

The Cardiovascular IP Landscape

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Knobbe Martens

Introductions & Overview

Litigation Trends and Statistics & Recent Litigation and PTAB Filings



Sabling Lee



Rabi Narula

Recent Litigation Decisions



Christy Lea



Introductions & Overview

USPTO Update



Shannon Lam

IP Related Transactions



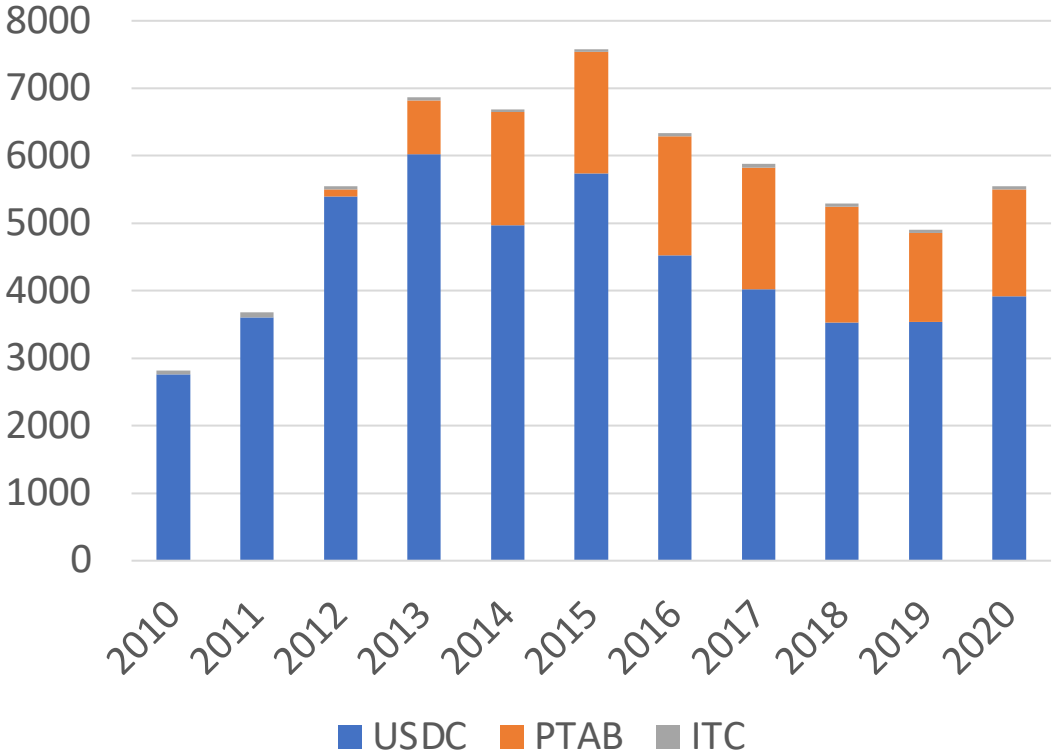
Adam Gilbert



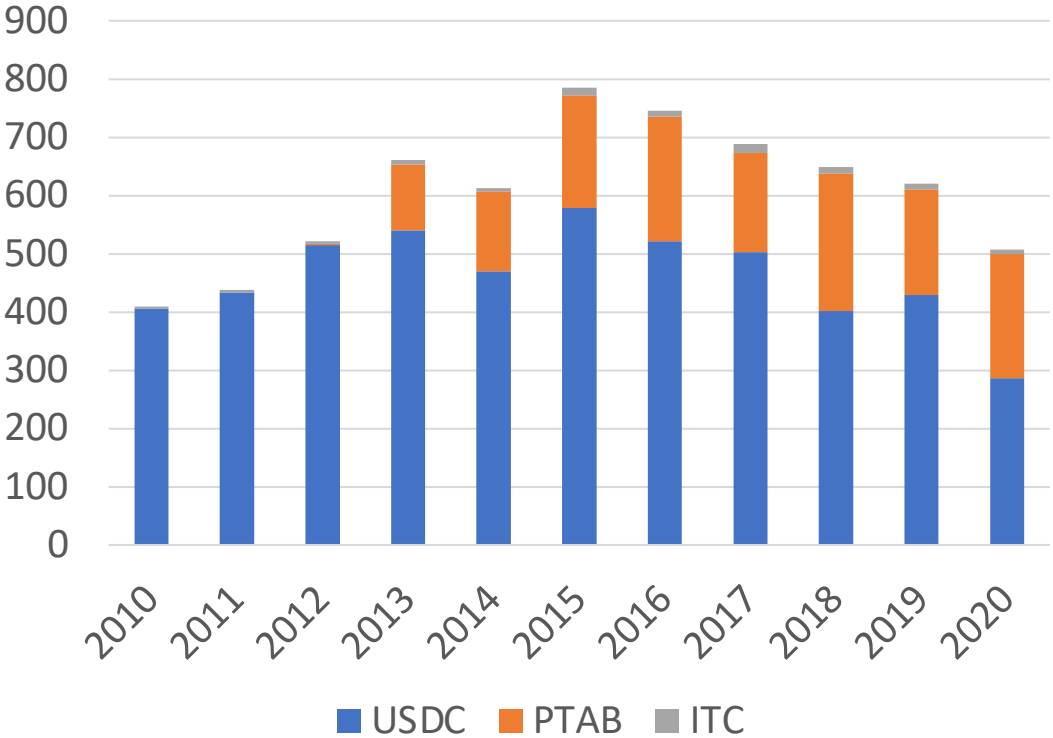
Litigation Trends and Statistics

Litigation Is On The Rise (But Maybe Not For Medical Devices)

