential offer for sale or sale is complete to determine critical date and file within one year of that date
- Critical date is later of completion of offer and invention being ready for patenting

Practical Recommendations

Considerations

- **Educate stakeholders:** instill on sale bar issue spotting skills and encourage regular communications concerning outsourcing arrangements or sales and marketing activities
- **Things to look out for:**
  - Outsourcing, joint development, collaboration, licensing and options, materials transfer and other agreements or circumstances involving transfers of materials embodying a claimed invention or performance of methods embodying a claimed invention for value
  - Marketing testing, trade show activities, beta testing, service offerings, project proposals, and other activities that may transfer control or rights or otherwise provide third parties with access or title to products or methods embodying a claimed invention even if for ostensibly experimental purposes
- **Manage risk:** understand and (if needed/possible) adjust terms of such arrangements in advance to have inflection points for filing decisions; file within one year of critical date

Further Considerations

- **Due Diligence:**
  1. Sophisticated diligence counsel (investors, partners, acquirers, etc.) may inquire about potential pre-critical date sales activities; be prepared when defending
  2. On the other side, look out for such issues and account for them in establishing risk profile around target patents

- **Information Disclosure Statement (IDS)**: Consider whether activities (even if private or confidential) relating to sales/marketing of a claimed invention necessitate disclosure to the patent office in an IDS – deliberate failure to disclose on sale bar activity can lead to unenforceability (GS Cleantech Corp. v. Adkins Energy LLC, 951 F.3d 1310 (Fed. Cir. 2020))
  - US Patent office has procedures for submitting confidential information for consideration by examiners – MPEP 724.02