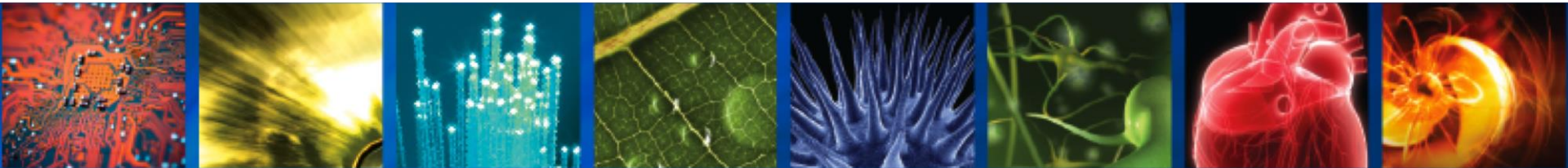


Medical Device Breakout Session

Brian Horne, Sabling Lee and Gerard von Hoffmann

November 6, 2014

IP Impact 2014

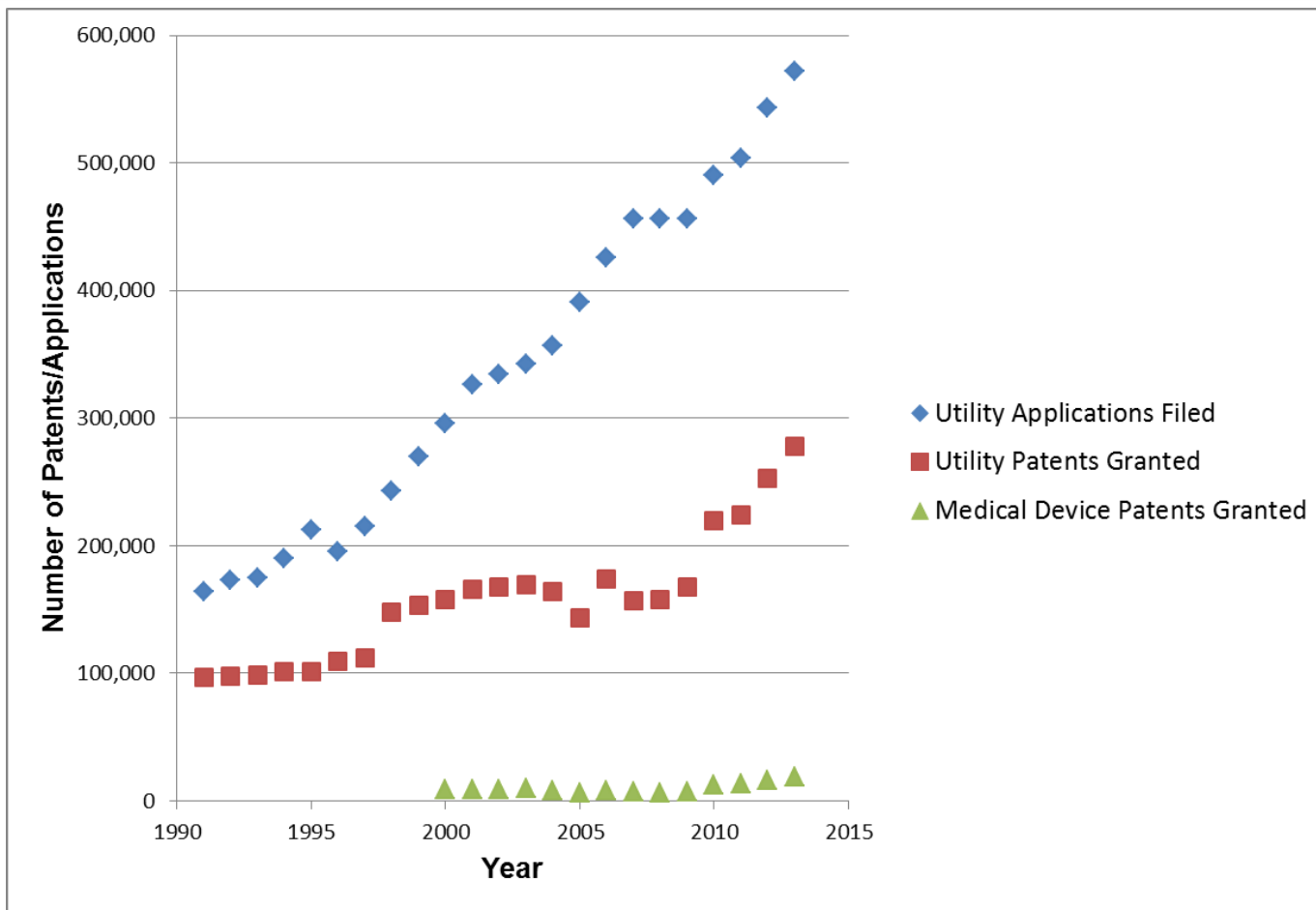


Overview

- Medical device patent statistics
- Non-practicing entity (NPE) litigation
- Inter partes reexam (IPR) update
- Important litigation
 - Edwards v. Medtronic
 - Masimo v. Philips
 - Injunctions (Depuy Synthes v. Globus and Smith & Nephew v. Arthrex)

