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2021 Update: Interplay between FDA Law and Patent Law: Avoiding Indigestion After Belcher v. Hospira

Before We Get Started...

Recording

A link to the recording and slides will be emailed to all registrants.

Questions

Type in the question box and we will answer in real time or during the Q&A.

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Panelist

Suneel Arora

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Areas of Practice:

- Medical Devices
- Electrical & Computers
- Mechanical & Electromechanical

Technologies:

- Circuits, Optics, Semiconductors
- Imaging, AI, Signal Processing
- Implantables. Wearables, Orthopedics
- Electrical and Radiation Therapy

IP Services:

- Due Diligence
- Foreign Rights
- Freedom To Operate
- Opinions
- Portfolio Management & Analysis
- Patent Prosecution

Suneel has established a 25-year track record as a collaborative counselor and pragmatic steward, capturing and curating IP of numerous industry-leading companies and successfully launched startup ventures. A Wisconsin native, he started his technology career as an integrated circuit engineer designing low-power ICs for power conversion and regulation, precision references, switched-capacitor filters, and analog-to-digital converters for implantable cardiac devices. Suneel applies his skills, honed on robust lifesaving designs without iteration, to his approach in crafting patents and portfolio strategies. Suneel worked full-time at the firm while earning his J.D. (summa cum laude; class valedictorian) from William Mitchell College of Law (1999). Suneel served as a judicial law clerk in U.S. District Court, District of Minnesota (1999-2000), where he worked primarily in the areas of IP, commercial transactions and securities, government contracts, franchise law, employment law, and constitutional violations. Suneel has been recognized as a "Super Lawyer" by Thomson Reuters (2009 – 2012) and in the IAM Patent 1000 (2021). He serves on the SLW Board of Directors, its Diversity, Equity, and Inclusion Steering Group, and on the IP Advisory Board of Mitchell Hamline law school. View Suneel's full profile here.

Panelist

Timothy Christman, MSEE

Principal | 612-359-3274 | tchristman@slwip.com

Areas of Practice:

- Electrical & Computers
- Mechanical & Electromechanical
- Medical Devices

IP Services:

- Acquisition Due Diligence
- Foreign Rights
- Freedom To Operate
- Licensing
- Opinions
- Patent Analytics
- Patent Prosecution
- Portfolio Management & Analysis

Mr. Timothy J. Christman has handled intellectual property matters for concepts ranging from the incremental to the revolutionary. He and Schwegman understand that all of the matters handled by our firm are important to our clients and deserve the highest level of care. Prior to joining Schwegman, Tim worked as a test engineer and later as a design engineer on active implantable medical devices. In addition to his medical device background, Tim is conversant in physics-oriented domains such as relating to imaging science, acoustics, electromagnetics, and spectroscopy, as well as electronics-related subject matter including device structures, circuits, fabrication techniques, and display technologies. Tim is a private pilot and is also interested in mechanical technologies, particularly in the aerospace, medical, and transportation domains.

View Tim's full profile here.

Panelist

Lea Westman

Attorney | 612-371-2115 | lwestman@slwip.com

Areas of Practice:

- Chemical & Materials Science
- Life Sciences
- Mechanical & Electromechanical
- Medical Devices

IP Services:

- Foreign Rights
- Freedom To Operate
- Patent Prosecution
- Trademarks

Lea prepares and prosecutes patents for clients in a wide variety of technological fields, including materials science, medical devices, chemical, and mechanical technologies. Lea's extensive aerospace patent prosecution experience includes electrode materials and thermal management, in addition to work on gas turbine engines. In her laboratory days, she researched fuel cells and batteries in the Materials and Sensors division at HRL laboratories, and characterized materials in the analytical chemistry lab at Pepperdine University. She additionally works with clients on freedom to operate and due diligence projects to help focus intellectual property strategy, as well as inter partes reviews. She is an adjunct professor at the University of St. Thomas, where she coaches the AIPLA Giles Sutherland Rich Moot Court Competition. In 2020, her students were finalists in the AIPLA Midwest Regional Tournament where they won Best Brief, and semi-finalists in the AIPLA National Tournament. View Lea's full profile here.

Panelist

John Swart

Attorney | 612-371-2147 | jswart@slwip.com

Areas of Practice:

- Medical Devices
- Chemical & Material Science
- Electrical & Computers
- Mechanical & Electromechanical

IP Services:

- Opinions
- Portfolio Management & Analysis
- Patent Prosecution

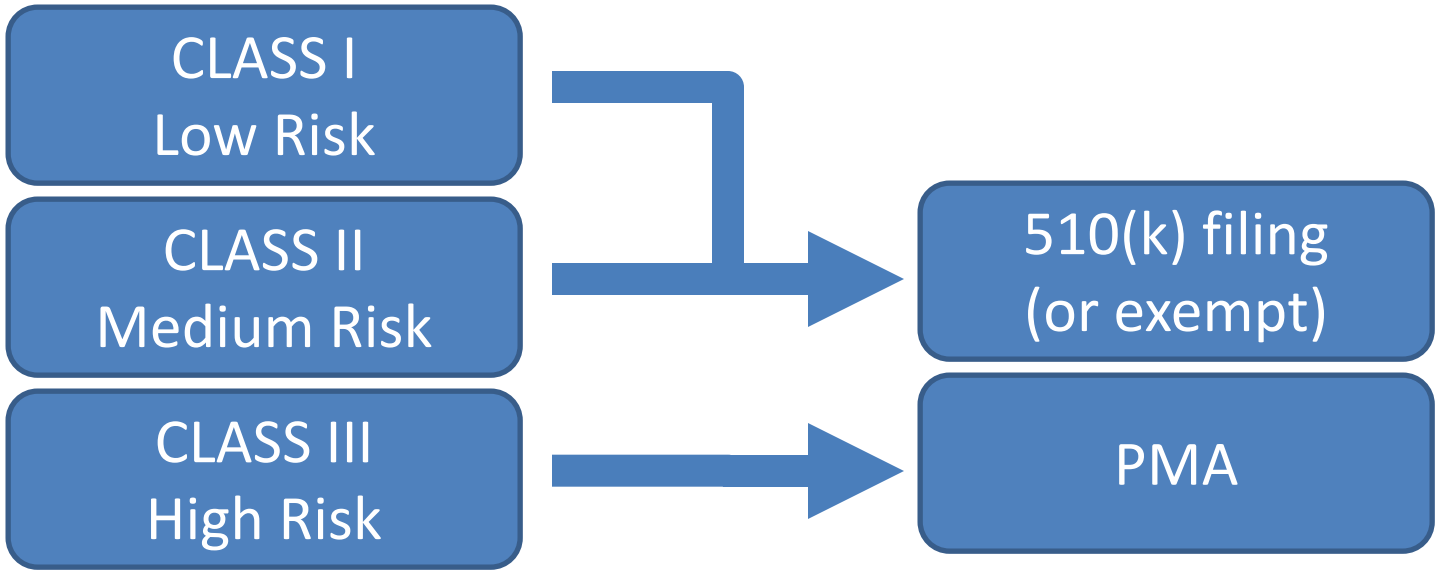
John Swart prepares and prosecutes patents in several fields including chemical, biomedical, mechanical, and electrical technologies. Additionally, John assists clients in a variety of research and opinion matters pertaining to portfolio management. Before his legal career, John worked in the construction and commercial cabinet industries. John is also a jazz pianist and teaching artist at Walker West Music Academy in St. Paul, MN. John draws from his experience across multiple industries and technical disciplines.

Overview

1. FDA Approval Process
2. FDA 510(k) Clearance vs. Premarket Approval (PMA)
3. Substantial Equivalence under 510(k)
   - Implications for Patentability and Patent Validity
   - Implications for Infringement
4. Candor – to FDA, and to the USPTO
   - Materiality standard for the USPTO
   - Potential Liability against FDA?
5. Exemption From Infringement Under 271(e)(1)
6. Patent Term Extension for Regulatory Approval Delay

FDA Approval Process

Identify device classification:



Submit for “clearance” under 510(k) process, or “approval” under premarket approval process, depending on device classification & subject to exceptions

FDA Premarket Approval (PMA)

...Generally, a more cumbersome route. Relevant FD&C statutes:

§ 513(a)(1)(C) CLASS III, PREMARKET APPROVAL, where the device

- is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or
- presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 515, to Premarket approval to provide reasonable assurance of its safety and effectiveness. **[21 USC § 360c]**

§ 515(c)(1)(A) – requiring "full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective" **[21 USC § 360e]**

FDA Premarket Approval (PMA)

Costly and time-consuming.