All Technologies



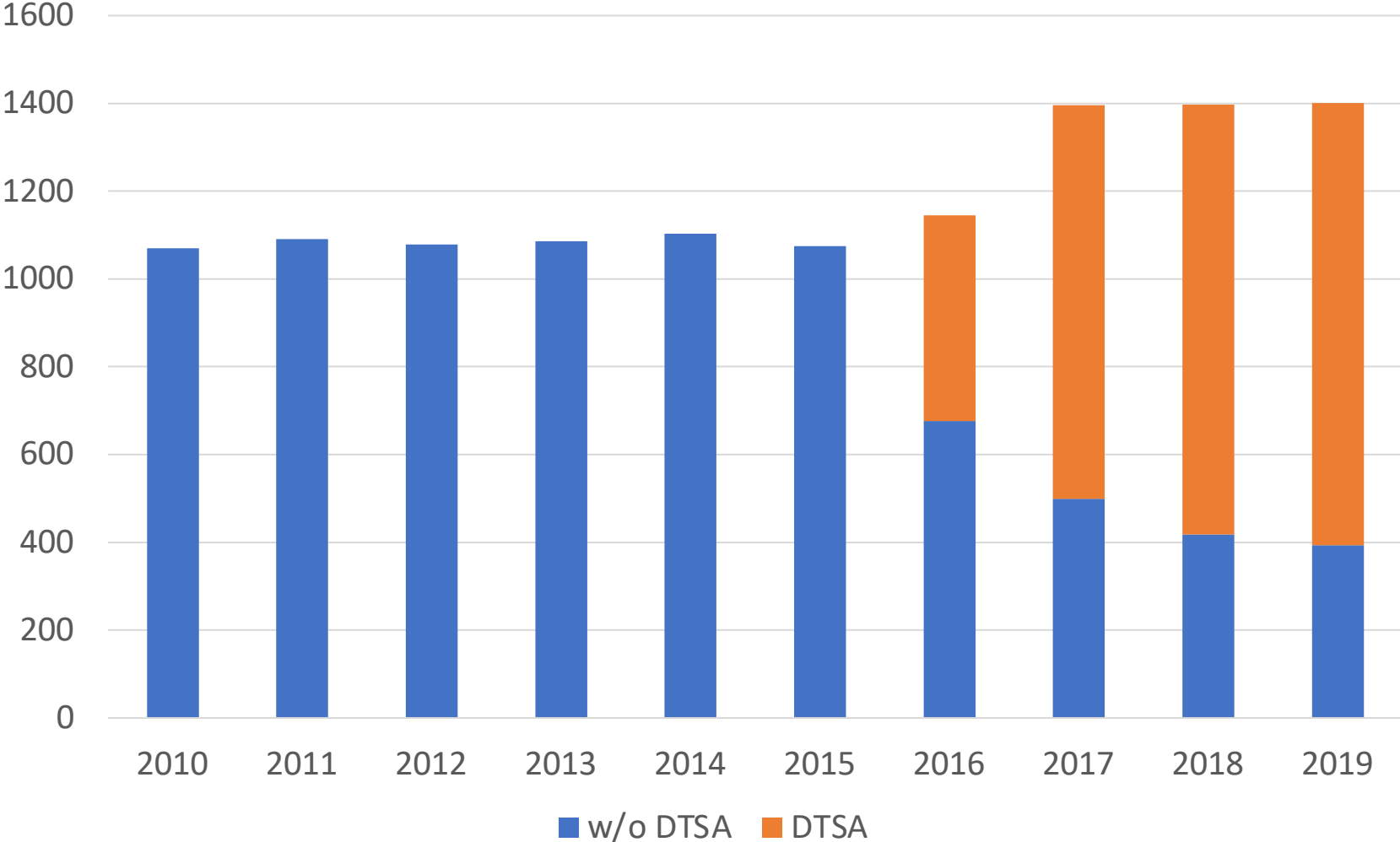
Technology Center 3700



Data through 10/4/2020
Source: Docket Navigator

Increase in Trade Secret Litigation

Trade Secret Case Filings 2010 to 2019



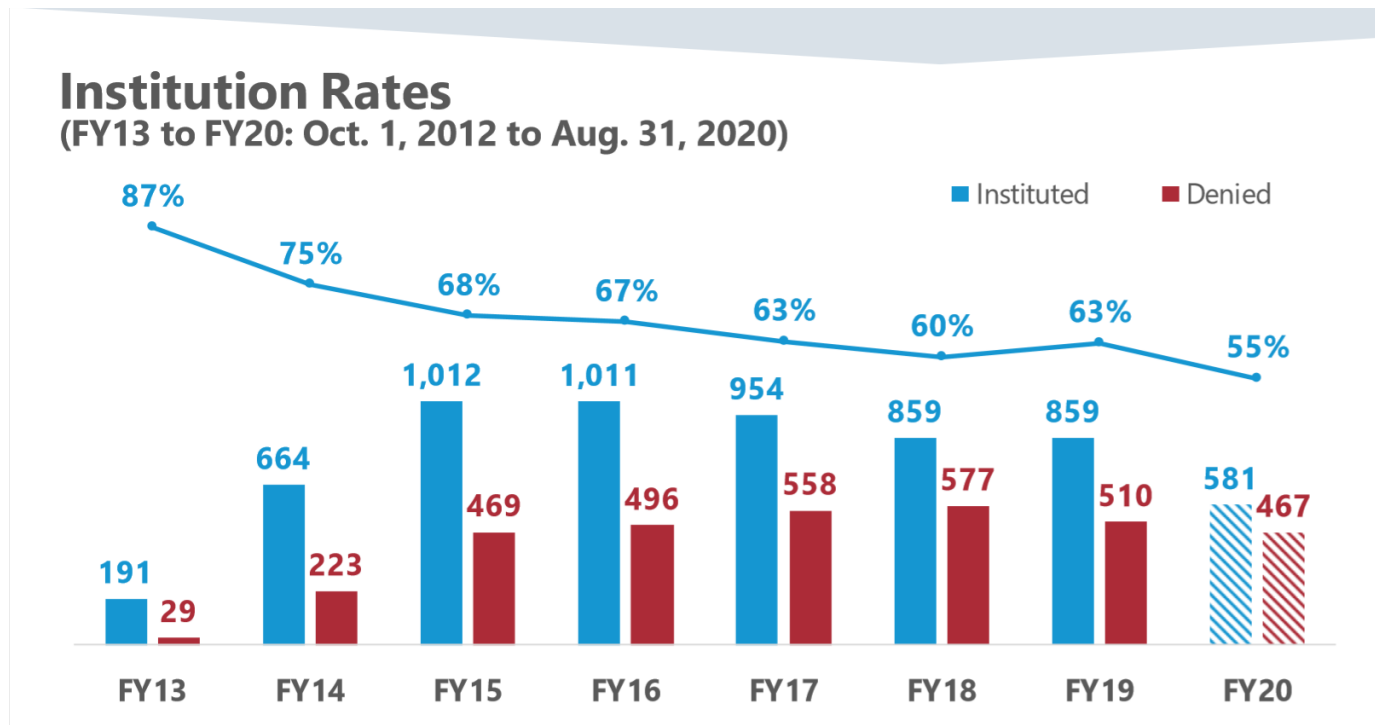
Trends at the Patent Trial and Appeal Board (PTAB)

- New procedures implemented in 2012 with America Invents Act
- Viewed as efficient mechanism to challenge patents outside of the litigation process
- Significant initial interest as many patent challengers were successful
- Current statistics show that PTAB challenges may postpone litigation, but do not avoid it completely
- Ongoing challenges to the constitutionality of these procedures



Observations on Institution Rates (September 2012 – July 2020)

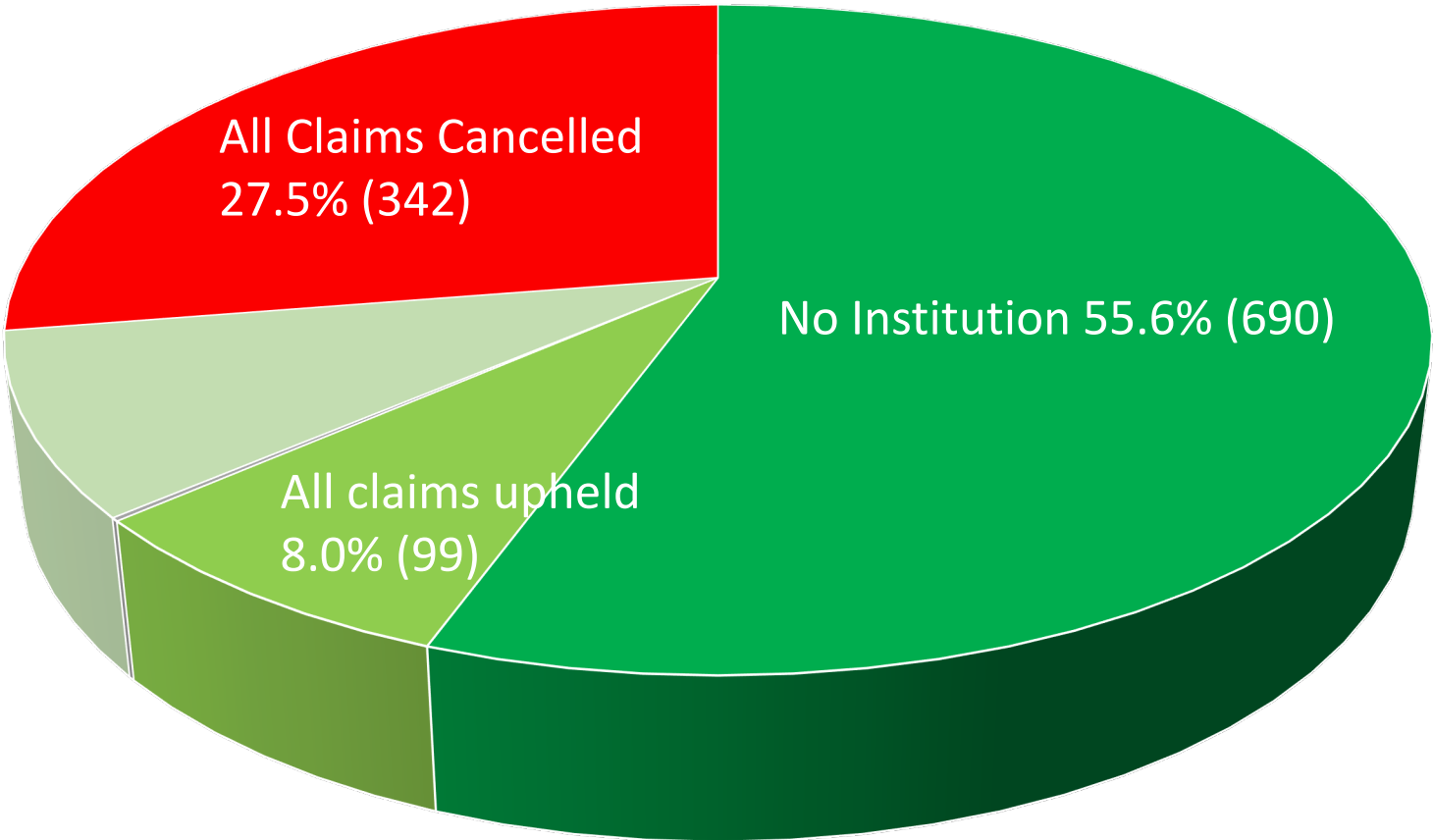
- 11,845 PTAB proceedings have been filed since creation of procedure
- Rates of institution have declined over time



<https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/statistics>

Recent Outcomes at the PTAB Favor Patent Owner

Outcomes Since January 2018 for 1242 petitions




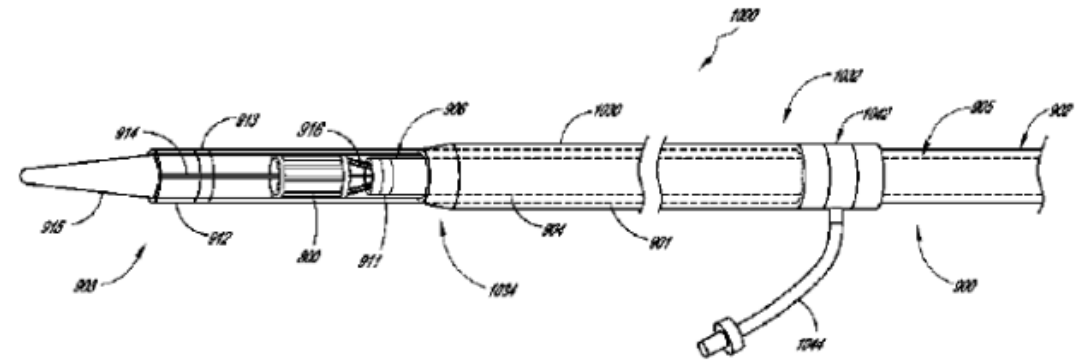
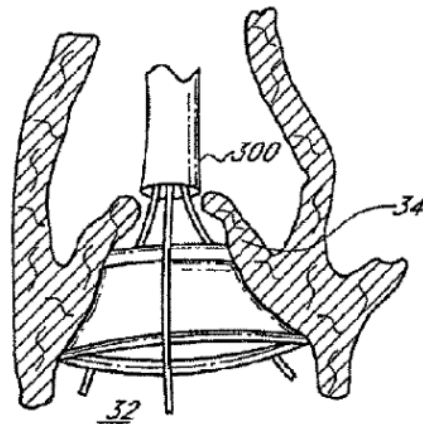
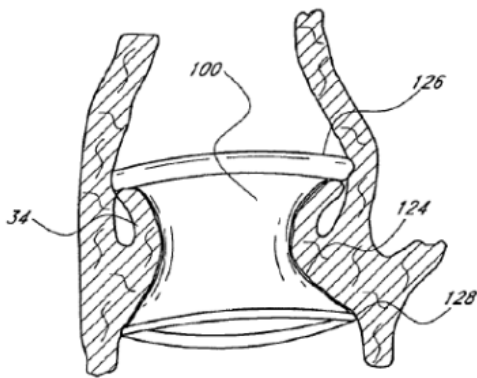
Source: LexMachina

- NO INSTITUTION (55.6%)
- ALL CLAIMS UPHELD (8.0%)
- AMENDED CLAIMS (0.2%)
- MIXED FINDINGS (8.8%)
- ALL CLAIMS CANCELLED (27.5%)

Recent Litigation Filings and Settlements – Heart Valves

Speyside Medical v. Medtronic

- Patents formerly owned by 
- Complaint filed March 13, 2020 in District of Delaware
- 5 patents asserted against CoreValve and Evolut products
- Medtronic alleged to have met with Direct Flow in 2006 and 2007





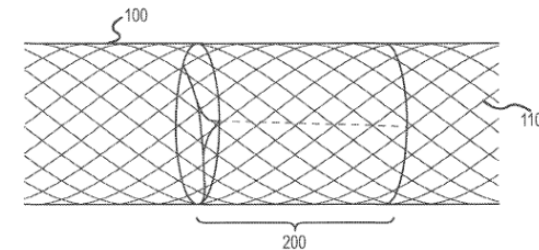
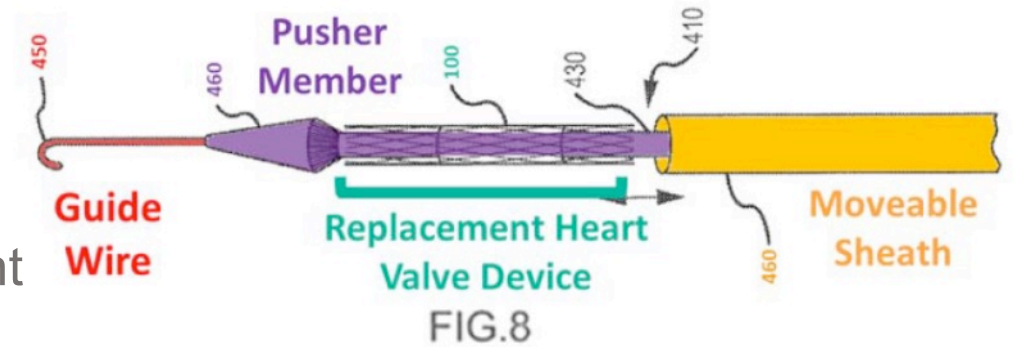
**Colibri**
Heart Valve

v.