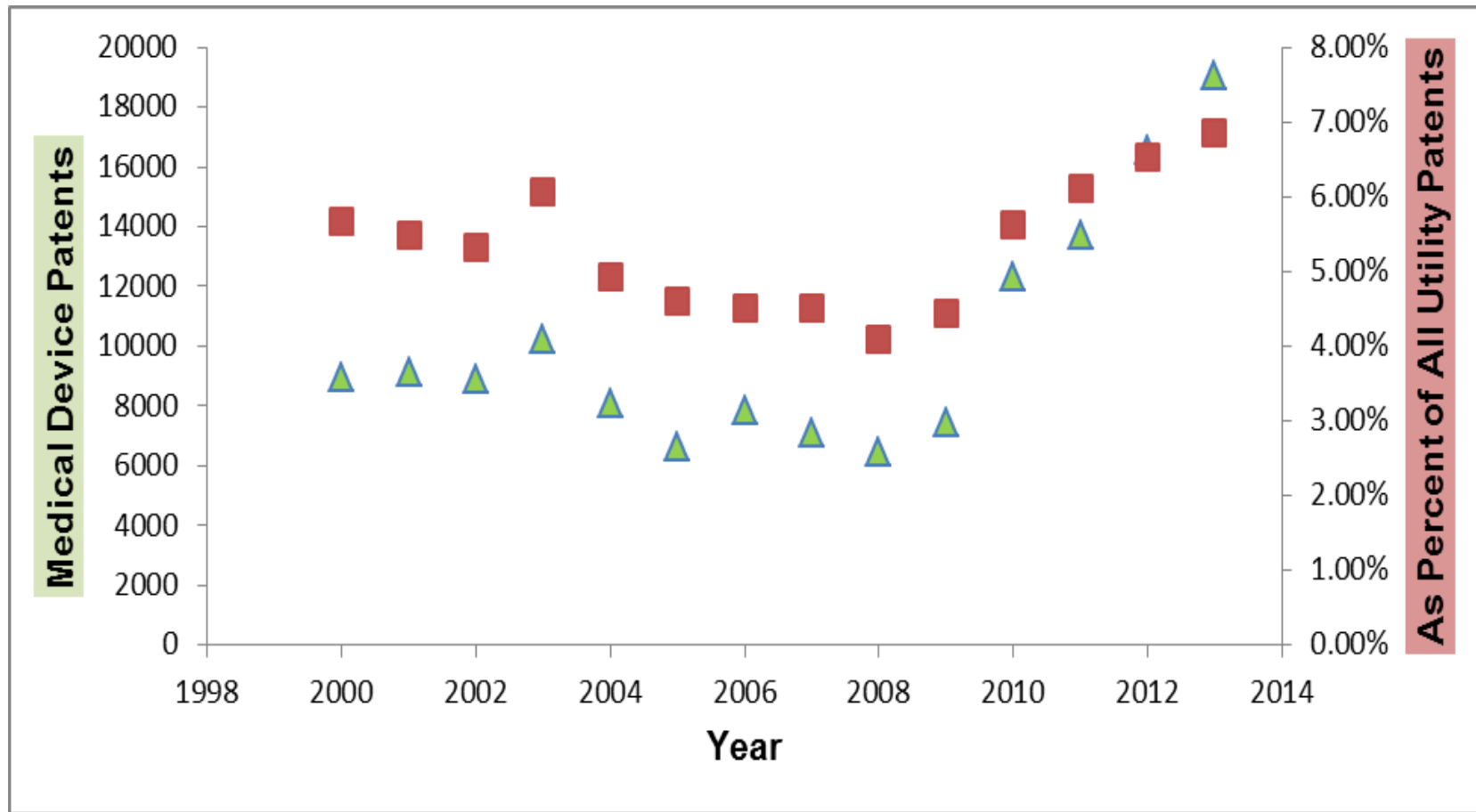
Medical Device Patent Statistics

Applications Filed and Patents Granted Per Year



*data from USPTO website
(as of December 31, 2013)

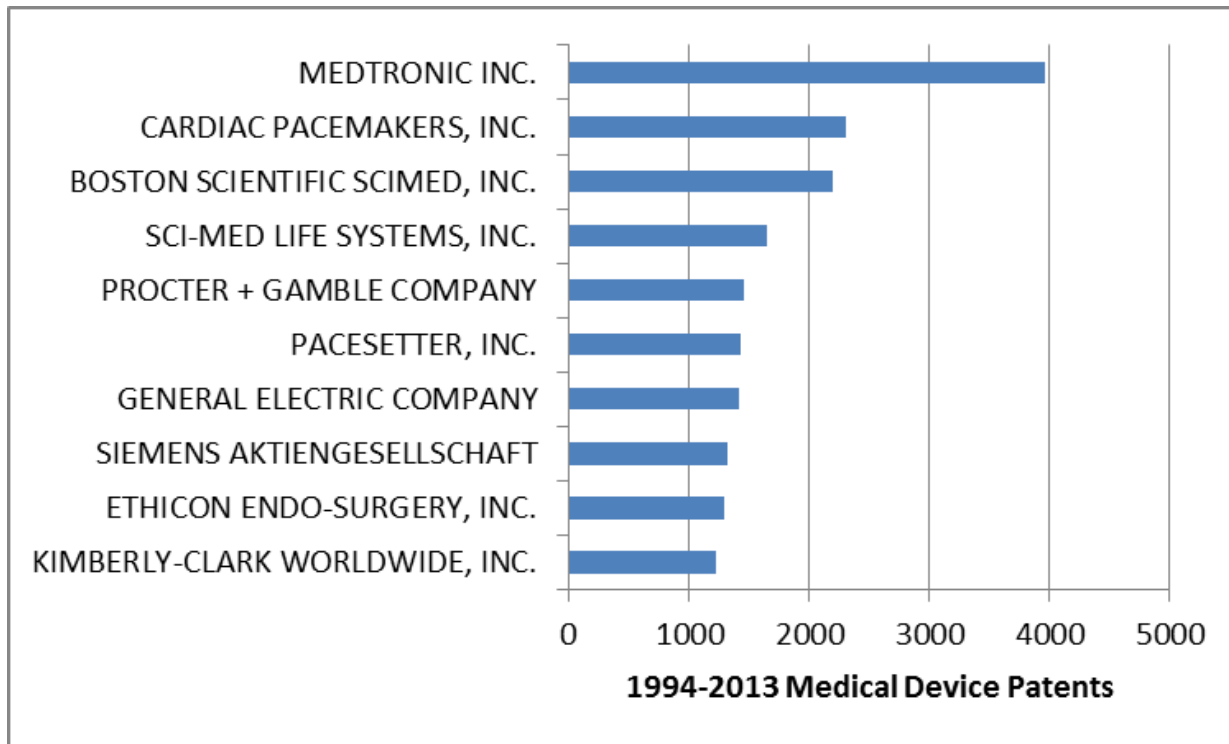
Medical Device Patents Granted



*data from USPTO website
(as of December 31, 2013)

1994-2013 Medical Device Patent Owners

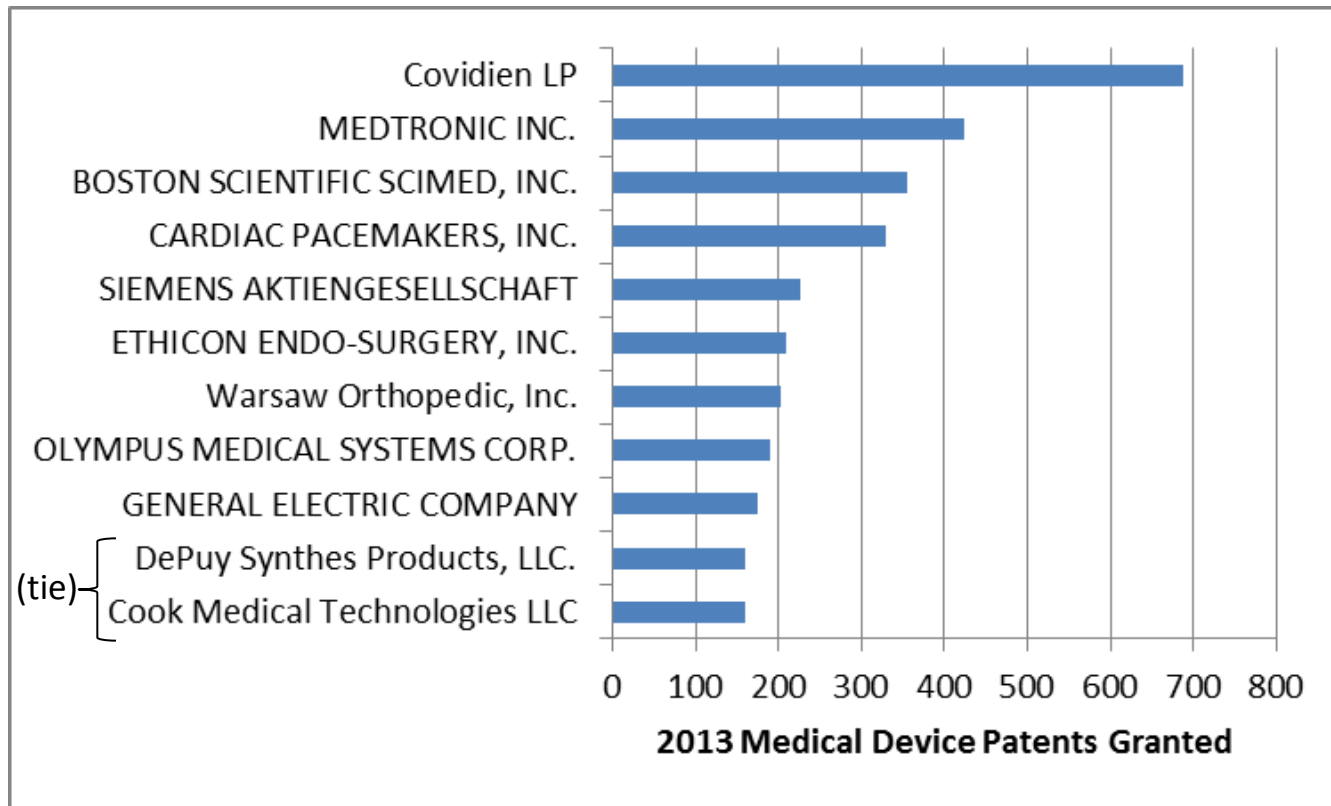
TOP TEN



*data from USPTO website
(as of December 31, 2013)