PMA route generally involves submission of

- device description and indications
- marketing and manufacturing information
- reference to pertinent performance standards
- preclinical investigatory studies
- clinical investigatory studies
- proposed labeling…

… and the list goes on.

Then you wait – potentially for *years*.

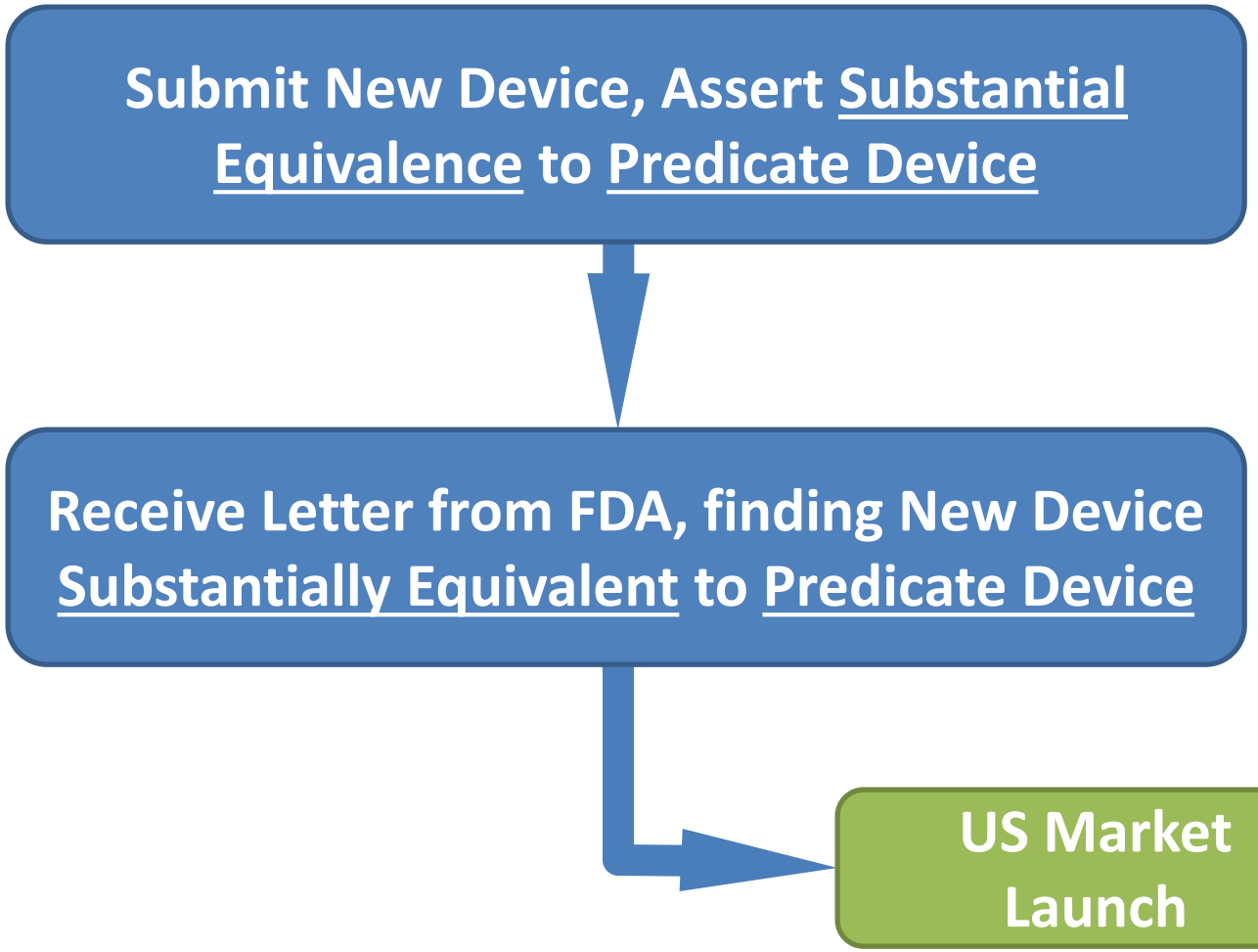
FDA 510(k) "Clearance" Process

§ 510(k) submissions are <u>abbreviated</u> compared to PMA pathway

- Generally available for Class I, II, and certain older Class III devices marketed before 1976
- Requirement of submission at least 90 days prior to launch (compare to at least 180-day delay for PMA review by FDA)

  [21 USC § 360]
- Specific requirements outlined in **27 CFR § 807** Subpart E

FDA 510(k) "Clearance" Process



Applicant "Notifies" (Submits)

FDA Clears

De Novo FDA Submissions

- Application sent to FDA by the medical device sponsor
- The De Novo process provides a pathway to classify novel medical devices which would otherwise be Class III, but if approved under de novo, can be Class I or Class II
- Provides reasonable assurance of safety and effectiveness for the intended use, but for which there is **no legally marketed predicate device**
- If granted, establishes new device type, and the device can serve as a predicate.
- Submissions include:
  - 513(f)(2) De Novo request (“Evaluation of Automatic Class III Designation”)
  - Administrative Information, such as the device's intended use, prescription use or over-the-counter use designated
  - Device Description, including technology, proposed conditions of use, accessory, components
  - Classification Information and Supporting Data

De Novo FDA Submissions

Option 1

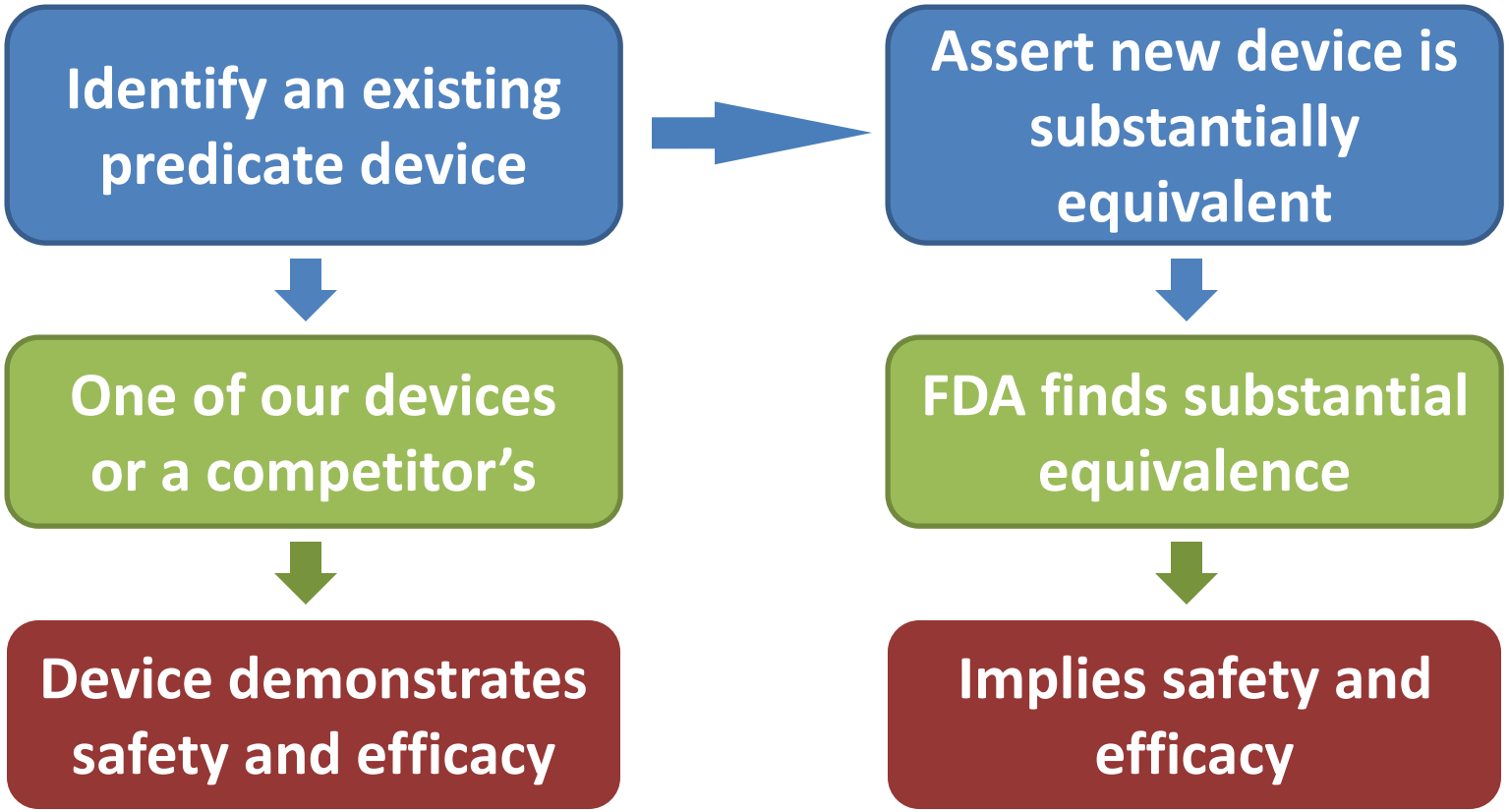
- After receiving a high-level not substantially equivalent (NSE) determination in response to a 510(k) submission
- After submission of 510(k)

Option 2

- Upon the requester's determination that there is no legally marketed device upon which to base a determination of substantial equivalence
- Before submission of 510(k)

Substantial Equivalence under 510(k)

This sounds much easier than PMA.