Medtronic



- Complaint filed May 4, 2020 in Central District of California
- 2 patents asserted against CoreValve and Evolut products
- Colibri alleged that it met with Medtronic in 2014 and discussed its TAVI system and patent applications
- Medtronic filed IPR petitions on September 2, 2020
- Edwards filed IPR petition against one of the patents on September 18, 2020





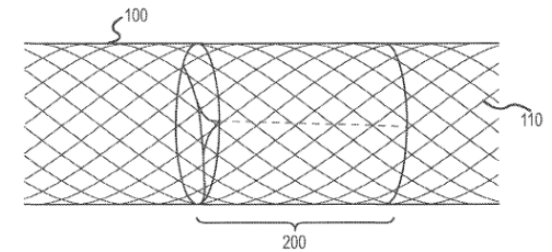
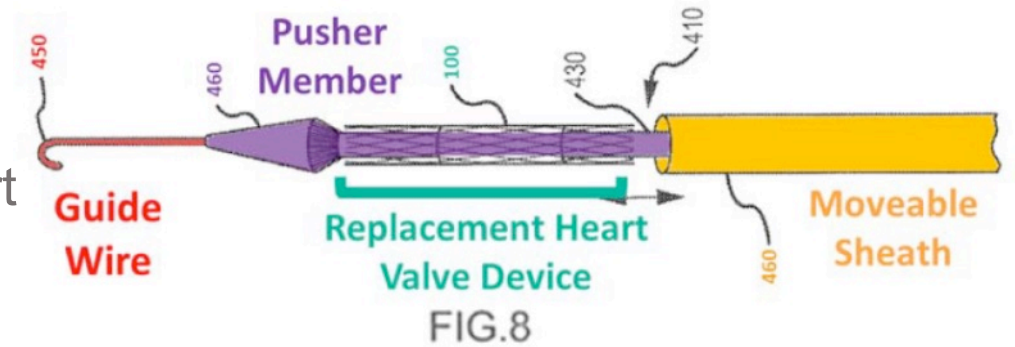
**Colibri**
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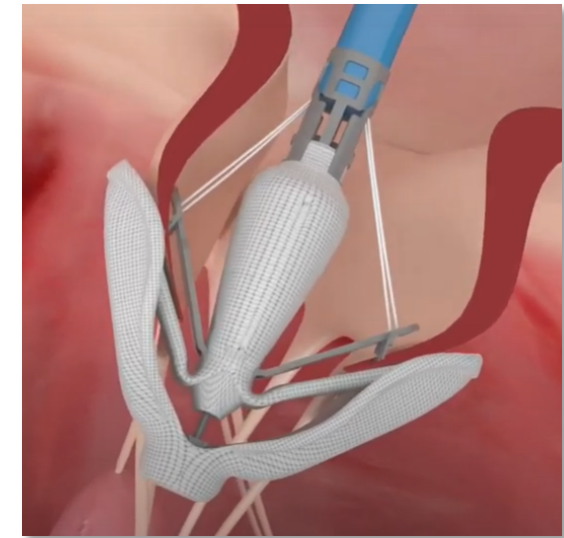


- Features claimed
 - Delivery system with pusher and moveable sheath
 - Deploying distal portion of replacement heart valve and restraining the replacement heart valve to allow for recovery
 - Stent that flares at both ends





v

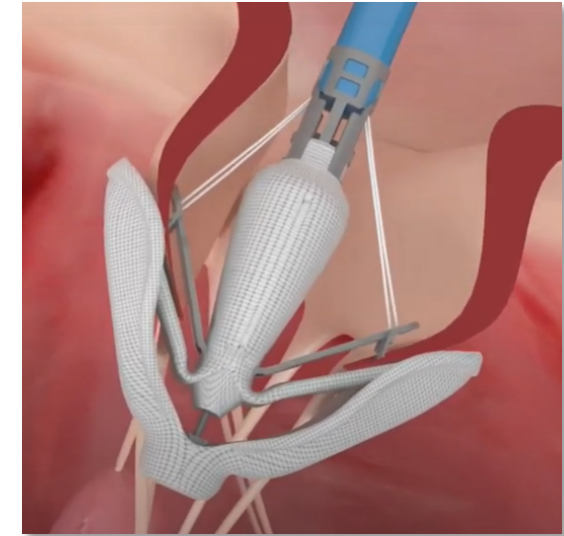


PASCAL Transcatheter
Valve Repair System

- Initial complaint filed by Abbott in January 2019
- Abbott asserted 5 patents in District of Delaware
- Edwards asserted 3 patents in Central District of California
- Both sides filed IPRs
- Litigations also in the UK, Switzerland, Germany, Italy, Ireland



v



PASCAL Transcatheter
Valve Repair System

- Preliminary injunction denied by Delaware court in June 2019
- Settled July 2020
 - Edwards paid Abbott \$368 million plus ongoing payments for sales of Pascal through May 2024, as well as potential sales milestone payment in 2026
 - No patent litigation disputes in the field of transcatheter mitral and tricuspid repair and replacement products for 10 years
 - Injunctions (UK and Switzerland) against Edwards' PASCAL device were lifted



Lotus



Watchman LAA implant



v.



Sapien 3

- Boston multi-front attack (April 2016)
 - 1 Boston patent asserted against Sapien 3 in Delaware
 - 8 Boston patents asserted against Sapien delivery system and crimper in Central District California
 - Suits in Germany, UK, Ireland, and France
- Edwards counterattack
 - 3 Edwards patents asserted against Lotus in Delaware
 - 2 Edwards patents asserted against Watchman in separate suit in Delaware (August 2018)
 - Suits in Canada and Germany



Lotus



Watchman LAA implant



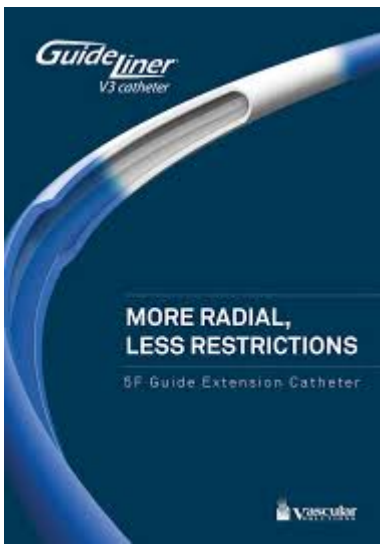
v.



Sapien 3

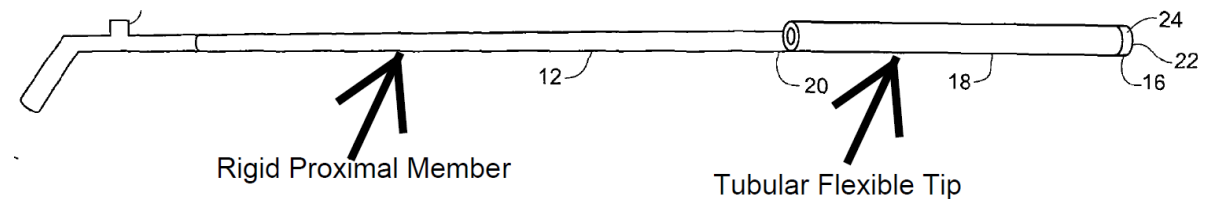
- March 2018: PTAB held Boston patent unpatentable
- Dec. 2018: Jury found Boston patent valid and infringed and Edwards patents not infringed
- Jan. 2019: Settled; Edwards paid Boston \$180 million, but no ongoing royalty
- Parties will not litigate patent disputes related to current portfolios of transcatheter aortic valves, certain mitral valve repair devices, and left atrial appendage closure devices
- Injunctions (UK and Germany) lifted

Recent Litigation & PTAB Filings (catheters and other non-heart valve technology)



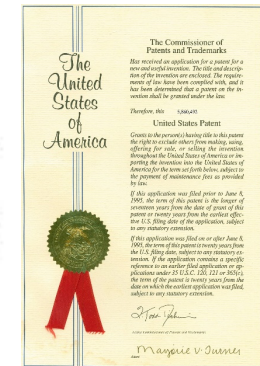
Teleflex® v. Medtronic

- Complaint filed July 2, 2019 in District of Minnesota
- 5 patents asserted against Medtronic's Telescope Guide Extension Catheter
- Patents directed to:
 - Guide catheter and extension catheter that includes a tubular flexible tip portion and a substantially rigid proximal portion
 - Guide extension catheter with a substantially rigid segment coupled to more flexible tubular structure
 - Methods of forming such a device
- Medtronic filed 12 petitions for IPR in November 2019 (most instituted and still pending)
- July 7, 2020 case stayed pending final resolution of IPR's

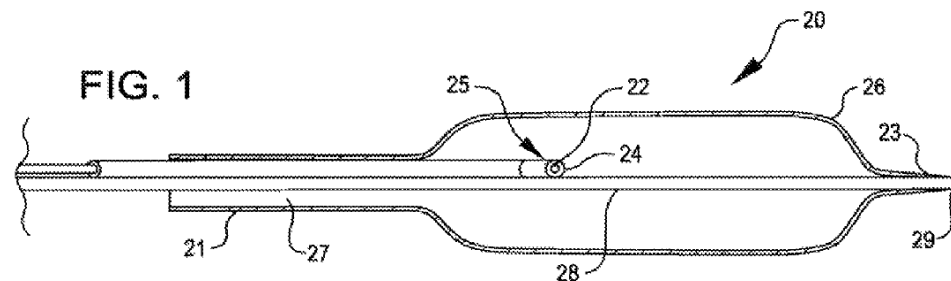




v.