2013 Medical Device Patent Owners

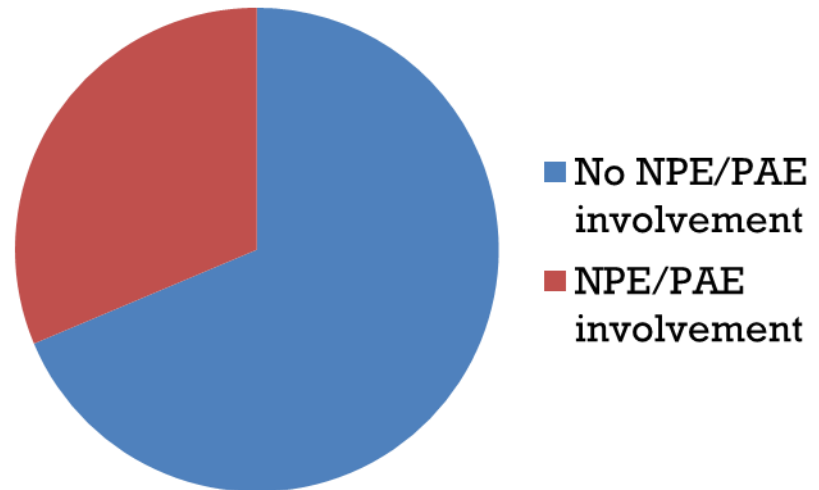
TOP TEN



*data from USPTO website
(as of December 31, 2013)

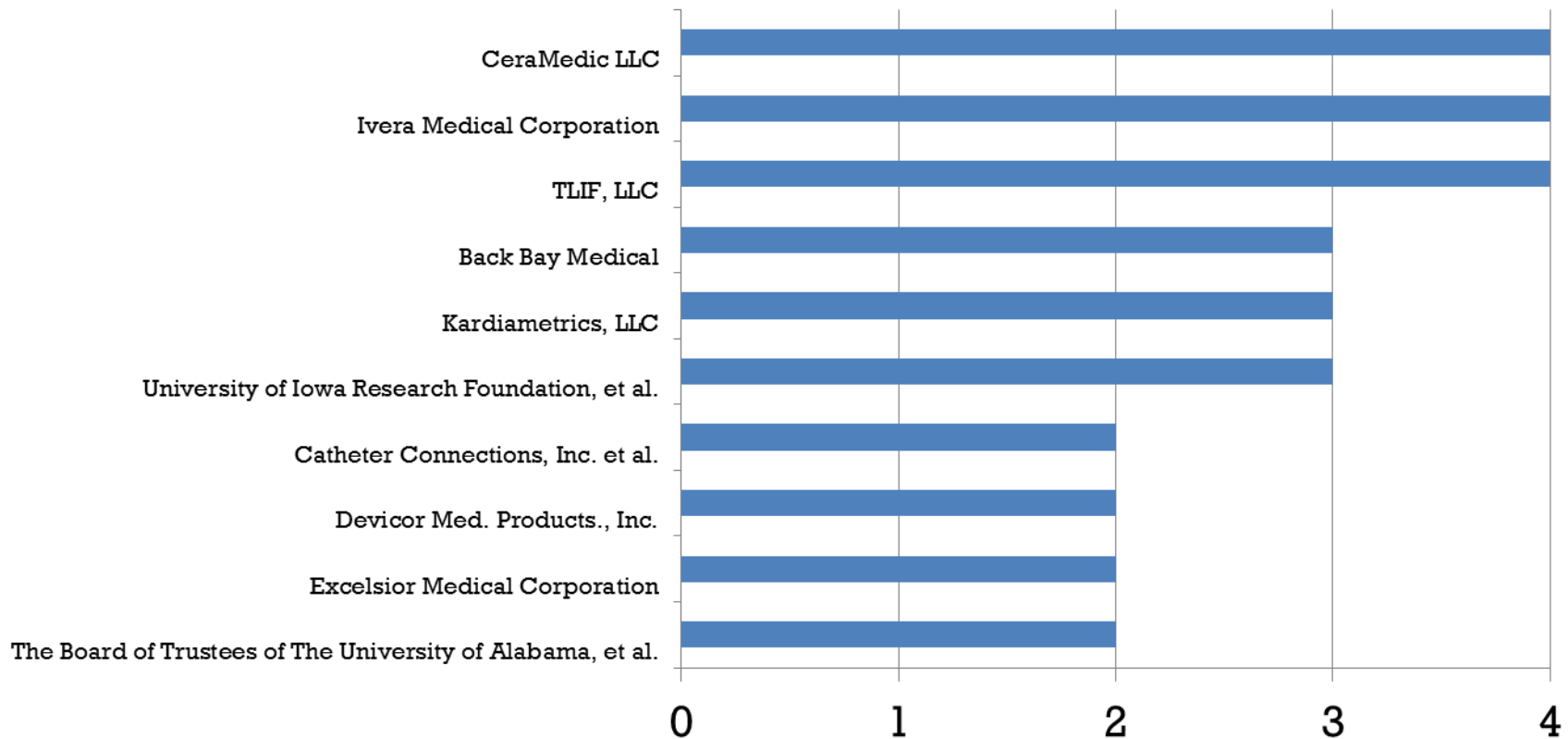
Medical Device Litigation Overview

- In a review of patent litigations identified by KnobbeMedical filed between August 2013 & October 2014:
 - 67 litigations were filed relating to medical device technology
 - 46 involved a litigation in which both parties were practicing entities
 - 21 involved a litigation involving an NPE/PAEs



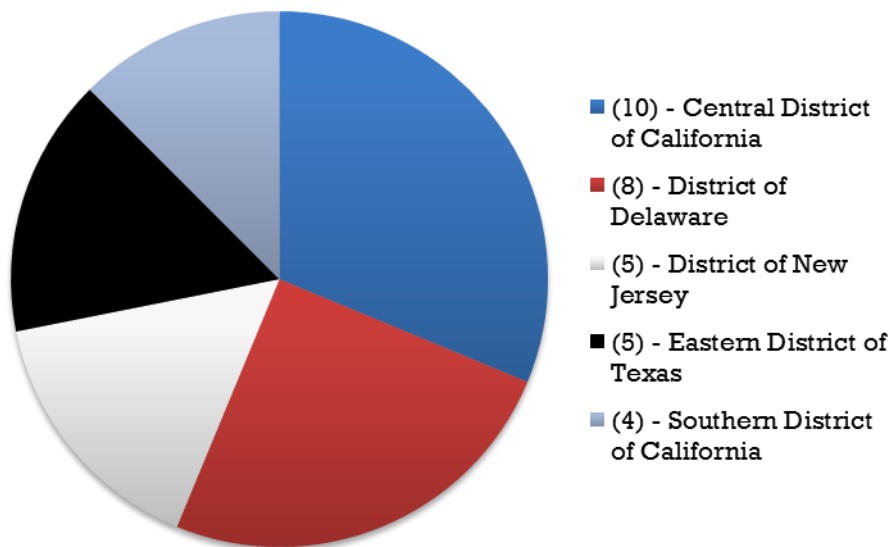
Medical Device Litigation Statistics

Top Filers (August 2013 – October 2014)