510(k) – Substantial Equivalence

According to FDA, a device is substantially equivalent if, in comparison to a predicate it:

has the same intended use as the predicate; **AND**

↓

has the same technological characteristics as the predicate.

OR

has the same intended use as the predicate; **AND**

↓

has different technological characteristics **AND** the information submitted to FDA:

↓

does not raise new questions of safety and effectiveness; **AND**

↓

demonstrates that the device is at least as safe and effective as the legally marketed device.

510(k) – Substantial Equivalence

What is a technological characteristic? It can include:

- Design
- Material
- Chemical composition
- Energy source . . .

510(k) – Substantial Equivalence

If the device has the same technological characteristics from the predicate device

- a summary of the technological characteristics of the new device in comparison to those of the predicate device.

If the device has different technological characteristics from the predicate device

- a summary of how the technological characteristics of the device compare to a legally marketed device.

[21 CFR § 807.92]

510(k) – Substantial Equivalence

What other information must be included in your 510(k) application summary?

Identification of the legally-marketed equivalent device

A statement of intended use, including general description of "diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended."

If different from predicate, an explanation of why the differences do not affect the safety and effectiveness of the device.

Remember: this summary provides the basis for FDA's substantial equivalence determination. **[21 CFR § 807.92]**

510(k) – Intersection with Patent Law

Two major patent-related issues to consider in relation to 510(k):	
Patentability, Validity, or Enforceability of Resulting Patent	Infringement

Also: Your device as predicate device "greases the skids" for followers—can this be countered with patent roadblocks?

Novelty: When does the 510(k) publish?

When cleared, decision & 510(k) summary are published on FDA website by the 5th of the next month . . .supporting information available via FOIA request.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm#main

Search 510(k) Database Download Files | More About 510(k)

510K Number	K **Type** [Traditional ∨]		
Model	[ ]	**Cleared/Approved IVD Products** [ ]	
Applicant Name	[ ]	**Expedited Review** [Yes ∨]	
Device Name	[ ]	**Third Party Reviewed** [ ]	
Panel	[Anesthesiology ∨]	**Product Code** [ ]	
Decision	[CLEARED FOR MARKETING AUTOMATIC CLASS III DESIGNAT (AN) ∨]		
Decision Date	[ ] to [ ] **Clinical Trials** [ ]		
Sort by	[Decision Date (descending) ∨]		

For full-text search, select *Go To Simple Search* button

[Search] [Clear] [10 ∨] Records per Report Page [Go to Simple Search]

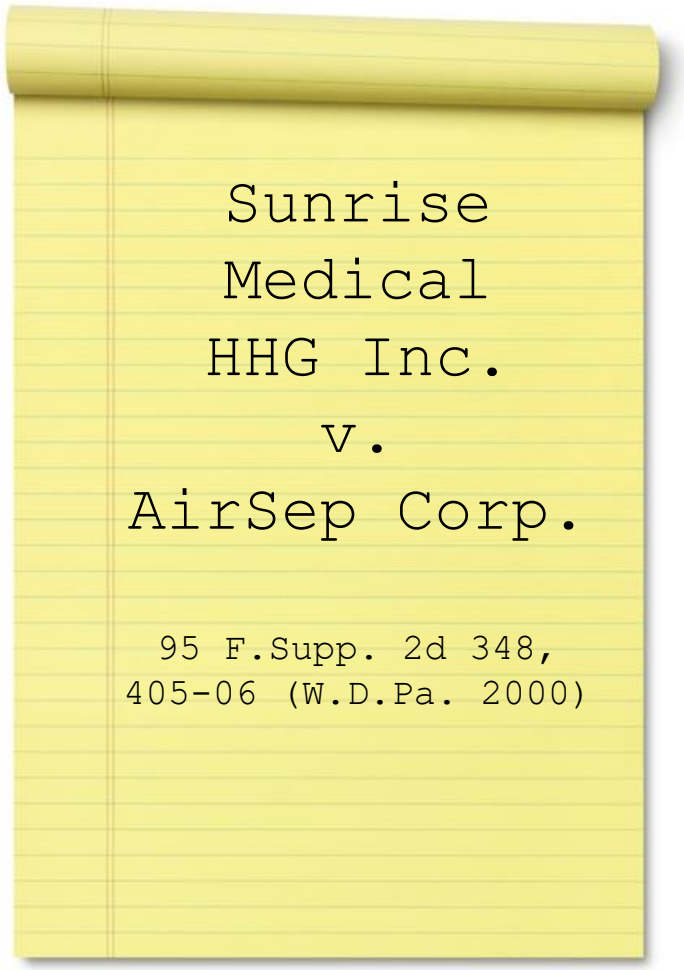
*See Koninklijke Philips N.V. v. Zoll Med. Corp., 2016 U.S. App. LEXIS 13710 (Fed. Cir 2016)(re availability of 510k as a prior art publication vs. corroboration of "on sale" product).

Obviousness: Impact of the 510(k)

Unlike anticipation, obviousness involves finding the pieces of the puzzle in various references.

- Often, all that is lacking is a **motivation to combine** the various references and **how** such a combination might be made
- Can the 510(k) submission inadvertently provide such a motivation or evidence of expectation of success?
- If the 510(k) submission draws upon multiple predicates, and all of the claim elements are present in the predicates in combination, does the risk increase?

Case Review: 510(k) & Patentability

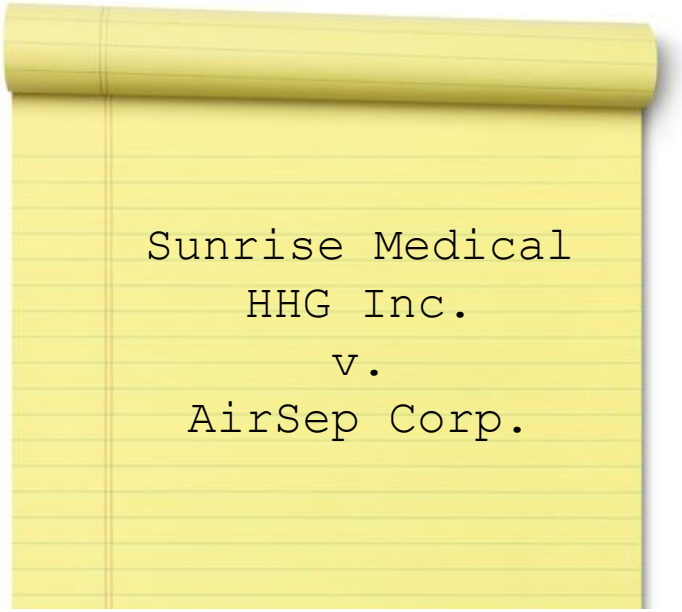


- Sunrise sued AirSep for patent infringement
- AirSep challenged validity based on Sunrise's 510(k) assertion of substantial equivalence between Sunrise's patented EX2000 device and the prior art.

The Sunrise 510(k) notification stated:

"The PulseDose series devices are **fundamentally repackaged** versions of the OMS 20 and 50, DeVilbiss current oxygen management systems. There are no **significant** changes in the materials or features. Therefore, based on the above-mentioned similarities, **especially the dosage methodology**, the PulseDose Series devices and the OMS 20 and 50 are substantially equivalent devices. . . . The gas dose methodology oxygen delivery specifications and performance of the device in the PulseDose series are **identical** to those of the OMS 20 and 50. . . Previous designs of the DeVilbiss OMS 50 and 20 had similar components except for the integral regulator and pressure relief."