- In December 2018, CSI filed IPRs against 3 Shockwave's patents directed to balloon angioplasty catheters that produces shockwaves to treat calcified lesions
- No co-pending litigation
- In July, 2020, final decisions were issued
 - 1 claim survived
 - Shockwave issued a press release touting that a key claim was found valid
- Continuations are pending





Dr. Joseph
Weisel

v.



Apple Computer

Apple Watch



- 2017: Dr. Weisel sent Apple notice letters
- December 2019: Dr. Weisel sued Apple Watch for patent infringement
- September 2020: Apple filed IPR petition

Patent directed to a method of detecting atrial fibrillation comprising

- (a) detecting irregular pulse rhythms from a succession of time intervals each corresponding to a respective interval of time between successive pulse beats of a sequence of the pulse beats;
- (b) analyzing the detected irregular pulse rhythms to make a determination of possible atrial fibrillation; and
- (c) indicating the possible atrial fibrillation from the determination.

Trends in Medical Device IP Litigation

1. More patent eligibility (§ 101) challenges against medical device patents
2. Remedies for sales outside the United States
3. Decreased ability to forum shop

Trend #1 – More patent eligibility (§ 101) challenges against medical devices

U.S. – Patent Eligible Subject Matter

§101 provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor....

Supreme Court (1980): “Anything under the sun made by man”

Supreme Court Limited Patent Eligibility Over Past Decade

Natural Laws (*Mayo* - 2012)

Natural Phenomena (*Myriad* - 2013)

Abstract Ideas (*Alice* - 2014)



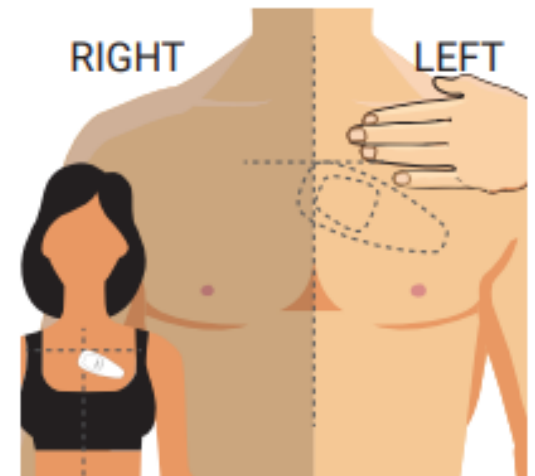
v.



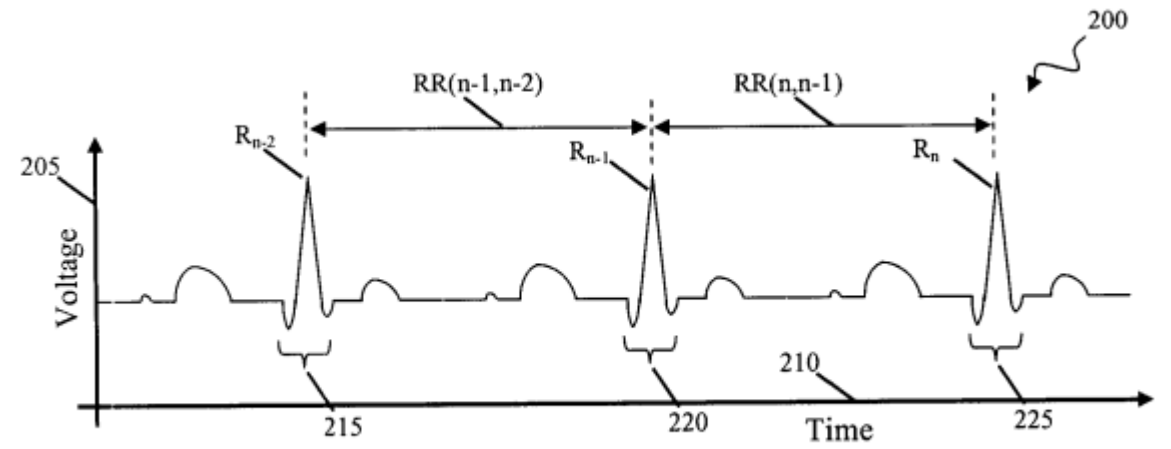
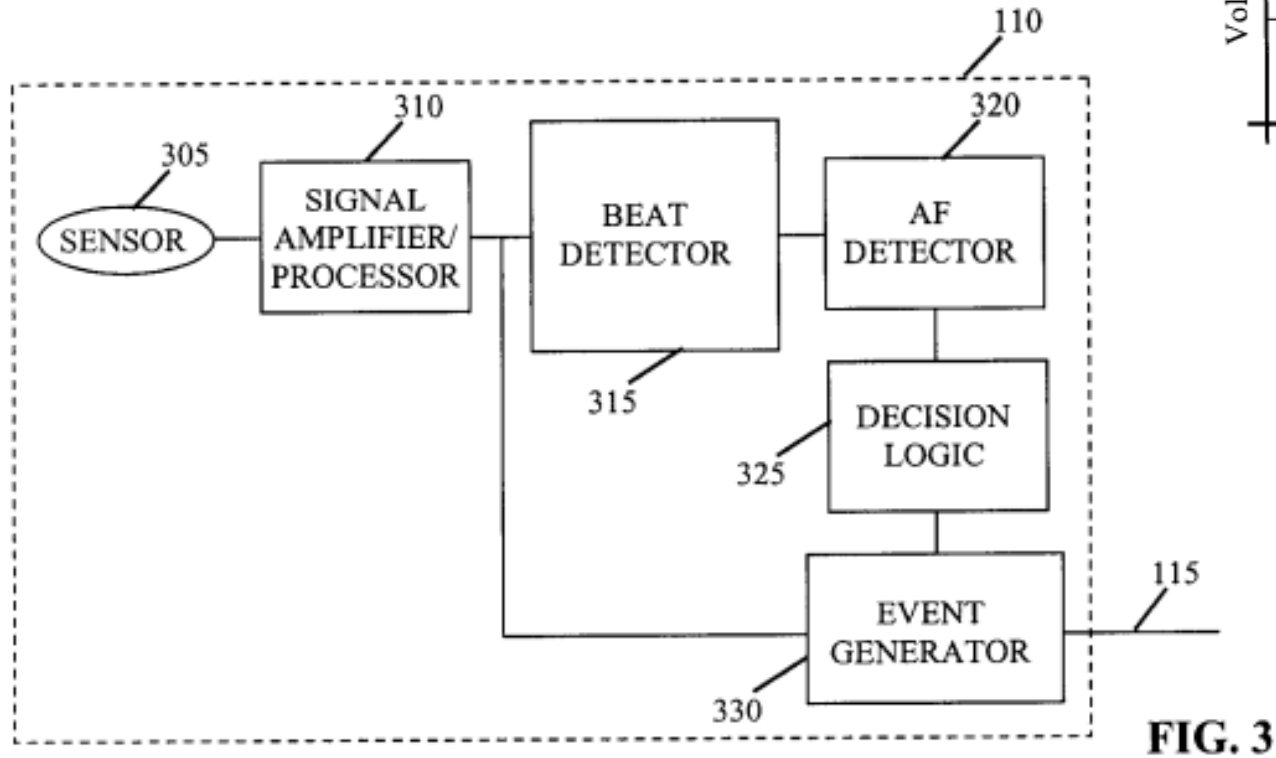
US market estimated at \$1.4B



- May 2015 - CardioNet sued InfoBionic on 6 patents in field of Mobile Cardiac Telemetry
 - Patents invalid or not infringed
- March 2017 – CardioNet sued InfoBionic on 1 patent
 - District Court: Patent invalid, subject matter not eligible under § 101
 - Federal Circuit: **REVERSED**



Telehealth - Abstract Idea?



Do claims focus on specific improvements to the relevant technology

or

Are they directed to a result that is the abstract idea and merely invoke generic machinery?"

Cardionet v. InfoBionic (Fed. Cir. 2020)

District court: Not patent eligible – automating known techniques

Federal Circuit: Reversed. Patent eligible.

- Improved cardiac monitoring device that
 - detects beat-to-beat timing of cardiac activity
 - detects premature ventricular beats
 - determines relevance of beat-to-beat timing
- Specification touts advantages of improved device

“The 101 patent-eligibility inquiry is only a threshold test.”

Trend #2 – Remedies for sales outside the United States

Damages for Foreign Sales

§271(f) provides:

Whoever supplies from the United States component(s) of a patent invention for combination outside the United States in a manner that would infringe if such combination occurred in the United States shall be liable as an infringer



Supreme Court (2018): Lost profits from foreign sales are recoverable for infringement of US patent

MAQUET GETINGE GROUP



May 2008: Maquet acquired patents-in-suit (but does not practice them)

Dec. 2015: Maquet sent cease & desist letter to Abiomed attaching a draft complaint

- Impella heart pump

Jan. 2016: Abiomed responded with claim charts



May 2016: Maquet responded demanding a license and threatening litigation

May 2016: Abiomed filed complaint (D. Mass.) seeking **declaratory judgment** on 6 patents



v.

MAQUET
GETINGE GROUP

Maquet's Counterclaims for Infringement Do Not Include § 271(f)

- Direct Infringement § 271(a)

73. Counterclaim Defendants have directly infringed, and continue to directly infringe, the claims of the '100 Patent, including at least Claims 9 and 16, in violation of 35 U.S.C. § 271(a).