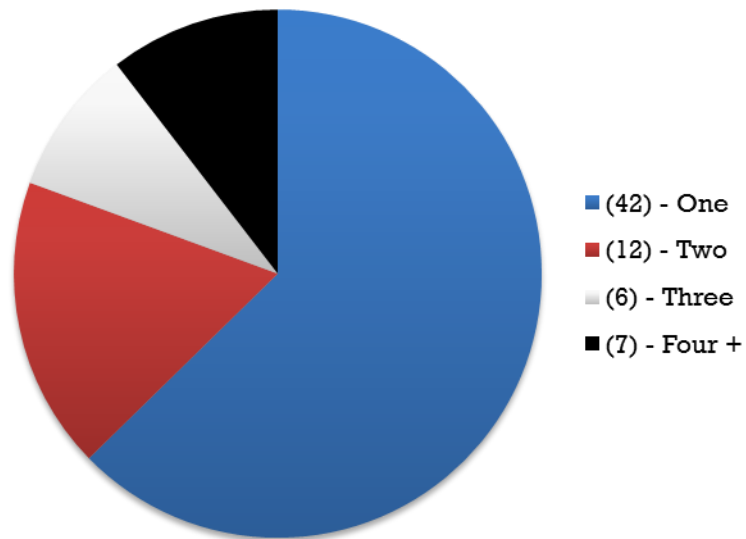


Medical Device Litigation Statistics (cont'd)

Top 5 Forums



Number of Patents Asserted

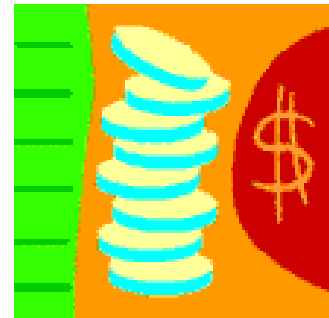


Non-Practicing Entity (NPE) Litigation

NPE Litigation Statistics

- 3,608 NPE cases filed in 2013
- This represents 67% of all patent litigation cases filed in 2013
- 91% of all NPE litigations were brought by patent assertion entities
- 2% of NPE defendants are considered “medical” (not including biotech and pharma)

Source: RPX Corp.



Healthcare and Pharma Statistics

- 474 unique operating company defendants
- 124 NPEs filing suits
- 369 litigated patents

Source: PatentFreedom (as of July 14, 2014)



LifePort/LifeScreen Litigation

- December 2012/January 2013 - Acacia Research acquires patents from Boston Scientific relating to vena cava filters and endovascular grafts
- 2012-2014 - LifePort Sciences LLC and LifeScreen Sciences LLC, affiliated with Acacia, sue in DE and E.D. TX against Cook (dismissed), Endologix, Medtronic (stayed), C.R. Bard, Cordis and W.L. Gore asserting infringement of vena cava filter and endovascular graft patents
- June 2014/August 2014 – IPRs filed by Medtronic (instituted), WL Gore (pending)
- June 2014 – Cordis has *Markman* hearing
- October 2014 - Cook, Endologix, and Gore served Invalidity contentions

Boston
Scientific

 acacia
RESEARCH CORPORATION

Orthophoenix Litigation

- 2007 - Medtronic acquires spinal device maker Kyphon for ~\$4 billion
- April 2013 - Medtronic sells over 500 patents to Orthophoenix, LLC, an entity associated with IP Nav, a known NPE.
- June-October 2013 – Orthophoenix sues Wright Medical, DFine, Osseon, Ascendx, Sinteia Plustek (dismissed), and Soteira/Globus (dismissed), Stryker
- June 2014/September 2014 – IPRs filed by Wright, Stryker (all pending)



KYPHON



Diagnose VCF



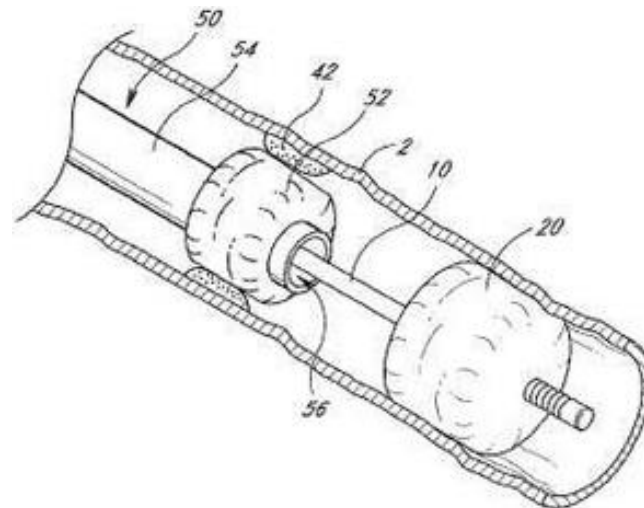
Restore Vertebral
Body Height



Stabilize the Fracture

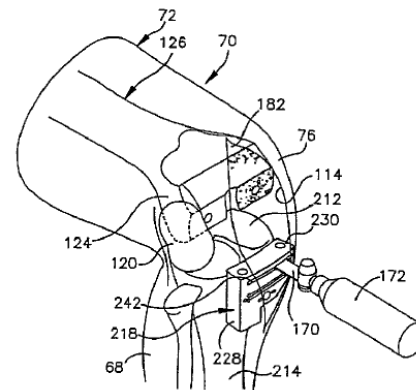
Kardiametrics Litigation

- October 2000 – Medtronic acquires PercuSurge, maker of embolic protection devices for \$225 Million
- April 2013 – Kardiametrics acquires patents from Medtronic
- September 20, 2013 – Kardiametrics sues in DE against Abbott, Boston Scientific, Control Medical Technology, Cordis, Covidien, Medrad and Merit Medical Systems
- All cases have been dismissed



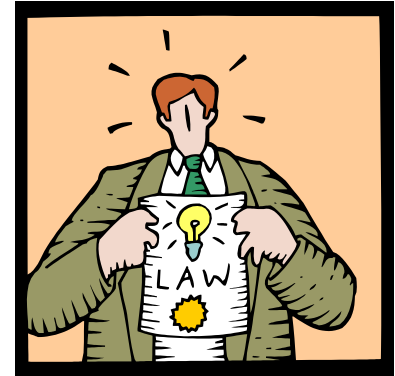
Bonutti Litigation

- More than 250 patents developed by Dr. Peter Bonutti, an orthopedic surgeon
- Dr. Bonutti partnered with Acacia
- Lawsuits in M.D. FL, DE, and E.D. TX against MicroPort Orthopedics, Lantz Medical, Zimmer (stayed), Wright Medical (stayed), Arthrex (dismissed), DePuy, ConforMIS (stayed), Smith & Nephew (dismissed), Linvatec (dismissed), Biomet (dismissed)
- IPRs filed by Arthrex, Smith & Nephew, Wright, Zimmer (6 instituted; 4 denied)



What Happened In Congress?

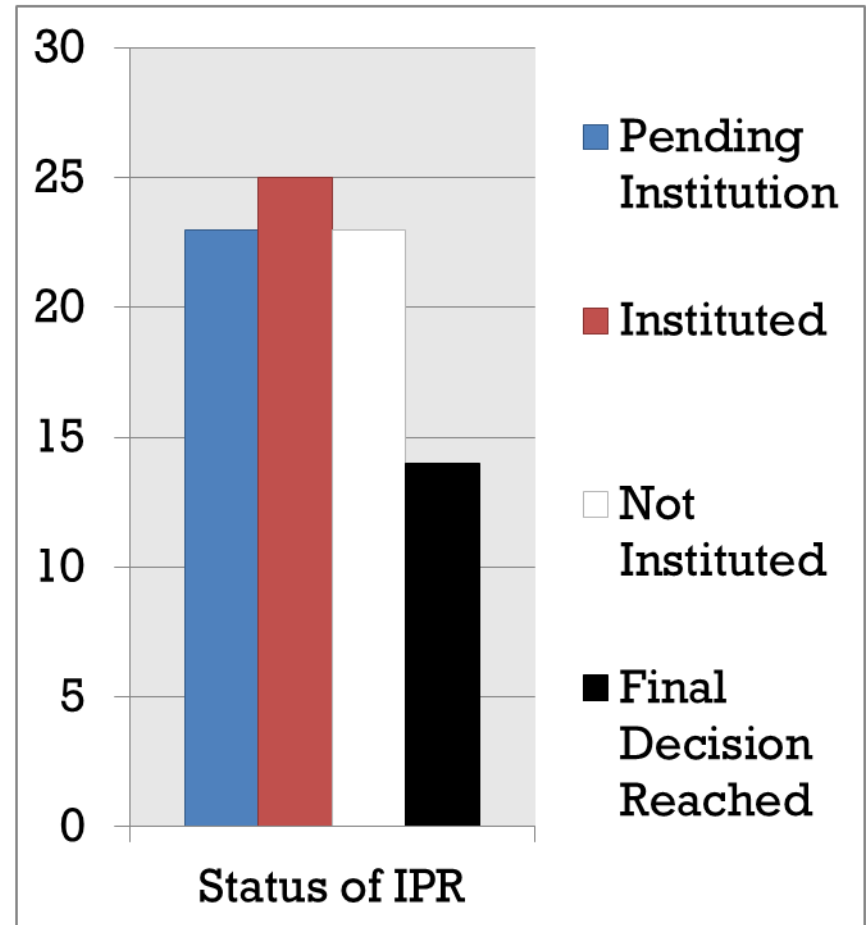
- Innovation Act, H.R. 3309
 - Intended to curb abusive litigation practices
 - Specific identification of patent claims and allegedly infringing products
 - Limit discovery to reduce litigation cost
 - Awarding of attorneys' fees to the prevailing party
- Passed by House 325-91 in December 2013
- Senate bill repeatedly delayed and ultimately pulled in May 2014