510(k) & Patentability



The court disregarded the 510(k) notification, stating:

- its sole purpose was to demonstrate to the FDA that the EX 2000 was as safe and effective as the predicate device
- The substantial equivalence assertion focused on the gas dose methodology, not the subject matter of the patent claims
- Other patented differences were omitted from the 510(k) because not essential to safety & effectiveness

Review: A substantial-equivalence assertion can be carefully worded to limit its scope to safety & efficacy. But the accompanying factual assertions can help or hurt, depending on whether they are focused toward or away from the patent claims.

- Here, it helped, because it focused the basis of the FDA substantial equivalence away from the subject matter of the patent claims.

510(k) & Patent Infringement

The 510(k) can remain at issue long after 510(k) clearance and grant of the patent.

The 510(k) may be factually relevant to a variety of infringement situations:

- **Direct**
- **Indirect (e.g., induced or contributory)**
- **Doctrine of Equivalents**
- **Willfulness**

[See **35 USC § 271 *et seq.***]

"Substantial Equivalence," by itself, does not admit patent infringement

1. Fundamentally different inquiries: (1) comparison of product to predicate device; and (2) element-by-element comparison of patent claim to product.

- *Johns Hopkins Univ. v. Datascope*, 543 F.3d 1342, 1351 (Fed. Cir. 2008)

2. Courts are wary of risk of confusing the jury with the 510(k) "substantial equivalence" assertion to the FDA.

- *Medtronic v. BrainLAB*, 417 F. Supp. 2d 1188, 1201 (D. Colo. 2006)(calling counsel's statement to jury that BrainLAB had admitted equivalence in its FDA submission an abuse of advocacy).
- *Cardiovention v. Medtronic*, 483 F.Supp.2d 830, 840-41 (D. Minn. 2007)(admitting 510(k) evidence would be misleading and unfairly prejudicial to Medtronic).

Many cases note these problems and make somewhat sweeping statements regarding the admissibility of FDA submission data—but be wary.

Supporting statements may be used to help establish/defeat infringement

1. "Technological characteristics" and other specific information in the FDA submission may be used to develop an infringement case.

- *U.S. Surgical v. Hospital Prods. Int'l.*, 701 F. Supp. 314, 347 (D. Conn. 1988)(noting that, beyond a generalized "substantial equivalence" assertion, the defendant also stated that "[b]oth devices utilize the **same** type of disposable cartridges . . . [which] utilize **similar staples**, **similar anvils**, **similar staple line configurations**, and the **same** tissue-joining methods.")
- *Abbott Laboratories v. Baxter Pharm. Prods.*, 2004 WL 2496459 (N.D. Ill. Nov. 3, 2004)(deeming admissible statements made by Baxter in its ANDA to the FDA regarding whether Baxter's proposed product as described in its ANDA contains an effective amount of Lewis acid inhibitor and statements made in those letters indicating that a water content of 300 ppm is required to effectively prevent degradation regardless of the container).

2. Such "technological characteristics" and other specific information in the FDA submission may also be used to refute an infringement case.

- *Univ. of Florida v. Orthovita*, 1:96-CV-82-MMP, 1998 WL 34007129 (N.D. Fla. April 20, 2008)(considering technical chart in 501(k) noting marked difference between cleared product and predicate device with regard to patented particle size).

510(k) – other infringement issues?

1. Doctrine of Equivalents – can 510(k) statements be used to build "function/way/result" or "insubstantial differences" analysis?

- *Abbott v. Sandoz*, 566 F.3d 1282, 1298 (Fed. Cir. 2009)(noting that bioequivalency statement to the FDA, by itself, does not constitute an admission of infringement, but may be relevant to the "function" prong of the "function-way-result" test for infringement under the DOE).
- *Mahurkar v. C.R. Bard*, 92 C 4803, 1993 WL 259446 (N.D. Ill. July 6, 1993)(noting that, although the actual 510(k) filing is irrelevant because it is controlled by a different regulatory scheme, the fact that Bard did not retest the Hickman II catheter is probative of functional equivalence).

2. Willfulness – can lead to treble damages and/or attorney fees

- Can 510(k) be used to establish knowledge of the patented predicate device?
- Can this be used in the "totality of circumstances test" to establish knowledge of the patent rights associated with the predicate device?

510(k) – Intersection with Patent Law

Other illustrative holdings:

American Medical System v. Laser Peripherals, 712 F.Supp.2d 885, 905 (D.Minn 2010) (finding material issues of fact remain on SJ motion regarding infringement because "a reasonable jury could find that the accused devices do not meet the [claim] limitations regardless of [defendant's] representations to the FDA)

- *See also Cardiovention, Inc. v. Medtronic, Inc.,* 483 F.Supp.2d 830, 840 (D.Minn 2007) (finding that a 510(k) notification is not an admission of infringement because substantial equivalence has different meaning in the FDA context than in the patent context)

Candor – Before the FDA

We have an obligation not to engage in puffery or mislead the FDA

- We must be honest in relation to our disclosures, including any equivalence assertion made in a 510(k) submission
- Certification required, by 510(k) submitter (not consultant):

(a)(1) A 510(k) statement submitted as part of a premarket notification shall state as follows:

- I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, *preferably the official correspondent in the firm*), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including *any adverse safety and effectiveness information*, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61. (emphasis added)

[21 CFR § 807.93]

Candor – Before the FDA

Consequences of non-compliance:

- FDA Enforcement Actions
  - Removal of product from market
  - Seizure
- Personal Financial Liability for Officers
  - *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1578-79 (Fed. Cir. 1986)
- Potential Criminal Liability for Fraud upon FDA
  - **Federal Conspiracy Offense – 18 USC § 371**
    - Micro Interventional Systems, Inc. submitted 510(k) applications that contained materially false and fraudulent documents
    - Director of Regulatory Affairs and Quality Assurance sentenced to 10 months in prison based on her role in submitted fraudulent 510(k) notifications

Candor – before the USPTO

We have an obligation to disclose any information "material to patentability" to the USPTO. [37 CFR § 1.56]

- Failure to comply can result in a finding of unenforceability of a patent, or even unenforceability of an entire patent family (e.g., a parent and/or its divisionals or continuations)
- Such an "inequitable conduct" defense is raised frequently during litigation, and can implicate inventors and patent counsel alike
- **Patents and other prior art are not the only forms of material information!**

Material information may include regulatory submissions, (adverse) clinical data, adverse event reports, etc.

Candor – Inequitable Conduct

Inequitable conduct doctrine in the wake of *Therasense . . .*

Elements of an inequitable conduct:

Materiality and **Intent**

Materiality:

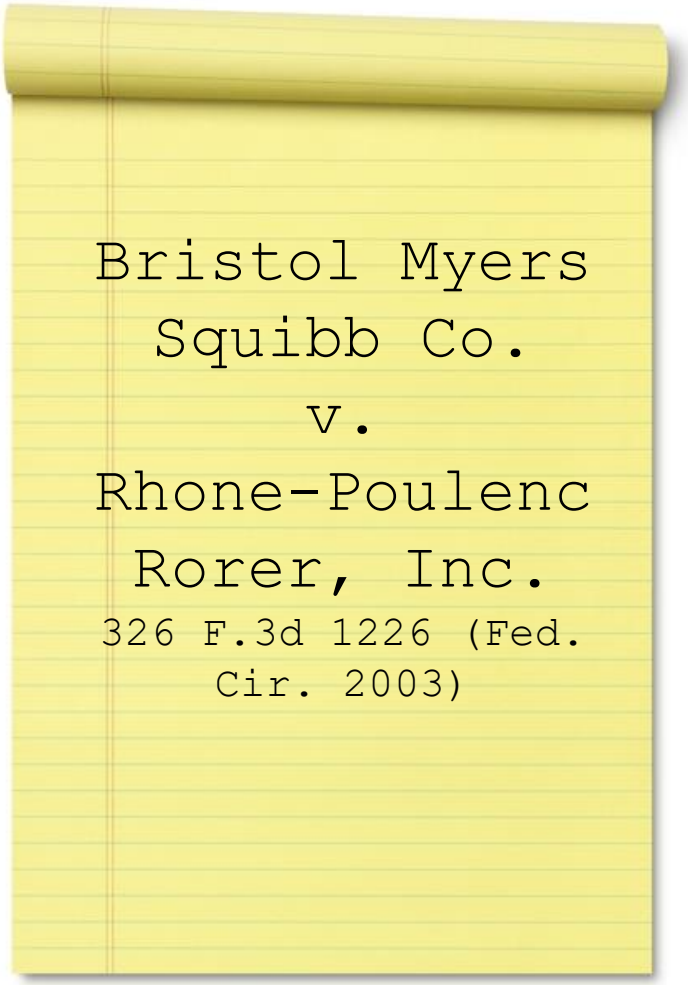
"This court holds that, as a general matter, the **materiality** required to establish inequitable conduct is **but-for materiality**. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Therasense, Inc. v. Becton, Dickinson and Company* (Fed. Cir. 2011) (en banc)