- Indirect Infringement § 271(b) and (c)

79. Counterclaim Defendants have also indirectly infringed, and continue to indirectly infringe, the claims of the '100 Patent, including at least Claims 9 and 16, in violation of 35 U.S.C. § 271(b) and (c). During the term of the '100 Patent, Counterclaim Defendants' customers and

- No infringement based on foreign sales § 271(f)

Maquet Sought Discovery of Foreign Sales But Never Amended Complaint

- Maquet requested discovery of Abiomed's foreign sales
- Abiomed objected because infringement counterclaims limited to US activities (making, selling, importing)
- Maquet never amended counterclaims



UPLOADED TO SHERVNET

Trend #4 – Decreased ability to forum shop

The Rise of the Western District of Texas

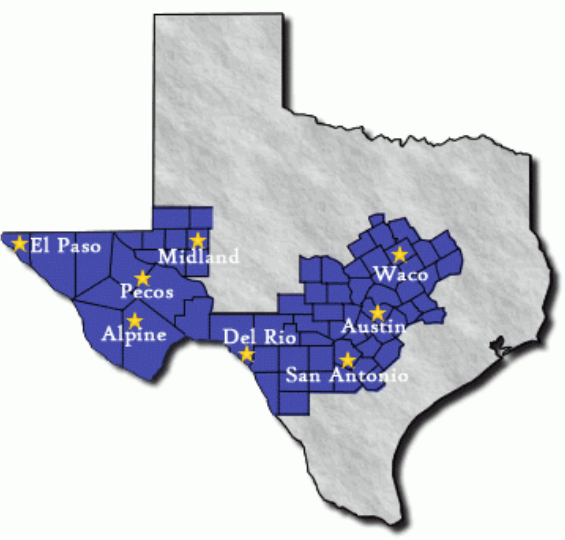
NEW HOTSPOT

Knobbe Headquartered

District	Cases (2019)	Percent (2019)	Cases (2020)	Percent (2020)
W.D.Tex.	288	8.07%	658	21.59%
D.Del.	1,000	28.03%	548	17.98%
E.D.Tex.	333	9.34%	302	9.91%
C.D.Cal.	344	9.64%	241	7.91%
N.D.Cal.	235	6.59%	185	6.07%
D.N.J.	145	4.07%	123	4.04%



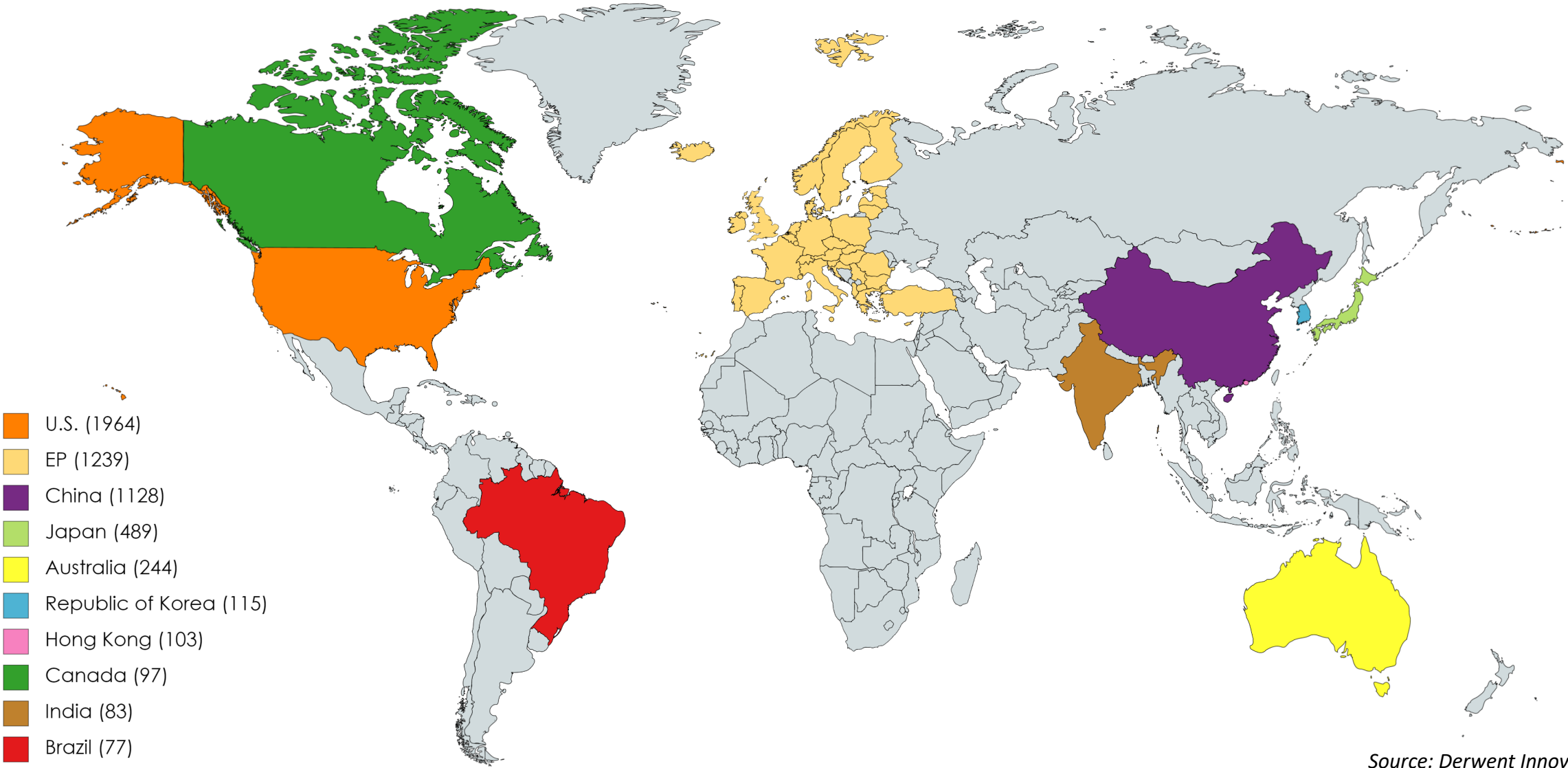
Data through 10/4/2020
Source: Docket Navigator



U.S. District Judge Alan D. Albright

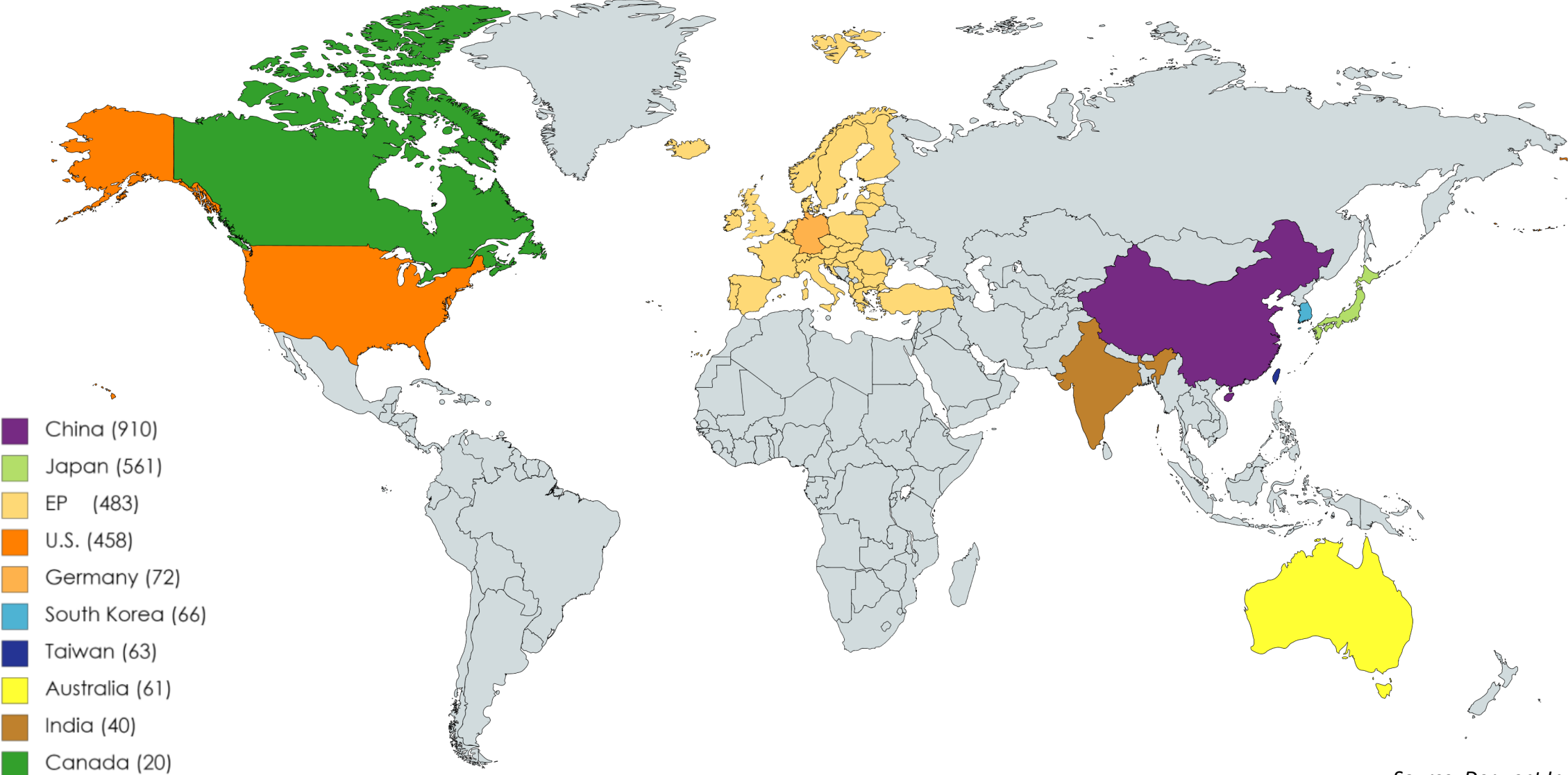
USPTO Update

Top 10 Countries for Cardiovascular Treatment Device Publications (2019-20)