Medical Device Inter Partes Review (IPR) Update

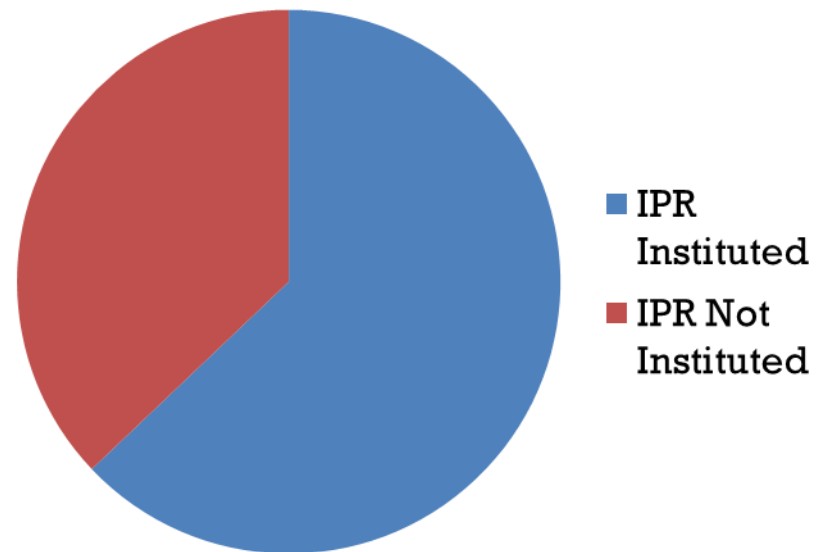
Medical Device IPR Overview

- In a review of the 85 IPRs relating to medical devices identified by KnobbeMedical that had activity between August 2013 & October 2014
 - 23 IPRs currently Pending Institution
 - 25 IPRs Instituted w/o Final Decision
 - 23 IPRs Not Instituted
 - 14 IPRs for which a Final Decision was issued

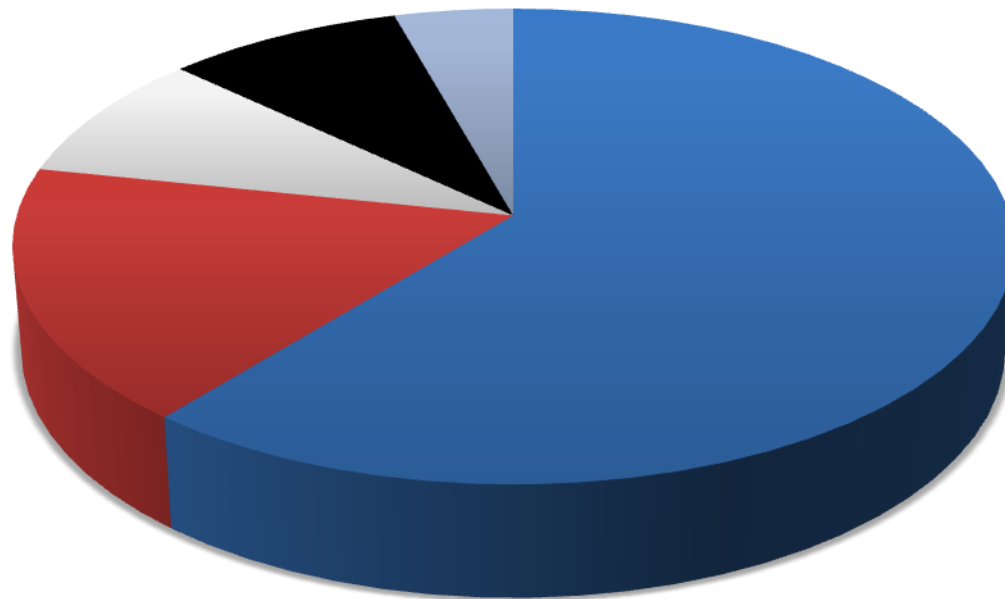


IPR Institution Rate

- Of the 62 cases in which the PTAB reached a decision regarding institution of the IPR
 - 62.9% were Instituted
 - 37.1% were Not Instituted



Reasons for Not Instituting an IPR



- 60.8% - USPTO terminated IPR as a result of settlement
- 17.4% - Challenger failed to "demonstrate a reasonable likelihood of prevailing"
- 8.7% - Patent owner disclaimed claims at issue
- 8.7% - PTAB determined IPR was too similar to previously filed IPR - i.e., "Second bite at the apple"
- 4.3% - Challenger failed to file within 1 year under 35 U.S.C. §315(b)

Time between Filing and Decision Regarding Institution

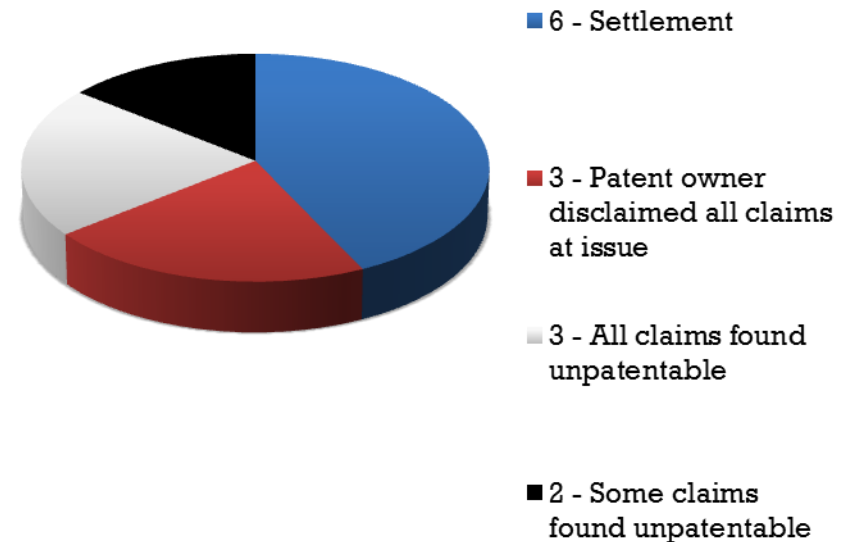
	Shortest Time	Longest Time	Average Time
All IPRs IPRs Instituted + IPRs Not Instituted (62 IPRs)	58 days	192 days	152 days
IPRs Instituted (39 IPRs)	138 days	192 days	169 days
IPRs Not Instituted (23 IPRs)	58 days (Settlement)	190 days (USPTO determined IPR was too similar to previously filed IPR)	124 days