Candor – Inequitable Conduct

- **However, intent must still be shown. Failure to disclose does not obviate the need to prove by C&C evidence specific intent**
  - "Intent to mislead and materiality ***must be separately proved***. ***There is no "sliding scale"*** under which the degree of intent that must be proved depends on the strength of the showing as to the materiality of the information at issue." *Therasense.*
  - "Intent need not be proved by direct evidence; it is most often proven by a showing of acts, the natural consequence of which are presumably intended by the actor." *Molins PLC v. Textron, Inc.,* 48 F.3d 1172, 1180 (Fed. Cir. 1995)
  - Intent to deceive cannot be "inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent." *Hebert v. Lisle Corp.,* 99 F.3d 1109, 1116 (Fed. Cir. 1996).
  - Good faith? Proof that non-disclosed information was highly material and that the patent applicant knew or should have known of that materiality makes it "difficult to show good faith to overcome an inference of intent to mislead." *Semiconductor Energy Lab. Co., Ltd. V. Samsung Elecs. Co., Ltd.,* 204 F.3d 1368, 1375 (Fed. Cir. 2000)

Candor – breadth of the Duty of Disclosure to the USPTO

What about post-filing materials that are not prior art?



Rhone-Poulenc obtained a U.S. patent based on semi-synthesis of the chemotherapy drug Taxol.

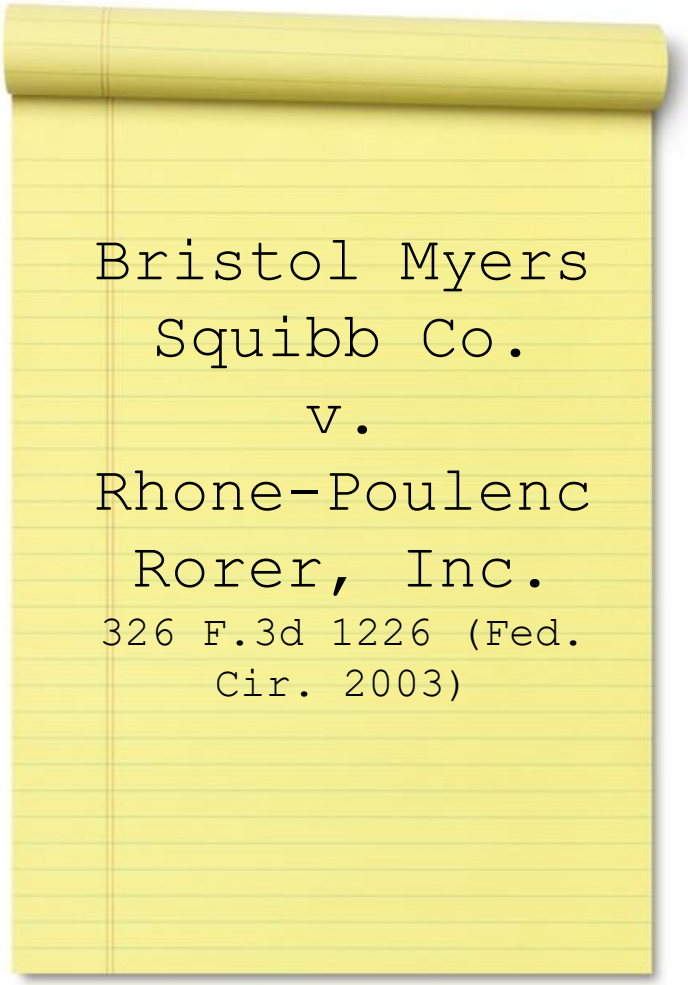
The U.S. matter claimed priority to an earlier-field French patent, the French patent itself based on a draft submission for a scholarly journal.

The final journal article noted certain protecting groups and unique reaction conditions.

The journal article was not disclosed to the USPTO, nor were the technical limitations of the article discussed in the U.S. patent.

The U.S. patent even seemed to suggest that the technical limitations did not even exist.

Candor – breadth of the Duty of Disclosure to the USPTO, cont'd.



Rhone-Poulenc, Cont'd.

The journal article was held to be material

- Not because it was prior art—its publication date precluded it from being considered as prior art
- Because it concerned issues of enablement, and contradicted positions taken in the patent application

Consider sharing pre-filing and post-filing information to attorney for review, for possible disclosure to USPTO

Post-filing information may arise from FDA submissions, including duty of candor to the FDA that may necessitate submitting negative information to the FDA that contradicts the earlier-filed patent.

Candor

Representative Case

Bruno Indep. Living Aids, Inc. v. Acorn Mobility Services, Ltd.

394 F. 3d 1348, 1350-51

(Fed. Cir. 2005)

Bruno sued Acorn on its patented stair-lift for the elderly.

- Acorn produced numerous prior-art stair-lifts and accused Bruno of having *intentionally* withheld *material* prior art on the "Wecolator" from the PTO.

Bruno had submitted information on several prior art stair-lifts to the FDA in its 510(k).

- Bruno argued that its claim of "substantial equivalence" between its SRE-1500 and the "Wecolator" was relevant only for the purpose of securing FDA approval.
- Bruno also argued that despite its awareness of the prior art lifts, it did not appreciate the Wecolator's materiality.

Candor

Representative Case

Bruno Indep. Living Aids, Inc. v. Acorn Mobility Services, Ltd.

394 F. 3d 1348, 1350-51

(Fed. Cir. 2005)

Bruno, cont'd.

– Bruno's materiality arguments were unpersuasive in both the district court and at Fed. Cir.

- » Prosecution history suggested that had the examiner been made aware of the Wecolator, Bruno's amendments would have been insufficient to achieve allowance
- » Bruno's argument was deemed "disingenuous" because the FDA submission was prepared by Wm. Belson, who was also involved in prosecution.

Candor

Representative Case

Bruno Indep. Living Aids, Inc. v. Acorn Mobility Services, Ltd.

394 F. 3d 1348, 1350-51

(Fed. Cir. 2005)

Bruno, cont'd.

– Regarding intent, Federal Circuit found that "while the district court indeed provided little explicit support for its finding of intent, it is well established that, as an appellate tribunal, we review judgments, not opinions."

» Review focused on the evidence of record

– Bruno failed to offer a "credible" explanation for the nondisclosure

Candor

Possible Mitigating Factors

- Immateriality of information to USPTO, or its cumulative nature with respect to other previously-submitted information
- Organizational structure
  - Regulatory group or submitter separate from patent counsel or R&D personnel working on patent application?
  - Size of organization?
- Good faith

Candor

Is there "plausible deniability" in a large organization?

Ranbaxy v. Abbott, 04 C 8079, 2005 WL 3050608 (N.D. Ill Nov. 10, 2005).

– "Abbott's argument appears to be that it is a **very large organization with many employees performing disparate tasks** in separate facilities who cannot all be required to know what each of the others is doing. In short, Abbott appears to be arguing that because it has many employees who do not all communicate with each other as well as they might, this Court should find no more than negligence on Abbott's part in its failure to disclose the material results of the clinical studies. . ."

– "However, this Court *preliminarily* finds that Abbott fails to provide a credible explanation for the failure to disclose the taste perversion results to the PTO. The results were highly material, but Abbott disclosed only the gastrointestinal results despite claiming reduced taste perversion . . ."

– Inventors approved clinical study reports and authored a journal article

Is there risk in having a named inventor certify the 510(k) submission?

Candor – *update*
Baxter v. CareFusion (N.D. Illinois 2017)

- Baxter's FDA submission for patented infusion pump referenced **three** infusion pumps as "substantially equivalent".
  - Stated that "the [Baxter] Colleague pump 'does not have any unique technological features as compared to currently marketed pumps."
  - Submitted manuals for 3 predicate devices to the FDA but not PTO
  - Included a feature comparison chart
  - Many of the named **inventors were actively involved** in Baxter's FDA submission
  - Patent **claim breadth** such that potentially anticipated by the undisclosed pump products (*but-for* materiality)
  - Followed *Bruno v. Acorn*: FDA submission may not be relevant to infringement, but can be used to establish knowledge or deceptive intent

Candor

Is it necessary to scour the FDA submission and exhaustively resubmit everything from the FDA file to the USPTO?