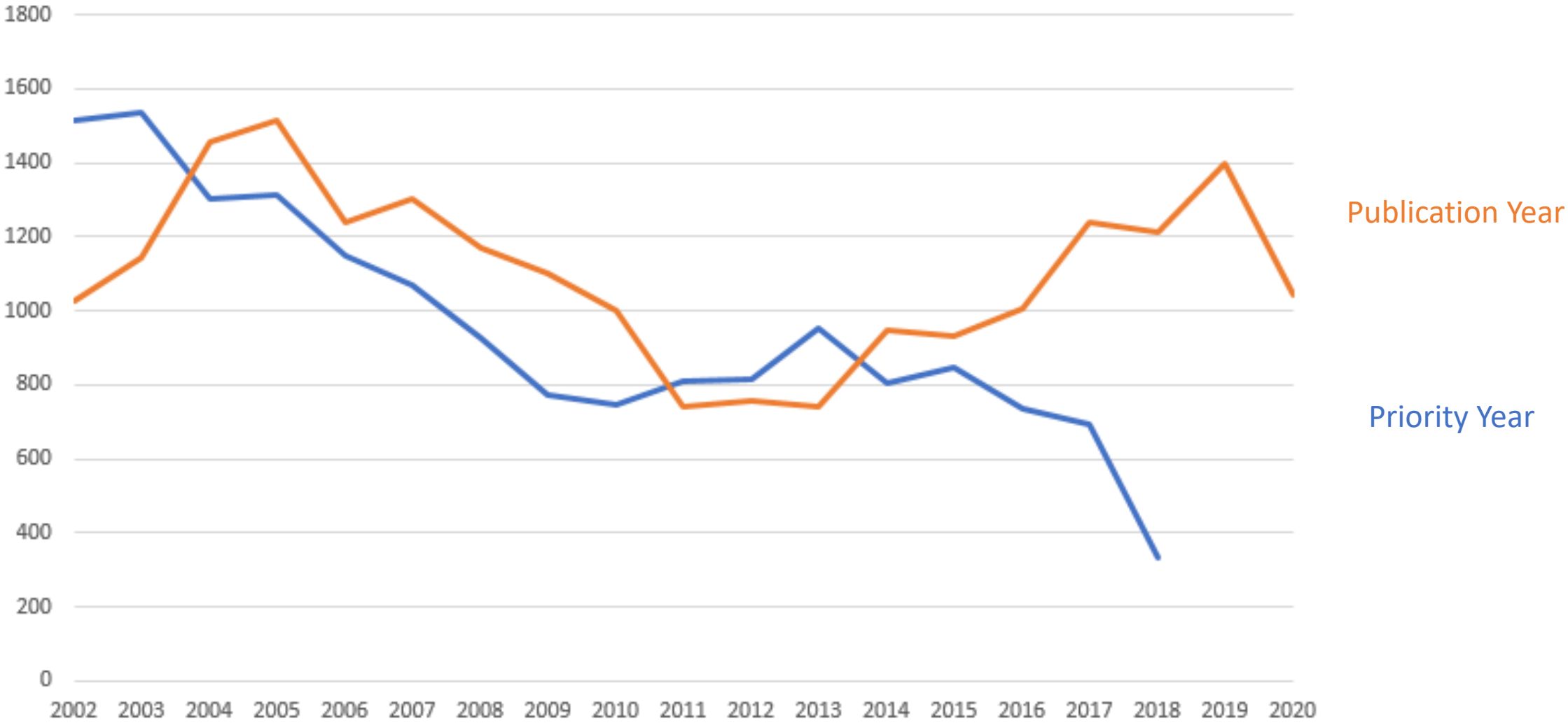
Source: Derwent Innovation

Top 10 Countries for Cardiovascular Diagnostic Device Publications (2019-20)



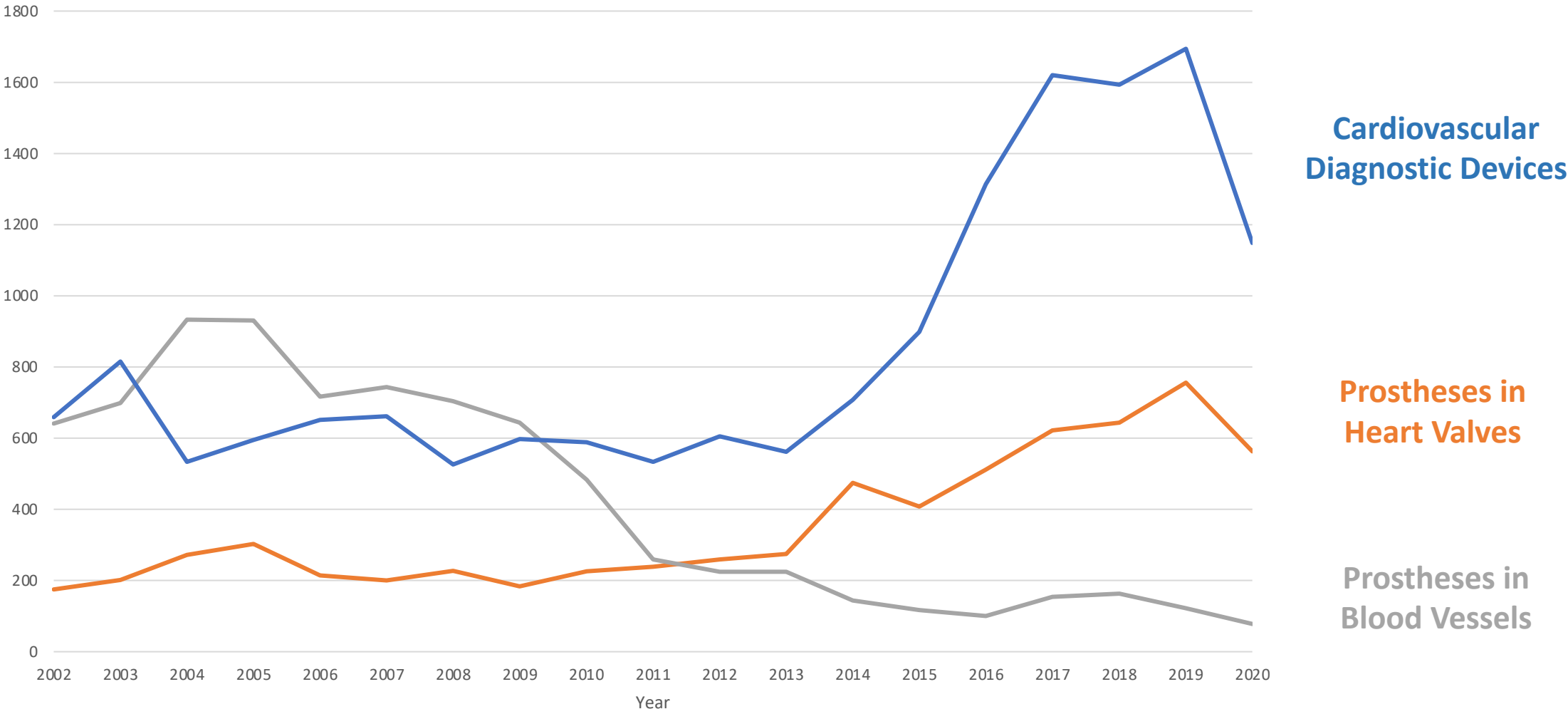
Source: Derwent Innovation

Trends in U.S. Cardiovascular Publications & Filings



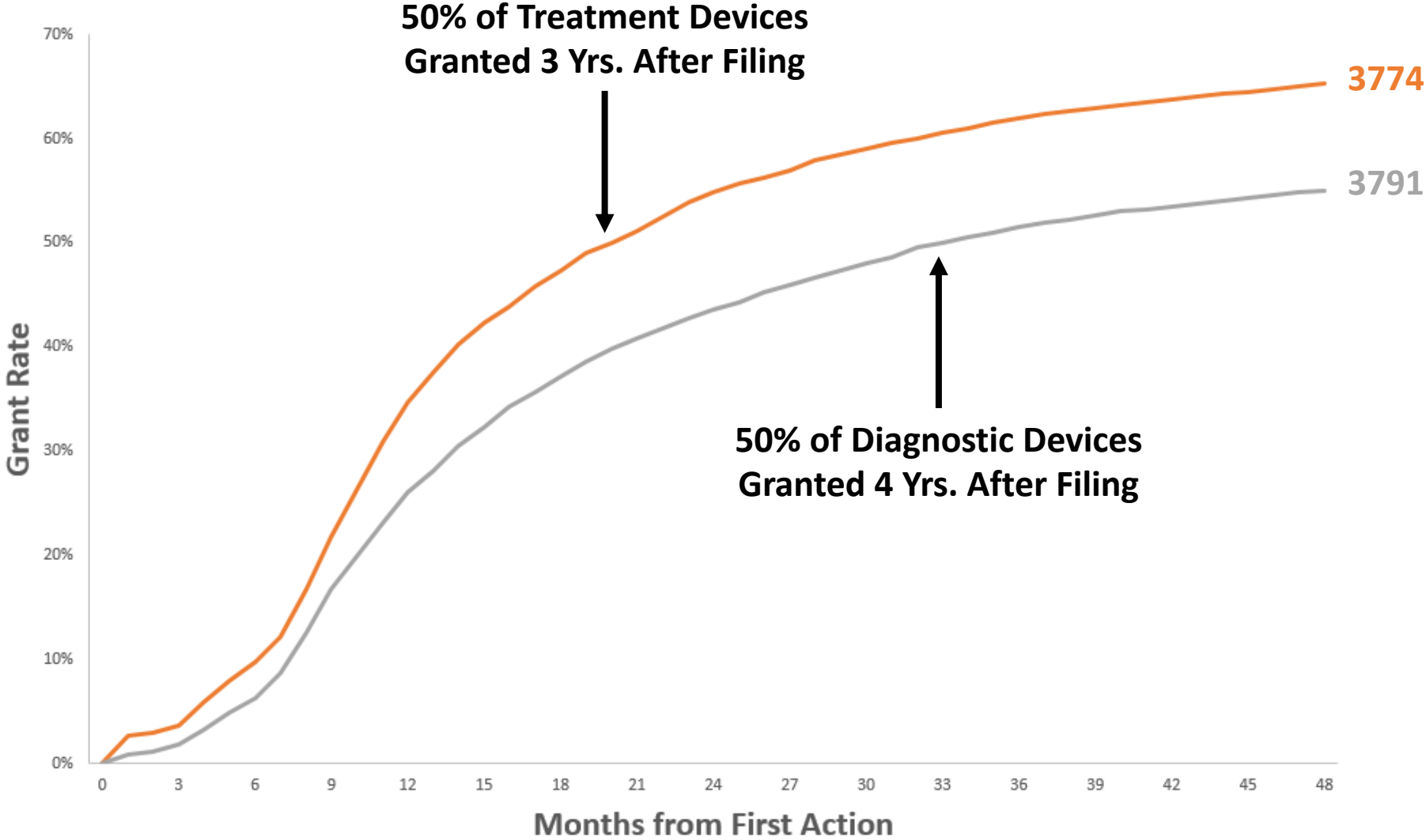
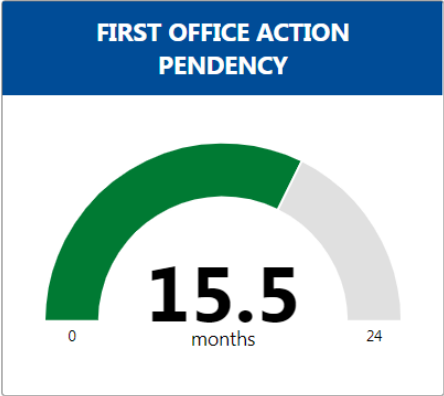
Source: Derwent Innovation