IPR Final Decision

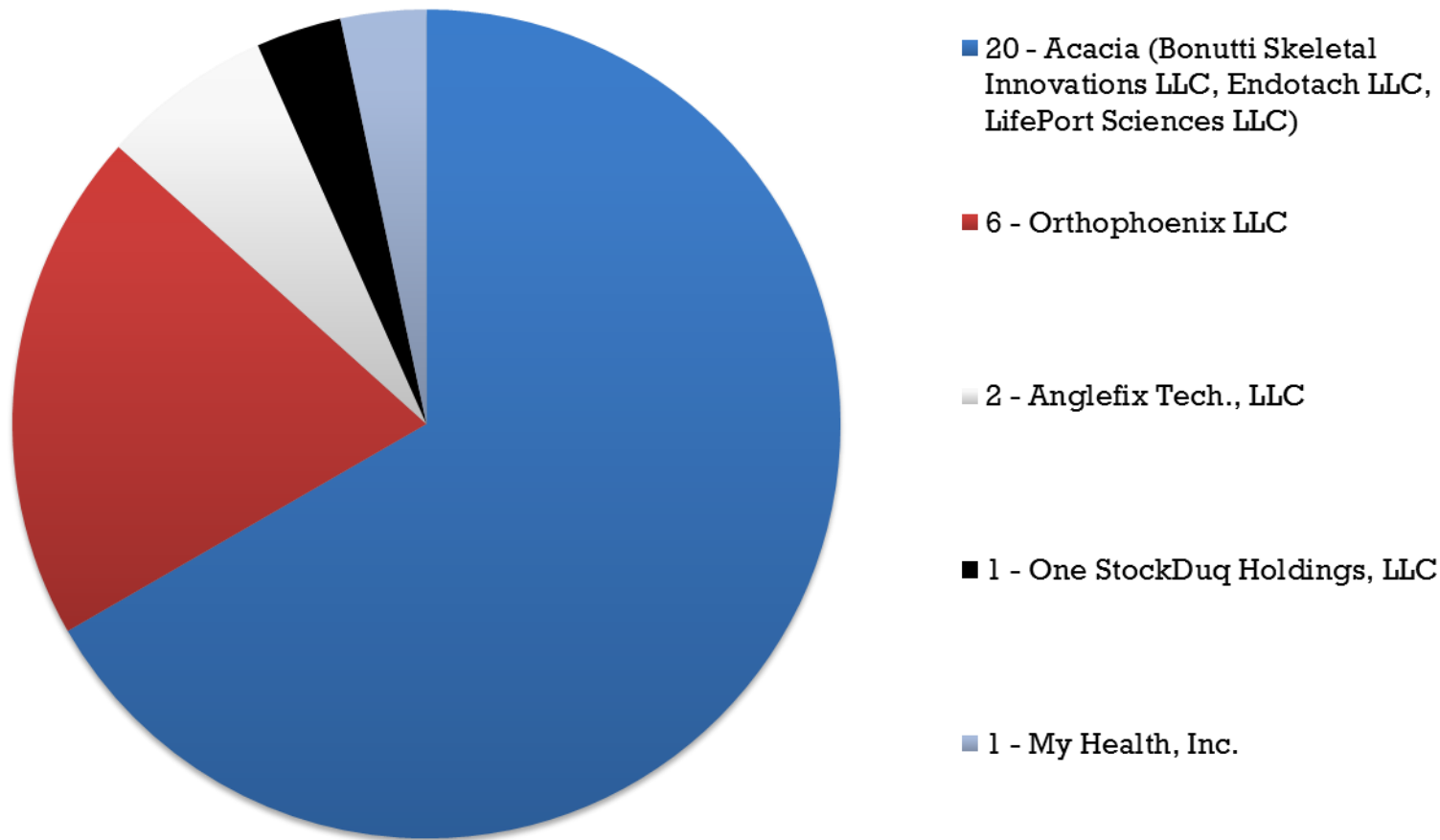
Time to Final Decision (from filing to final decision)

	Shortest Time	Longest Time	Average Time
Final Decision Reached (14 IPRs)	180 Days (IPR where Patent Owner disclaimed all claims at issue)	539 Days (IPR where all claims held unpatentable)	328 Days

Basis of Final Decision

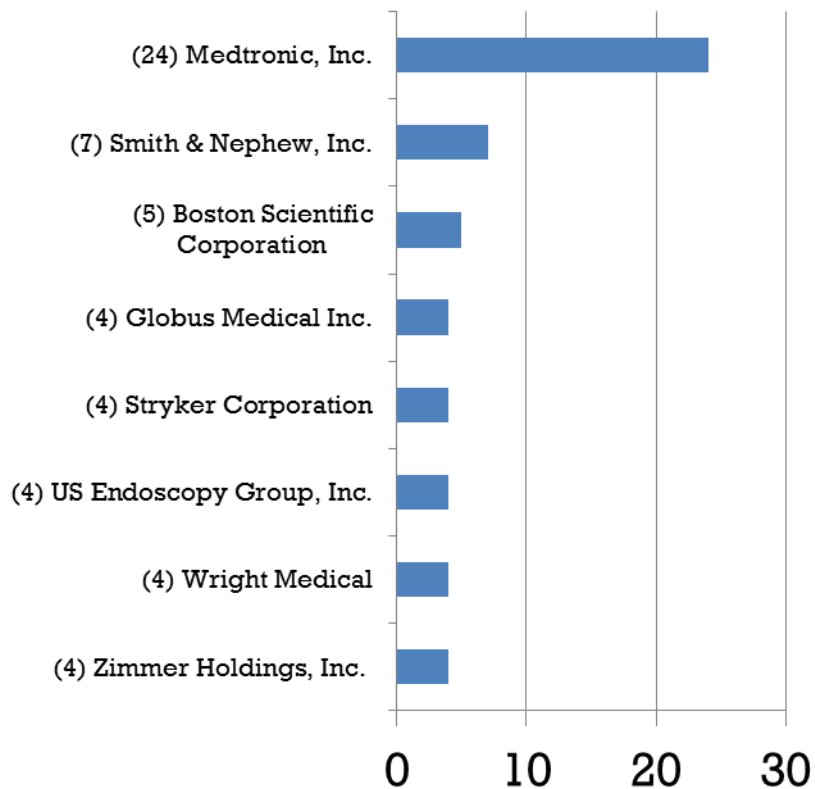


NPE/PAEs Involved in IPR

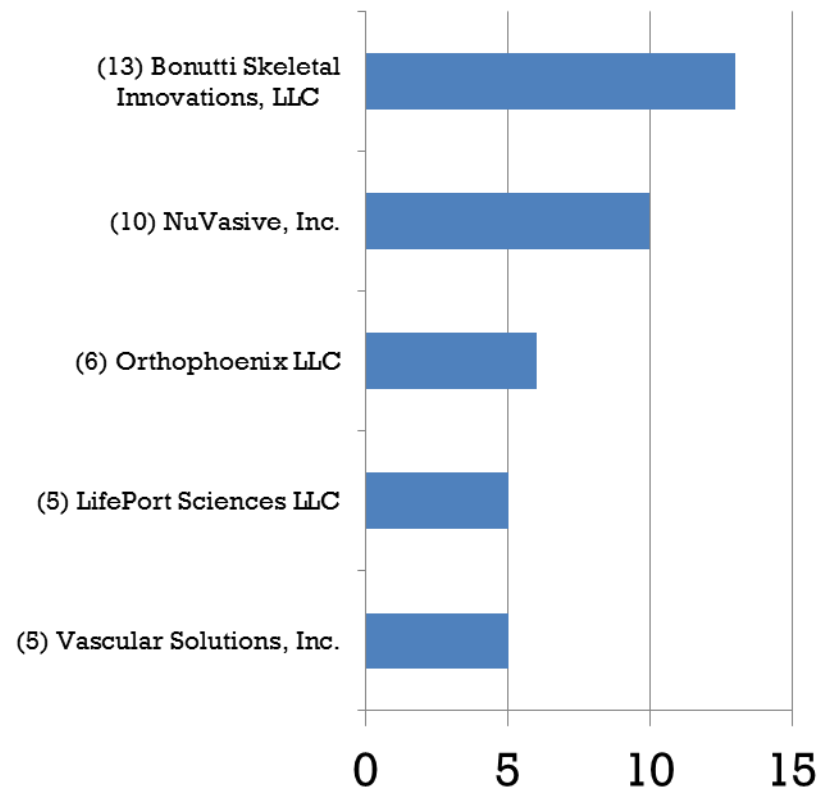


IPR Filers & Defendants

Top 5 IPR Filers



Top 5 IPR Defendants



IPRs with Associated Litigation Involving NPE/PAEs

- Of the 85 IPRs, 80 IPRs were associated with an ongoing federal litigation.
- Of these –
 - 50 involved a litigation in which both parties were practicing entities
 - 30 involved a litigation involving an NPE/PAEs