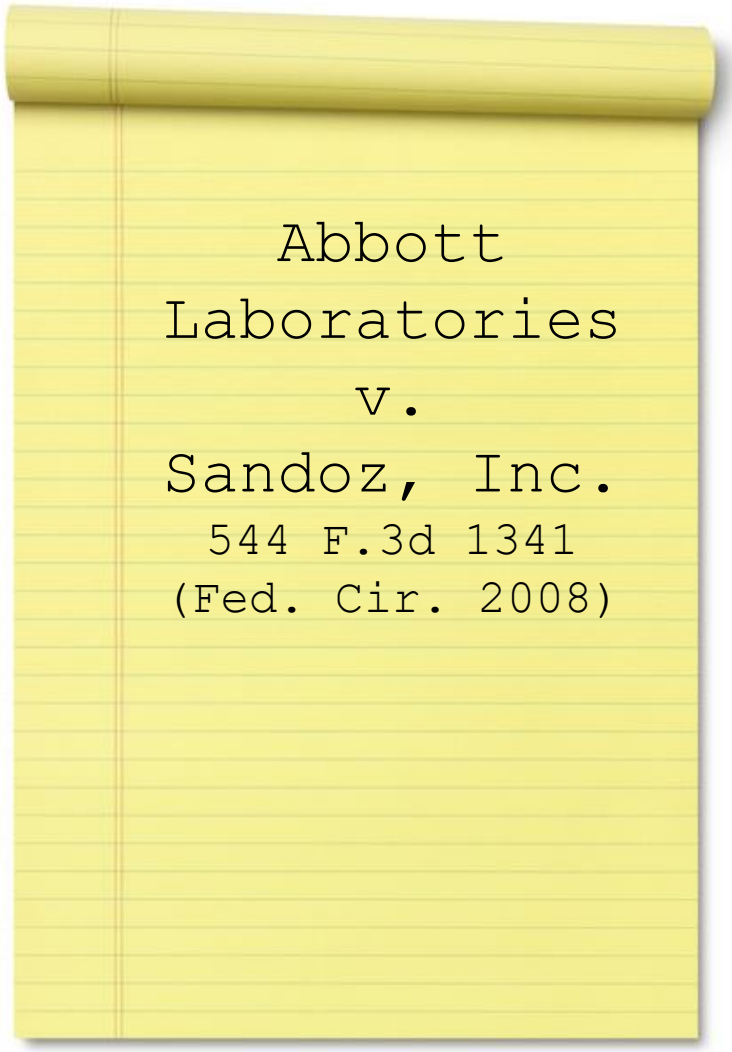
Pfizer Inc. v. Ranbaxy Laboratories Ltd., 405 F. Supp. 2d 495, 523-24 (D. Del. 2005) *aff'd in part, rev'd in part and remanded sub nom. Pfizer, Inc. v. Ranbaxy Laboratories Ltd.,* 457 F.3d 1284 (Fed. Cir. 2006)(distinguishing *Bruno).*

- *Bruno* involved non-disclosure of prior art
- *Pfizer* involved data submitted to FDA for *Lipitor* approval
- No inequitable conduct for failure to submit similar data to USPTO

– Finding was based on (1) credible assertion that data was unreliable, thus immaterial, **and** (2) that the submitter of the data to the FDA was not the same as the inventor, Dr. Roth

Again, is there risk in having a named inventor certify the 510(k) submission?

Candor



Abbott Laboratories v. Sandoz, Inc., 544 F.3d 1341, (Fed. Cir. 2008)

- Drug-related patent involving Abbott's Biaxin®XL antibiotic
- Studies submitted to the FDA indicated a lack of support for the '616 patent's claimed method of reducing GI side effects
- District court found that the information was "not material to patentability" because various other tables of information demonstrating no change in GI side effects had already been submitted (**cumulative**).

Candor

No inequitable conduct for failure to cite data to USPTO that had been cited in the FDA submissions?

- **Not** a safe assumption
- *Pfizer* and *Abbott* both relied on specific factual considerations involving the un-submitted data

- In one case the data was questionable (*Pfizer*)
- In the other case, the data was cumulative (*Abbott*)

Rule: Err on the side of caution and submit, or be **certain** that an **objectively credible explanation exists** for not submitting the information

Candor – *update*
Belcher v. Hospira (Fed Cir. 2021)

- Belcher's patented epinephrine formulation held unenforceable for inequitable conduct
  - Submitted New Drug Application (NDA) to FDA with in-process pH range 2.4 – 2.6 to avoid "racemization"
  - Reverted to 2.8 – 3.3 pH range of prior art Sintetica batches to expedite FDA approval
  - Argued "criticality" of 2.8 – 3.3 pH range at PTO as "unexpectedly" reducing racemization--allowed based on accepting that argument.
  - Belcher did not disclose to PTO three **"but-for" material** references
    - JHP prior art product, tested by Sintetica, with pH within 2.8-3.3 range
    - Sintetica's product having 2.8 – 3.3 pH range
    - Stepinsky reference cited during NDA submission process to FDA
  - Belcher's Chief Science Officer (CSO) deeply **involved in both** FDA and PTO submissions and examinations.
  - **Intent inferred from characterizations of criticality** over post-hoc rationalizations of cumulative nature of omissions

510(k) & Patentability Considerations

1. Can you disclose only what is necessary to demonstrate equivalence from a safety and efficacy perspective? Keep in mind your FDA candor obligation.

- Omit patentable feature? Can this be done without violating FDA candor obligation? Is it related to safety or efficacy? Better approach: File patent before submitting 510(k).

2. Avoid overbroad statements of equivalence (e.g., "identical") that may impact novelty or non-obviousness.

510(k) & Patentability Considerations

3. You only need one predicate device. Choose carefully, with patentability and infringement in mind, as well as "substantial equivalence" considerations.

4. The requisite statement of substantial equivalence in terms of safety and efficacy is less likely to hurt than the accompanying factual summary of technological characteristics, which can hurt or help.

5. Can provide a "disclaimer" defining "substantial equivalence" in accordance with Food Drug and Cosmetic Act, and disclaiming definition according to the Patent Statute (e.g., "This document uses the term "substantial equivalence" as defined in 21 CFR § 807.87 and not as defined in Title 35 of the U.S. Code").

Candor – *update*
Leahy and Tillis Sept. 9, 2021 Letter to PTO

United States Senate

WASHINGTON, DC 20510

September 9, 2021

Mr. Andrew Hirshfeld
Performing the Functions and Duties of Director
U.S. Patent and Trademark Office
600 Dulany St.
Alexandria, VA 22314

Dear Mr. Hirshfeld:

We are now requesting the PTO take steps to reduce patent applicants' making inappropriate conflicting statements in submissions to the PTO and other federal agencies. These conflicting statements too often are submitted confidentially or go unnoticed until after a patent issues, and only then do third parties have the incentive or ability to review the patent owner's statements before both agencies. There is a clear need for the PTO to take action to require applicants to disclose relevant statements they have made to other agencies relating to inventions discussed in their patent applications or about prior art that is being applied in the patent examination process.

Candor – *update*
Leahy and Tillis Sept. 9, 2021 Letter to PTO

For example, inconsistent statements submitted to the Food and Drug Administration (FDA) to secure approval of a product—asserting that the product is the same as a prior product that is already on the market—can then be directly contradicted by statements made to the PTO to secure a patent on the product. When a certain piece of prior art is already being applied by the examiner, and the patent applicant has made statements about that prior art to another federal agency that establish that the invention claimed is not novel, making conflicting statements to the PTO should be cause for rejecting the application and, when made knowingly and with bad intent, potentially other sanctions.

Of course, we understand that requiring patent examiners, who are already time constrained, to consider even more prior art information will impose some costs. But we believe that such costs can be reduced and constrained by the creation of a smooth, predictable, and regular channel of information from other federal agencies to the Patent Office. This, in turn, could create savings that accrue from the earlier entry of truly new and innovative competitors.

We ask that you take steps as soon as is feasible to enforce patent applicants' obligations to disclose statements made to other government agencies. Thank you for your prompt attention to this matter. We look forward to continuing to work with you to improve the quality of patents issued by the PTO and promote competition in our economy.

Exemption from Patent Infringement: 271(e)(1)

35 USC § 271(e)(1) states:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of **drugs or veterinary biological products.**

Potential Questions Raised by the so-called "Research Exemption":

1. How broad is "solely for uses reasonably related"?
2. What is the applicability to medical devices?

Does 271(e)(1) apply to Medical Devices?