Trends in U.S. Cardiovascular Publications



Source: Derwent Innovation

50% of Cardiovascular U.S. Patents Granted Within 3 to 4 Years



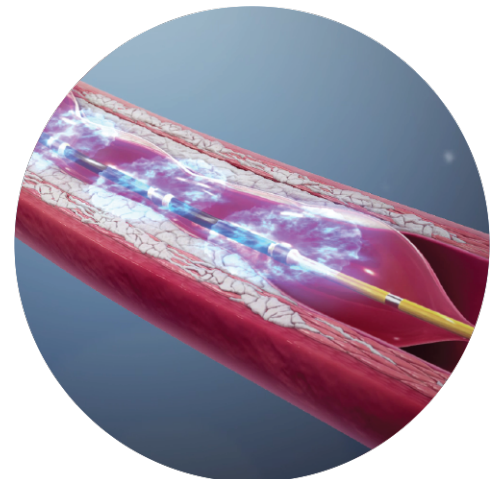
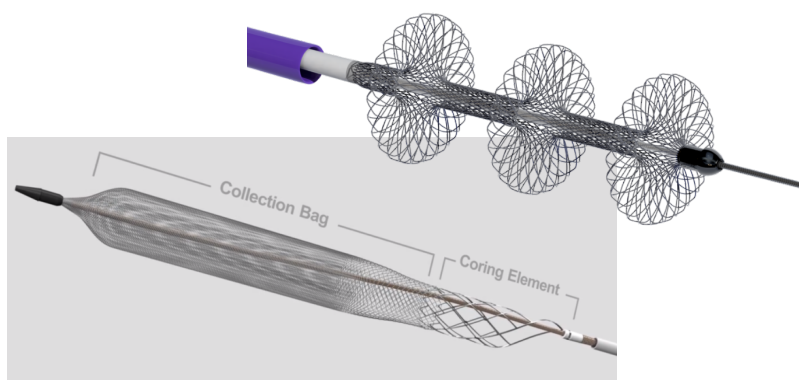
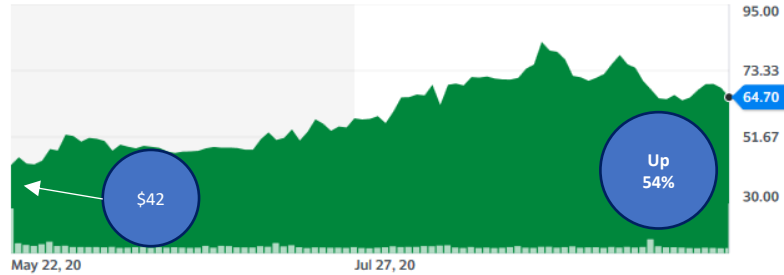
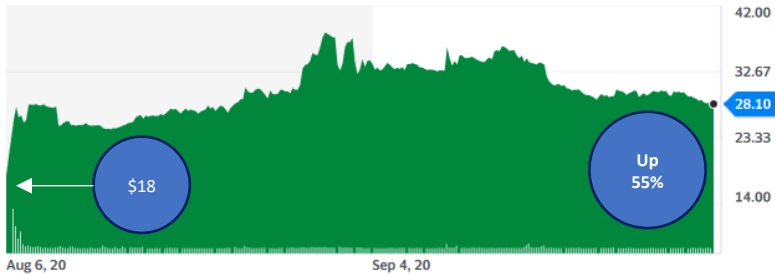
IP Related Transactions

Three Very Successful Cardiovascular IPOs

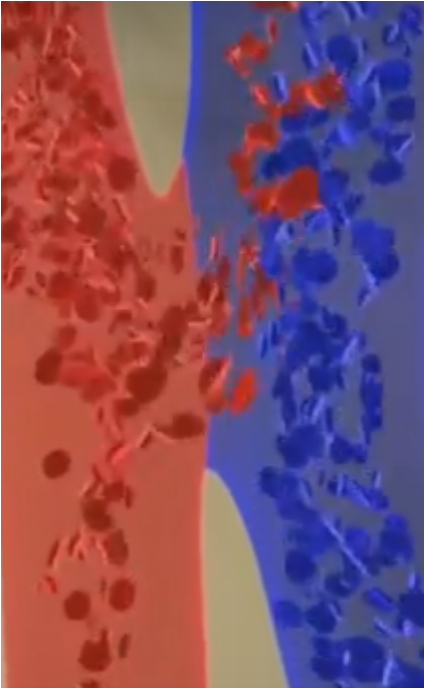
Acutus Medical (AFIB)
\$158.8M

Inari Medical (NARI)
\$156M

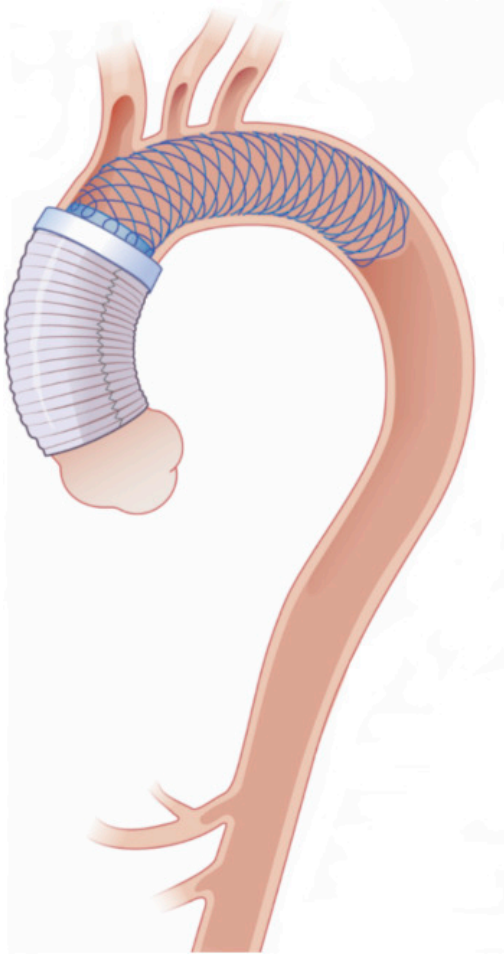
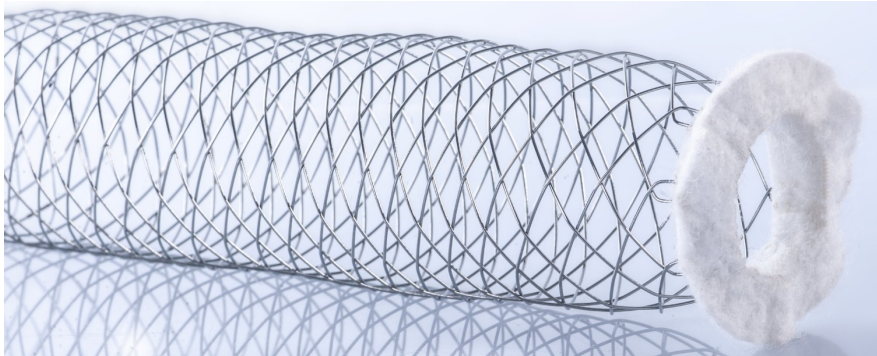
Shockwave Medical (SWAV)
\$75M



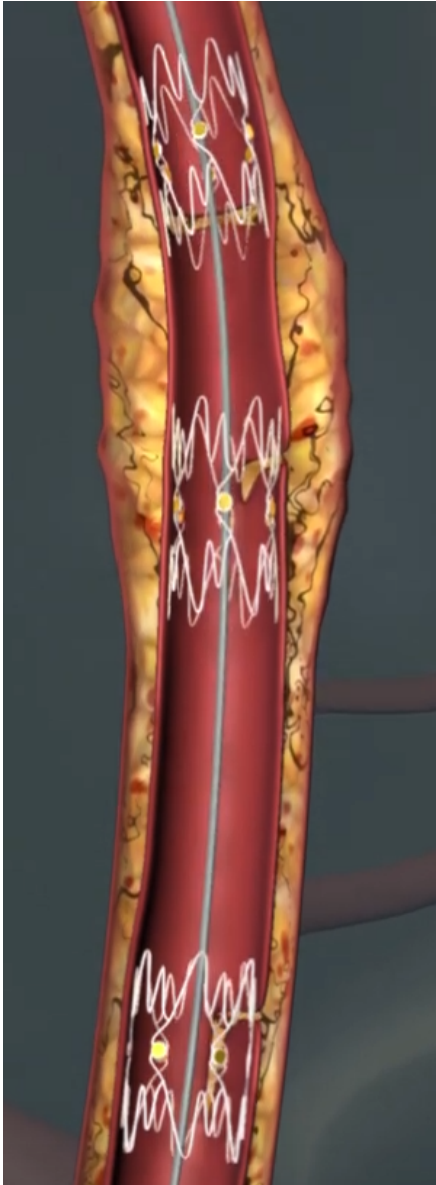
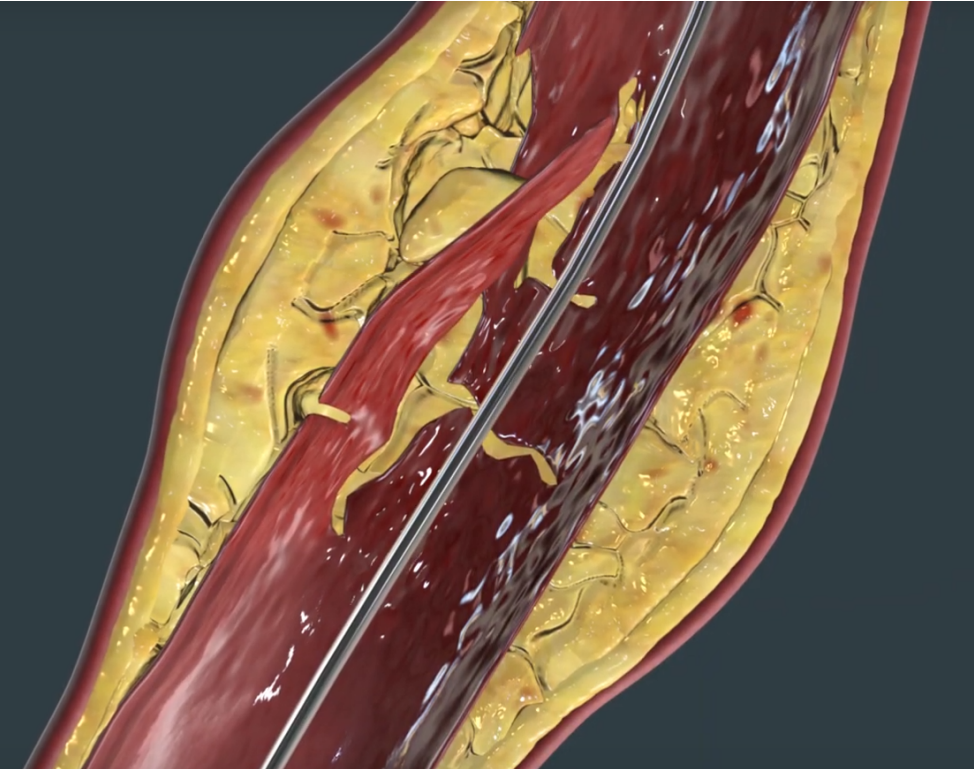
Breaking: Medtronic to Acquire Avenu Medical