Edwards v. Medtronic

EW v. MDT/CoreValve – The Products

Medtronic CoreValve



Edwards Sapien



EW v. MDT/CoreValve - World-Wide Fight

Year	Patent	Jurisdiction	Plaintiff	Defendant	Outcome
2009	Andersen	UK	Edwards	CoreValve	Not Infringed Affirmed on Appeal
2008	Andersen	Germany (Infrin't)	Edwards	CoreValve	Not Infringed Affirmed on Appeal
2010	Andersen	Germany (Invalidity)	CoreValve	Edwards	Not Invalid
2010	Andersen	Delaware	Edwards	CoreValve	Infringed - \$83M Affirmed-in-part
2012	Seguin	California	MDT	Edwards	Invalid
2013	Spenser	Germany (Infrin't)	Edwards	MDT	Infringed (injunction)
2014	Spenser	EPO (Invalidity)	Edwards	MDT	Invalid
2014	Cribier	California	Edwards	MDT	Infringed - \$392M

EW v. MDT/CoreValve - World-Wide Fight

Year	Patent	Jurisdiction	Plaintiff	Defendant	Outcome
2009	Andersen	UK	Edwards	CoreValve	Not Infringed Affirmed on Appeal
2008	Andersen	Germany (Infrin't)	Edwards	CoreValve	Not Infringed Affirmed on Appeal
2010	Andersen	Germany (Invalidity)	CoreValve	Edwards	Not Invalid
2010	Andersen	Delaware	Edwards	CoreValve	Infringed - \$83M Affirmed-in-part
2012	Seguin	California	MDT	Edwards	Invalid
2013	Spenser	Germany (Infrin't)	Edwards	MDT	Infringed (injunction)
2014	Spenser	EPO (Invalidity)	Edwards	MDT	Invalid
2014	Cribier	California	Edwards	MDT	Infringed - \$392M
2014	Andersen	Delaware	Edwards	CoreValve	Prelim. Injunction

EW (Andersen) v. CoreValve - Timeline

- 11/13/2012: Federal Circuit
 - Affirms willful infringement
 - Remands denial of permanent injunction
- 11/25/2013: Edwards files motion for preliminary injunction to enjoin CoreValve post approval launch
- 01/17/2014: FDA approves CoreValve Generation 3
- 04/15/2014: District Court grants-in-part motion for preliminary injunction
- 04/21/2014: Federal Circuit grants emergency stay of preliminary injunction
- 05/20/2014: Medtronic announces settlement agreement

EW (Andersen) v. CoreValve - PI

To secure a preliminary injunction under Section 283, the movant must establish four factors:

- The likelihood of success on the merits of the underlying litigation
- Whether irreparable harm is likely if the injunction is not granted
- The balance of hardship as between the litigants
- Factors of the public interest

EW (Andersen) v. CoreValve - PI

The court concludes ... that, despite the three preliminary injunction factors that establish Edwards' entitlement to the injunction, the public interest requires making some accommodation that would grant patients with large annulus sizes access to the CoreValve Generation 3.

April 15, 2014 Memorandum at 17

EW v. MDT/CoreValve - Settlement

MDT will pay EW:

- A one-time payment of \$750 million
- Royalties through April 2022, not less than \$40 million annually

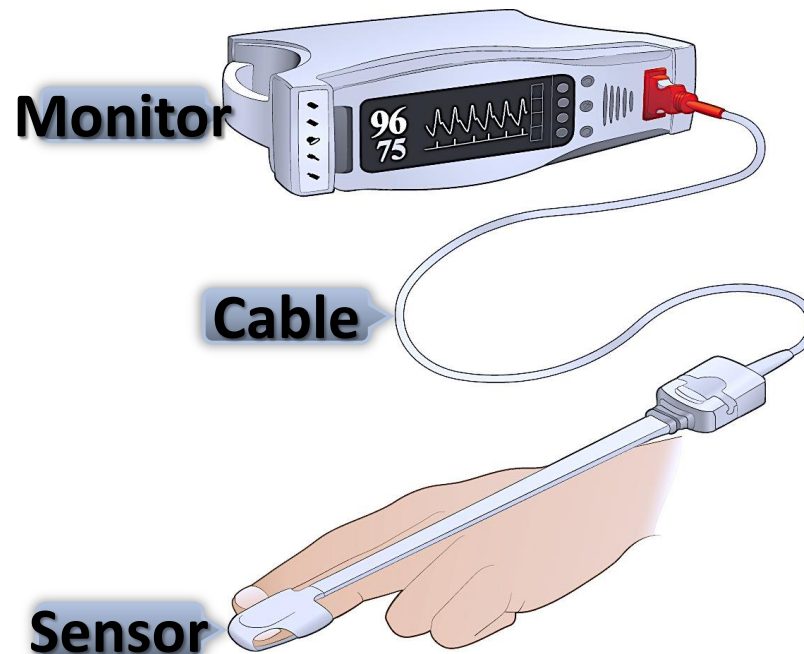
The parties agreed to:

- Dismiss all of the pending litigation matters and patent office actions between them
- Grant each other broad releases to patent litigation claims
- Not sue each other “for patent matters anywhere in the world for eight years in the field of aortic and all other transcatheter heart valves.”

Masimo v. Philips

Masimo v. Philips (Delaware)

- Irvine based Masimo Corporation alleged infringement of a family of patents directed to “pulse oximetry” technology that can provide accurate measurements in the presence of patient motion



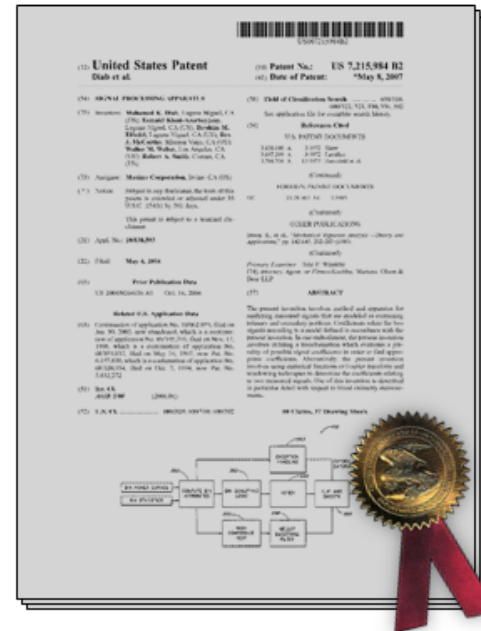
Masimo v. Philips (Del.) – Trial

- In a first trial, Masimo asserted two patents

Masimo's '222 Patent: Measure-Through Motion



Masimo's '984 Patent: Multiple Calculation Techniques



- Shortly before trial, Philips admitted infringement. Philips challenged validity and the amount of damages

Masimo v. Philips (Del.) – Trial

Claim 17 is Indefinite –
It Does Not Provide Sufficient Notice to the Public

DDX 0195



45

Masimo v. Philips (Del.) – Trial

Socket



Cables



Sensors



Masimo v. Philips (Del.) – Verdict

- Jury found Masimo's patents valid and awarded damages

7. What is the total amount of damages to which Masimo is entitled as compensation for Philips' infringement of the '222 Patent and/or the '984 Patent?