§ 271(e)(1) applies to a "patented invention" – *Eli Lilly*

- In *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990), the Supreme Court concluded that "a patented invention" under § 271(e)(1) is defined to include all inventions, subject to an FDA approval process, not drug-related inventions alone.
- Medical devices are included in the research exemption from patent infringement under § 271(e)(1).

Are all types of medical devices included in the exemption?

- The device in *Eli Lilly* was a class III medical device.
- Does the exemption also apply to class I & II medical devices?
- Calling the above question, a "novel question of law," in *Abtox v. Exitron*, 122 F.3d 1019 (Fed. Cir. 1997), the Federal Circuit concluded that § 271(e)(1) applies to all medical devices regardless of FDA classification.

How broad is the 271(e)(1) exemption?

Applies to activities "solely for uses reasonably related" to the FDA approval process—what activities are exempt?

In *Intermedics v. Ventritex*, 775 F. Supp. 1269, 1272 (N.D.Cal.1991), the district court stated that the inquiry is not focused on whether the alleged infringer has engaged in conduct that has purposes beyond presenting data to the FDA.

The alleged infringer need only believe there was a "decent prospect" that the use would contribute information relevant to an FDA submission.

The activities at issue in *Intermedics v. Ventritex*:

- Manufacture of several hundred Cadence defibrillators
- Sales of the Cadence to hospitals in the U.S.
- Sales of the Cadence to international distributors
- Testing of the Cadence (including certain testing done in Germany)
- Demonstrations of the Cadence at "trade shows"

District court found these activities within 271(e)(1), and Federal Circuit affirmed in an unpublished opinion.

How broad is the 271(e)(1) exemption? (cont'd)

More Ventritex . . .

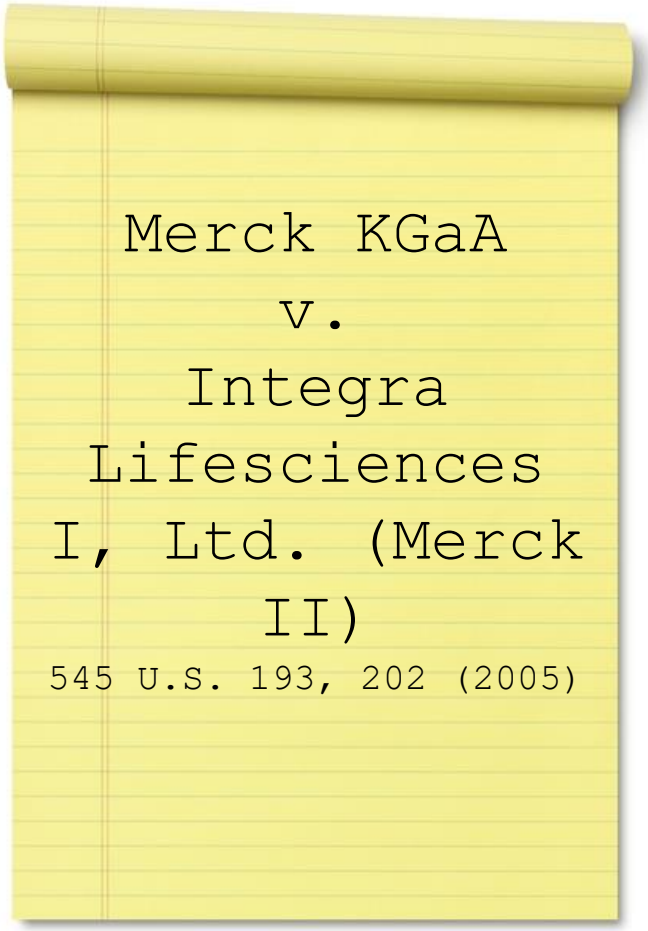
In *Telectronics Pacing Systems, Inc. v. Ventritex*, Inc., 19 U.S.P.Q.2d (BNA) 1960 (N.D. Cal. 1991), *aff'd*, 982 F.2d 1520 (Fed. Cir. 1992), the Federal Circuit applied the exemption when the accused infringer, Ventritex, demonstrated an infringing device at a medical conference.

The dissemination of data initially collected for the purposes of FDA approval is not an act of infringement under 271(e)(1) even when the data is then used for collateral fundraising activities.

Reasoning: the accused infringer should be permitted to search for qualified investigators to conduct clinical trials

How broad is the 271(e)(1) exemption? (cont'd)

The U.S. Supreme Court weighs in. . .



- Declared the safe harbor applicable to "all uses of patented inventions that are reasonably related to the . . . submission of any information under the FDCA."
- Exemption includes both clinical trials and pre-clinical studies that are appropriate FDA regulatory submission.
- **However . . .**"[d]oes not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process." (e.g., basic scientific research)

Recent cases...*Edwards Lifesciences Corp. v. Meril Life Scis. Pvt.*, No. 19-cv-06593, (N.D. Cal. 2020)

Motion for SJ granted on the basis that:

- Transportation of "Myval" transcatheter heart valve and delivery system samples to UW was exempt because it generated pre-clinical data; and
- "TCT Conference" in France was exempt because Meril was providing information in part to identify potential clinicians for its FDA PMA application.

Plaintiff argued:

- Meril did not [yet] submit any information in connection with the pre-clinical work in either of its pre-submissions.
  - This fails. As a matter of law, *Merck* controls. Safe harbor applies to preclinical studies even if the data is not ultimately submitted to FDA.
- No safe harbor b/c defendants "actual purpose" was to promote?
  - This also fails. Because the alleged infringing act was reasonably related to obtaining FDA approval, the safe harbor applies, regardless of defendant's intent or purpose. Safe harbor analysis focuses on uses, not "purposes" or "motives." Intent or alternative uses are irrelevant.
  - *See Genentech, Inc. v. Insmed Inc., 436 F. Supp. 2d 1080, 1095 (N.D. Cal. 2006)*(addressing the question of 271(e)(1) as an affirmative defense at the SJ stage), and *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997).

Recent cases…*Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327 (Fed. Cir. 2019)

- Same inquiry applies in the method-of-manufacture context.
  - Aff'd Dist. Ct. jury instructions; not legal error to instruct the jury that:

    "[i]f Hospira has proved that the manufacture of a particular batch," that is, Hospira's use of Amgen's patented methods, "was ***reasonably related*** to developing and submitting information to the FDA . . . Hospira's **additional** underlying purposes for the manufacture and use of that batch **do not remove** that batch from the Safe Harbor defense." (emphasis added)
  - But, Fed. Cir. warns that "to the extent Hospira suggests that the Safe Harbor exemption *always* applies in the pre-approval context, we have previously rejected that reading of the statute. It is incorrect to "assume[] that all otherwise infringing activities are exempt if conducted during the period before regulatory approval is granted." *Amgen Inc. v. Int'l Trade Comm'n*, 565 F.3d 846, 852 (Fed. Cir. 2009)."

How broad is the 271(e)(1) exemption? (cont'd)

Is there a "Research Tools" exception to the 271(e)(1) exemption?

- If your "patented invention" is used to generate FDA regulatory submission data on an unrelated product, would not a broad application of § 271(e)(1) would render your patent meaningless?

  Proveris Sci. Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1265-66 (Fed. Cir. 2008)

  - Defendant sold an optical spray analyzer (OSA) only to pharma companies and the FDA for use to measure parameters of aerosol sprays of nasal drug delivery systems.
  - Court noted that in Eli Lilly v. Medtronic, the Supreme Court stated that <u>all</u> products listed in 35 USC § 156(f) were entitled to safe harbor under § 271(e)(1).
  - Therefore, 271(e)(1) does not apply since the OSA is not subject to a required FDCA approval process under 35 USC § 156(f).

Considerations

1. **Can Freedom-To-Operate (FTO) investigation be carried out well in advance of clinical investigation, such as to help choose a predicate device wisely?**
2. **Can the inappropriate choice of a predicate device, relying on 271(e)(1), lock you in to a position of patent infringement?**
   - Safe harbor under 271(e)(1) expires (at latest) upon FDA approval.
   - If patent at issue has not expired, you may now be infringing, and you may be unable to modify the product without re-submitting the modified product to the FDA

3. **Can clinical study be designed (or clinical study protocol be written) in such a way as to document the 271(e)(1) safe harbor?**
4. **Is the caselaw's statements emphasizing the breadth of the safe harbor of 271(e)(1) misleading?**

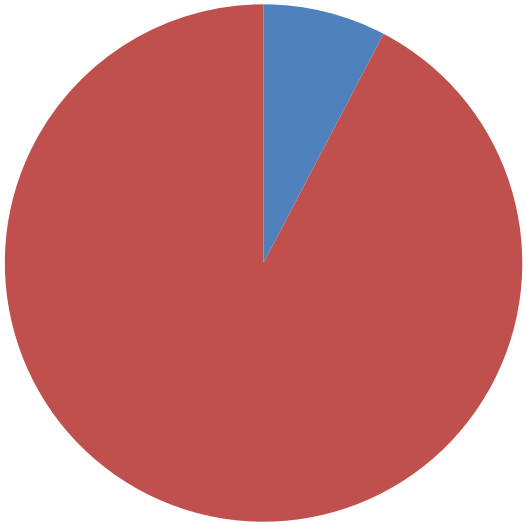
Key: Coordination between regulatory and intellectual property personnel

Patent Term Extension for PMA Regulatory Approval Delay

35 USC § 156: Extension of Patent Term

(a) "The term of a patent which claims a product, a method of using a product or method of manufacturing a product shall be extended … if-"

(4) "the product has been subject to a regulatory review period before its commercial marketing or use."