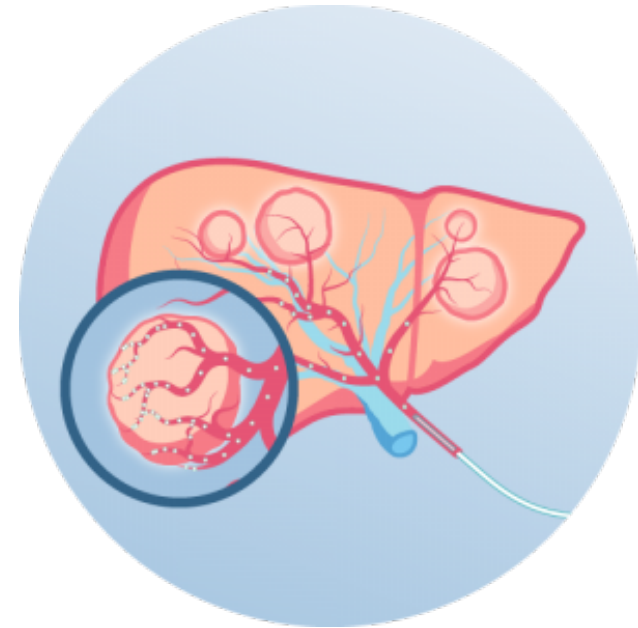
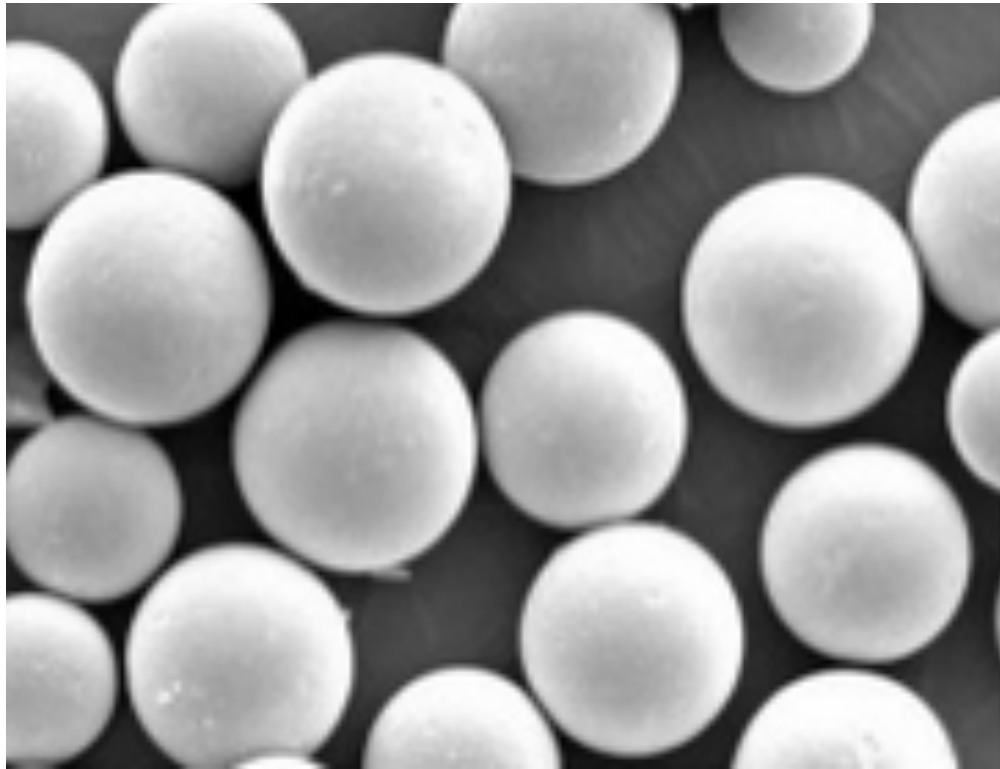
Breaking: CryoLife acquired Ascyrus Medical for \$200M



Philips Acquired Intact Vascular for \$275-360M



Terumo Acquired Quirem Medical for \$45M



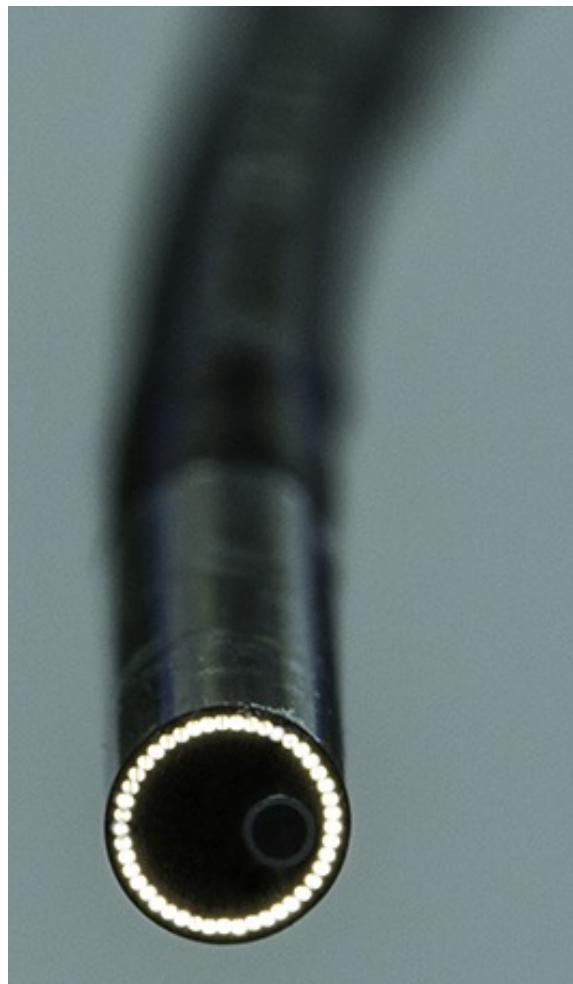
LeMaitre Vascular Acquired Artegraft for \$90M



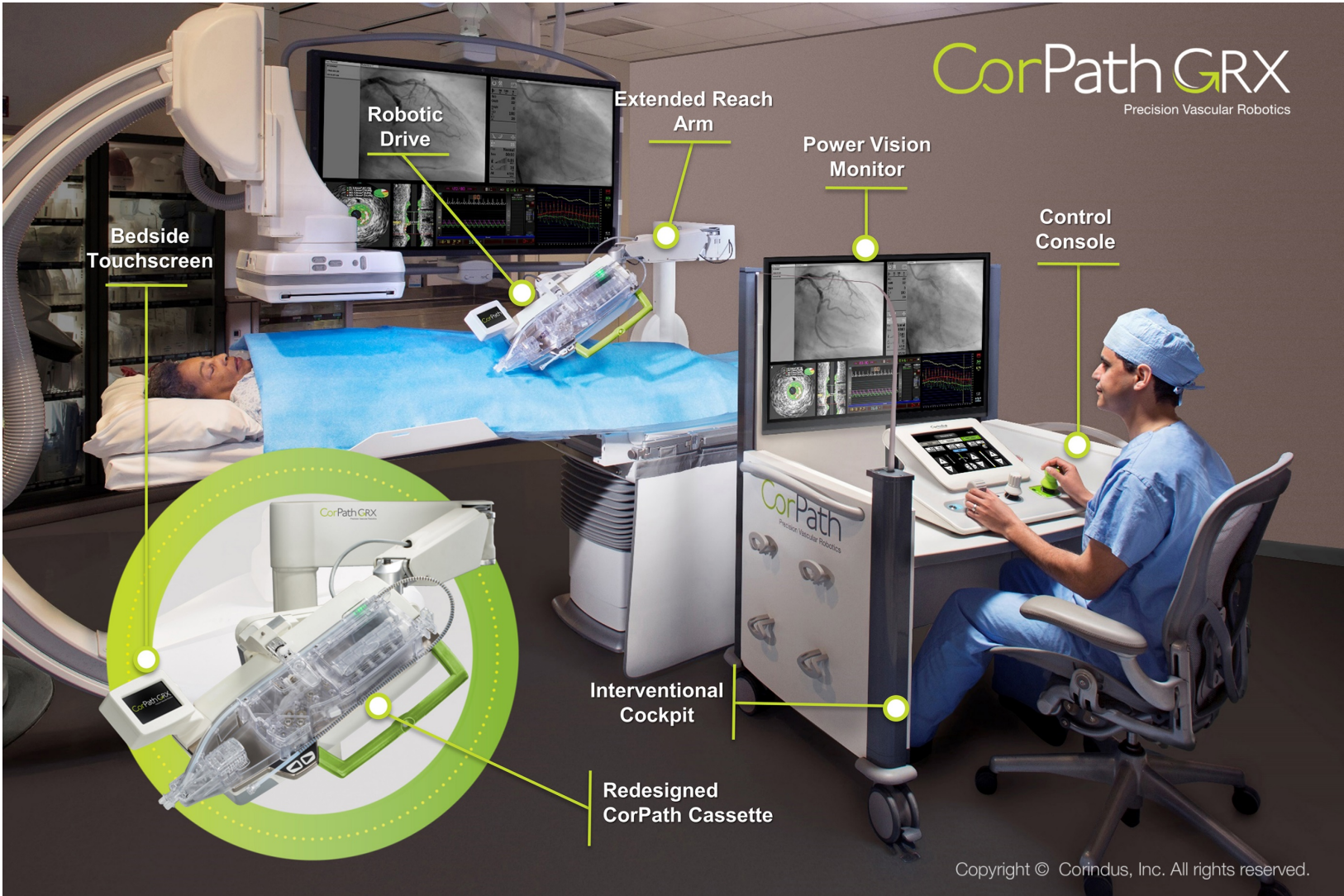
Keystone Heart Acquired 510 Kardiac Devices for \$90M



AngioDynamics Acquired Eximo Medical for \$66M



Siemens Acquired Corindus Vascular Robotics for \$1.1B



Thank you!