\$ 466,774,783.00

Medical Device Permanent Injunctions

-*DePuy Synthes Products, LLC v Globus Medical, Inc.*, C.A. No. 11-652-LPS (D. Del., Apr. 2, 2014) (denying permanent injunction)

-*Smith & Nephew, Inc. et al., v. Arthrex, Inc.*, Civil No. 3:04-CV-00029 (D. Or., Sept. 17, 2013) (granting permanent injunction)

Permanent Injunction – Legal Standard

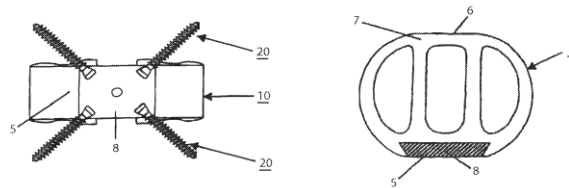
- 35 U.S.C. § 283
 - May grant “in accordance with principles of equity to prevent violation of any right secured by patent, on such terms as the court deems reasonable”
- Burden on requesting party to show:
 - 1) Suffered irreparable injury;
 - 2) Remedies at law are inadequate to compensate for injury;
 - 3) Remedy in equity is warranted based on balance of hardships between plaintiff and defendant; and
 - 4) Public interest not disserved by permanent injunction.

DePuy Synthes Products v. Globus

- Synthes filed suit against Globus for infringement of 3 patents
- Patents related to “inter-vertebral implants” and methods of implanting between adjacent vertebrae in spinal fusion procedure
- Jury verdict found Synthes’ patents valid and infringed



Synthes SynFix-LR System



7,875,076 “Intervertebral Implant”



Globus Coalition,
Independence
and
InterContinental

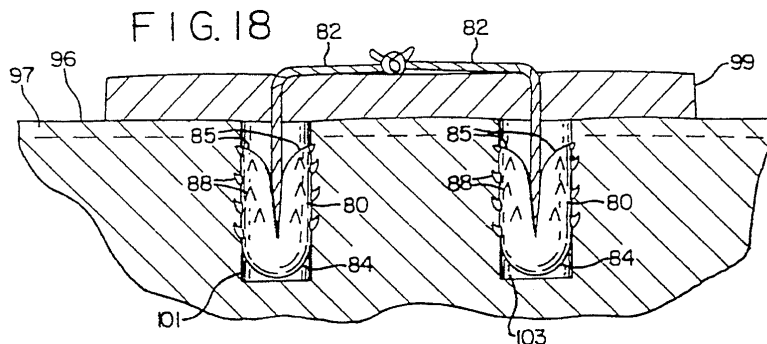


DePuy Synthes Products v. Globus

- Synthes failed to prove irreparable injury under either the Federal Circuit’s prior holding in *DePuy* or under the arguably different standard in *Apple v. Samsung III*
 - *DePuy*: “[s]ales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature.”
 - *Apple III* “calls into question...the causal nexus requirement”
- Synthes failed to prove that it could not be adequately compensated by a (15% pre-judgment and 18% post-judgment) reasonable royalty
- Synthes presented “persuasive arguments” on the balance of hardships and public interest factors
- “However, Synthes has not met the entirety of its burden, so a permanent injunction is not appropriate.”

Smith & Nephew v. Arthrex - Background

- Smith & Nephew created the plastic, push-in suture market
- Arthrex executives – including its President – were aware of SNN's patent
- Arthrex took a large portion of the market, and credited its infringing plastic, push-in suture (in place of the metal, screw-in suture they previously used)
 - Two of Arthrex's top three largest selling suture anchors were infringing products



US 5,601,557 "Anchoring and Manipulating Tissue"



Smith & Nephew
BIORAPTOR
Suture Anchor

Arthrex SutureTak



Smith & Nephew v. Arthrex – Procedural History

2004 – SNN sues

2007 - First trial results in hung jury

2008 - SNN wins second trial

2009 - Federal Circuit vacates SNN's win due to claim construction

2011 - SNN wins third trial, but district court rules for Arthrex on JMOL

2013 - Federal Circuit reinstates SNN's victory

Smith & Nephew v. Arthrex – Irreparable Harm

- The parties directly compete in a portion of the market that Smith & Nephew created and that Arthrex took over through its infringement
- Infringement caused SNN to suffer, and continued infringement will result in:
 - Lost sales,
 - Loss of market share,
 - Lost sales of collateral products,
 - Lost licensing revenue, and
 - Damage to reputation as an innovator

Smith & Nephew v. Arthrex – Adequacy of Monetary Relief

- Difficult to quantify SNN's damage – especially lost market share and lost reputation, customer relationships and goodwill
- SNN does not generally license competitors
 - SNN had licensed Ethicon, but it was part of a settlement and restricted the type of anchors Ethicon could sell
 - Ethicon license occurred before SNN introduced an anchor that it now sells to compete with Arthrex

Smith & Nephew v. Arthrex - Hardships

- Arthrex was aware of the patent and the risk of infringing
- Found to willfully infringe and did not consult opinion of counsel
- Injunction “will not even come close to driving Arthrex out of business” not even in the suture anchor business as Arthrex sells non-infringing products too
- Arthrex’s U.S. sales of infringing product were ~9% of total U.S. sales (~\$40M out of \$444M)
- Far greater harm to Smith & Nephew without an injunction
 - Over 12 years of infringement
 - Competitors may feel free to infringe
 - Smith & Nephew will continue to suffer harms mentioned earlier

Smith & Nephew v. Arthrex – Public Interest

- Substantial public interest in enforcing valid patents
- Arthrex argued at trial that there are a variety of other acceptable substitute anchors available to surgeons
- SNN's products are available on the market

How to Reconcile DePuy Synthes (not granted) with Smith & Nephew (granted)?

- Desire for infringing product driven by patented features?
 - Synthes: Globus presented evidence that consumers use Globus products for reasons other than the patented features
 - Smith & Nephew: link not discussed explicitly by court, but said “identity of form and function” between infringing product and patentee’s product covered by the patent
- Is willfulness a factor?
 - Arthrex: knowledge of patent and no opinion of counsel
- Pioneer v. commodity?
 - Smith & Nephew: able to show lost sales correlating with Arthrex’s introduction of infringing product; substantial R&D investment related to patented products; Smith & Nephew heavily-invested in field as a pioneer in plastic, push-in suture market
 - Synthes: unable to show that reasonable royalty would not provide adequate compensation
- Patentee bears burden of proving entitlement to injunction

Questions and Discussion

Thank You

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Gerard von Hoffmann

Gerard.vonHoffmann@knobbe.com



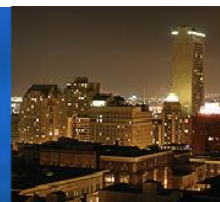
Orange County



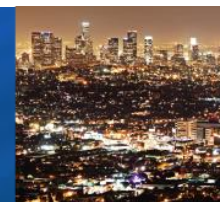
San Diego



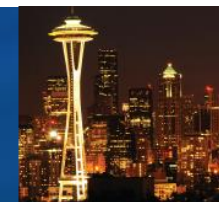
San Francisco



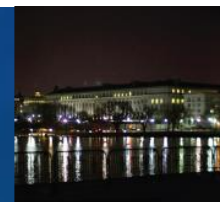
Silicon Valley



Los Angeles



Seattle



Washington DC