Through March 4, 2010, 599 patents have been extended.

- Medical Devices - 46
- Pharmaceuticals - 553

How do I know if a patent's term has been extended under § 156?

PAIR or http://www.uspto.gov/patents/resources/terms/156.jsp

PATENT NO. : 4,379,785

ISSUED : April 12, 1983

INVENTOR(S) : Rudi Weyer et al.

PATENT OWNER : Hoechst Atiengesellschaft

This is to certify that there has been presented to the

COMMISSIONER OF PATENTS AND TRADEMARKS

an application under 35 U.S.C. § 156 for an extension of the patent term. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

1,571 days

from December 17, 2000, the original expiration date of the patent, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

I have caused the seal of the Patent and Trademark Office to be affixed this 5th day of September 1997.

Bruce A. Lehman

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks

Image of Certificate Exter

NOTE: This list is for informational purposes only and is not intended to have legal effect. Furthermore, this list does not include patents which have been extended only under § 156(e)(2) or § 156(d)(5) (patents which have only received an interim extension). Each patent number is hyperlinked to a copy of its certificate of extension, if available. A copy of the certificate of extension should be included in the "correction" section of the patent's images. See http://www.uspto.gov/patft/index.html to access the patent image database. Items shown in a bold red font are new relative to the last version of this web page.

For further information, contact Mary C. Till, at (571) 272-7755 (telephone) or by e-mail at: mary.till@uspto.gov.

Please note that many patent term extension applications are available on PUBLIC PAIR; see http://portal.uspto.gov/external/portal/pair.

Additional information concerning patent expiration dates of human drug products can be obtained from the Food and Drug Administration, Center for Drug Evaluation and Research. The Patent and Exclusivity Addendum of the "Orange Book" the Approved Drug Products with Therapeutic Equivalents Evaluations includes an alphabetical listing of human drug products according to generic name with related patent information. The "Electronic Orange Book," a searchable version of the Orange Book, is available at: http://www.fda.gov/cder/ob/default.htm.

Some content linked to on this page requires a plugin for Acrobat Reader.

Patent No.	Tradename of Approved Product	Original Exp. Date (Note 1)	Extension	Approval Date (If Relevant) (Note 2)	Extended Expiration Date
RE 27,757	CARDIOVERTER/ DEFIBRILLATOR SYSTEM	26-Oct-88	2 years		26-Oct-90
RE 30,577	BEPADIN/VASCOR	08-Jun-93	2 years		08-Jun-95
RE 30,633	DEMADEX	19-Apr-94	5 years		19-Apr-99
RE 30,811	ENKAID	20-Dec-94	2 years		20-Dec-96
RE 30,910	DEURSIL	07-Jan-92	2 years		07-Jan-94

When must I apply for such term extension?

Time period to submit application for extension

- **35 USC § 156(d)(1); MPEP § 2754 *et seq*.**

"To obtain an extension of the term of a patent under this section … an application may only be submitted within the **sixty-day** period beginning on the date the product received permission … for commercial use."

"the trigger date for the 60-day filing window of section 156(d)(1) is the date stamped on the face of the FDA approval letter."

- Decision re: PTE application for U.S. Patent No. 5,196,404, March 19, 2010.

What must the application include?

Application requirements

- **35 USC § 156(d)(1); 37 CFR § 1.740; M.P.E.P § 2753**

Application submitted to the Director shall contain:

- ✔ Identity of product and the federal statute for the regulatory review
- ✔ Identity of the patent and identity of each claim
- ✔ Information for Director to determine eligibility for patent extension
- ✔ Dates and description of activities during the regulatory review period
- ✔ Other information the Director may require

Can look at various examples in PAIR database . . .

How much term extension is possible?

35 USC § 156(c): Length of patent extension

35 USC § 156(g)(3): Medical device terms defined

Three important dates:

1. When clinical investigations on humans began
   - 21 CFR § 60.22(c)(1): IDE date, IRB approval date, if req'd.
   - See, e.g., U.S. Pat. 5,716,981 (Angiotech) re BSC TAXUS™ Express 2™ stent
2. When the FDA application was initially submitted for the device under 21 USC § 515 (i.e., **PMA** route)
3. When the FDA § 515 application was approved

Length of Extension =

½ * (Number of days between #1 and #2)

+ (Number of days between #2 and #3)

Limitations, Caveats, Details

Availability limited to regulatory delay under PMA, not 510(k)

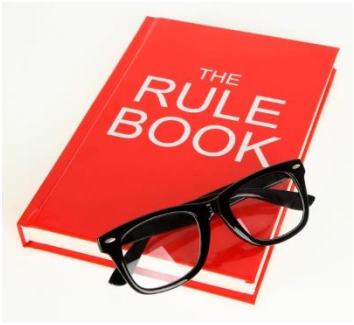
- See 35 USC § 156(g)(3)
- See MPEP § 2751

Two exceptions to the length of the extension:

- 35 USC § 156(g)(6)(A): The extension cannot be longer than 5 years
- 35 USC § 156(c)(3): The patent's expiration date (including the extension) cannot be more than 14 years from the date of regulatory approval

Can only extend term of <u>one patent</u> on the product

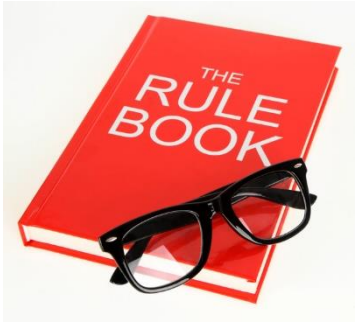
- "in no event shall more than one patent be extended under subsection (3)(i) for the same regulatory review period for any product" (35 USC § 156(c)(4))



Limitations, Caveats, Details (cont'd)

Applicant's diligence affects available term extension

- "each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period." (35 USC § 156(c)(1))
- Diligence = diligence before the FDA, not the USPTO
  - See 21 CFR § 60.36
- Third party can petition § 156 patent term extension, by asserting Applicant's lack of diligence
  - See 21 CFR § 60.30



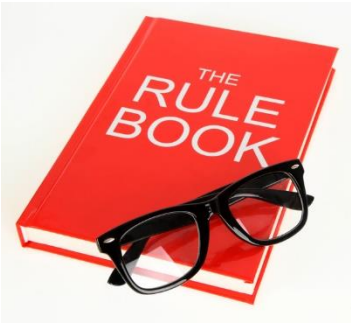
Limitations, Caveats, Details (cont'd)

Regulatory Approval Delay Extension Adds to PTA for PTO Delay

- "A patent term extension generally extends the patent from its "original expiration date," as defined by 35 USC 154 to include extension under 35 USC 154(b)." (MPEP § 2758)

Terminally-Disclaimed Patent Is Eligible for § 156 extension

- See MPEP § 2751



Opportunities

1. **Can take § 156 extension into account in 510(k)/PMA decision**
2. **Can map patents to products undergoing PMA**
3. **Can choose "best" patent to apply for the § 156 extension**
   - Actual infringement
   - Patent strength: infringement, validity, enforceability
   - Amount of extended term available
4. **FDA personnel can communicate the appropriate docket deadline to the patent personnel**
5. **Consider whether a potential third party can challenge diligence of FDA regulatory approval investigation and submission**

Key: Coordination between regulatory and intellectual property personnel

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Thank you for your participation.

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The presentation was based on "The Interplay between FDA and Patent Law: Infusing Organizational Knowledge for Medical Device Companies", authored by Suneel Arora, Timothy Christman, Ashley Mays, and Andrew Schmidt, William Mitchell Law Review, Vol. 39, No 4 [2013].

Thank you for your interest.

Questions?

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