

Recent Developments in Patent Law for Medical Device Companies

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IN3 Medical Device Summit

San Francisco



Paul Conover

RECENT PATENT CASES FROM THE SUPREME COURT

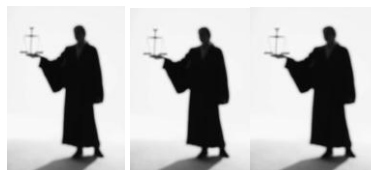
Federal Court System for Patent Infringement Lawsuits

U.S. SUPREME COURT



discretionary

U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT



appeal as of right

FEDERAL DISTRICT COURT



Patent Law from Congress

Patents should be awarded for “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”

(35 U.S.C. § 101)

Supreme Court long ago created an exception:

No patents for “laws of nature, natural phenomena, and abstract ideas”

Alice Corporation PTY. LTD. v. CLS Bank International

- **Unanimous decision by Justice Clarence Thomas (July 2014)**
- Alice owns a patent for using a computer system to mitigate risk in a financial transaction with an intermediary.

Supreme Court Ruling:

- (a) This financial transaction is just an abstract idea
- (b) Merely using a computer to perform it does not make it worthy of patent protection

Problem:

There is no clear line between
“inventions” and “abstract ideas”

Example from Supreme Court of patent-worthy invention:

Computerized method of manufacturing
rubber that used a “thermocouple”

Attorney's Fees

In the United States, each opposing side in a lawsuit is normally responsible for its own attorney's fees, regardless of who wins or loses

Exception to This Rule:

The loser in a patent infringement case must pay the attorney's fees of the opposing party
"in exceptional cases"

- (35 U.S.C. § 285)

Previous Rule from Court of Appeals

“Clear and convincing” evidence of:

- (a) Material inappropriate conduct**
- (b) Objectively baseless case**
- (c) Brought in subjective bad faith**

Octane Fitness, LLC v. Icon Heath and Fitness, Inc.

Unanimous decision by Justice Sotomayor

(April 2014)

Now much lower standard for getting attorney fees:

- An exceptional case in one that stands out from others in the **“*strength of a party’s litigation position*”** (facts or law); or the **“*unreasonable manner in which the case was litigated*”**
- Also, no special level or proof required

Patent Law from Congress

Patents need to be sufficiently clear to enable the public to know what types of products are covered, or not covered, by a particular patent.

Patent Law from Congress:

Patents must “particularly point out and distinctly claim the subject matter which the applicant regards as [the] invention”

(35 U.S.C. § 112 ¶ 2)

Previous Rule from the Federal Circuit Court of Appeals

- Claims were considered unclear only if they were **“insolubly ambiguous”**

(Relatively easy standard to satisfy)

New Rule from U.S. Supreme Court

In *Nautilus, Inc. v. Biosig Instruments, Inc.*:

Unanimous decision by Justice Ginsberg (April 2014)

- A patent must “inform, **with reasonable certainty**, those skilled in the art about the scope of the invention”

(More difficult standard to satisfy)

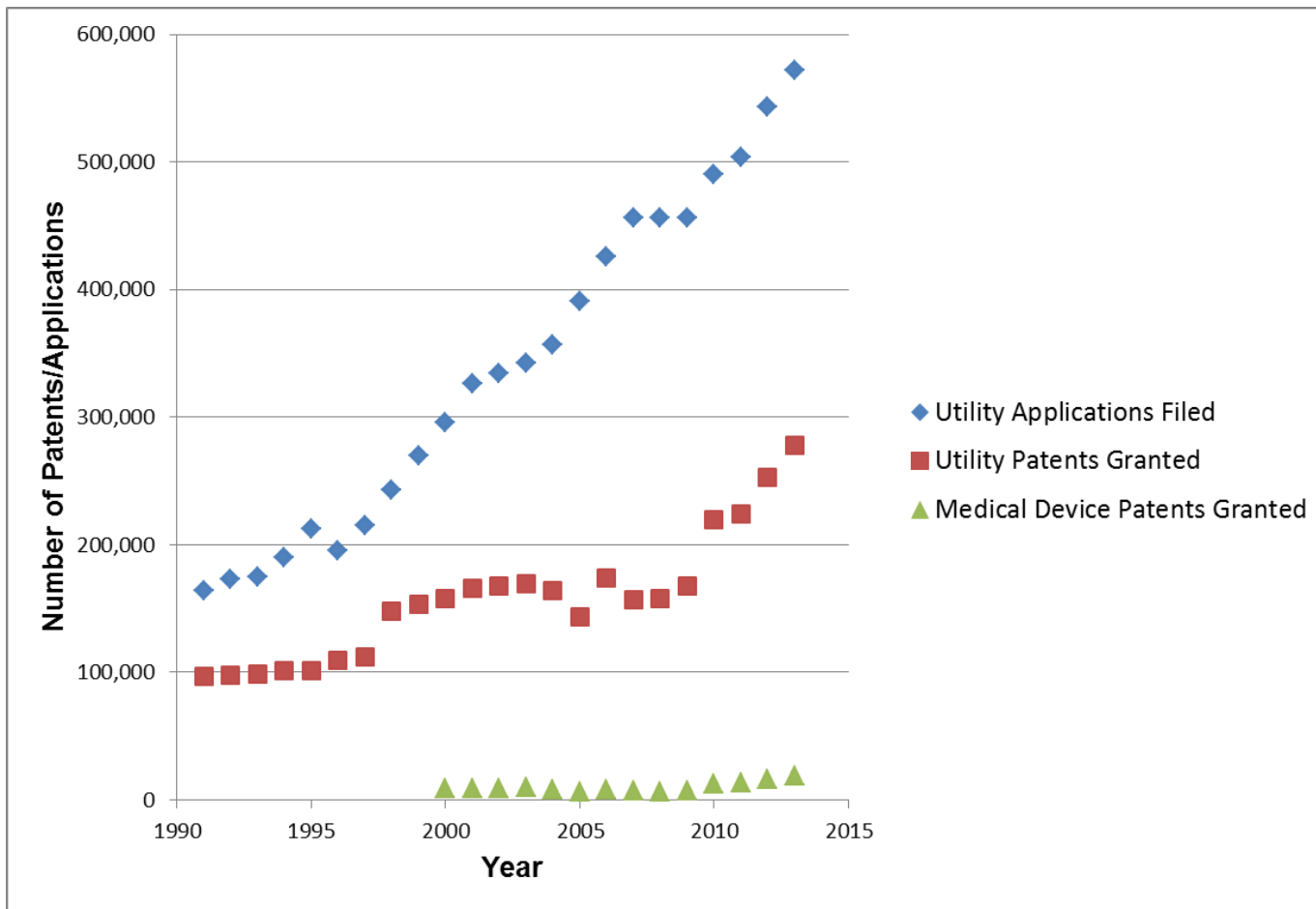
Facts from Supreme Court Case:

- Patent claim referred to two electrodes that are “mounted...in space relationship with each other.”
- This language was held invalid as not sufficiently specific.

Curtis Huffmire

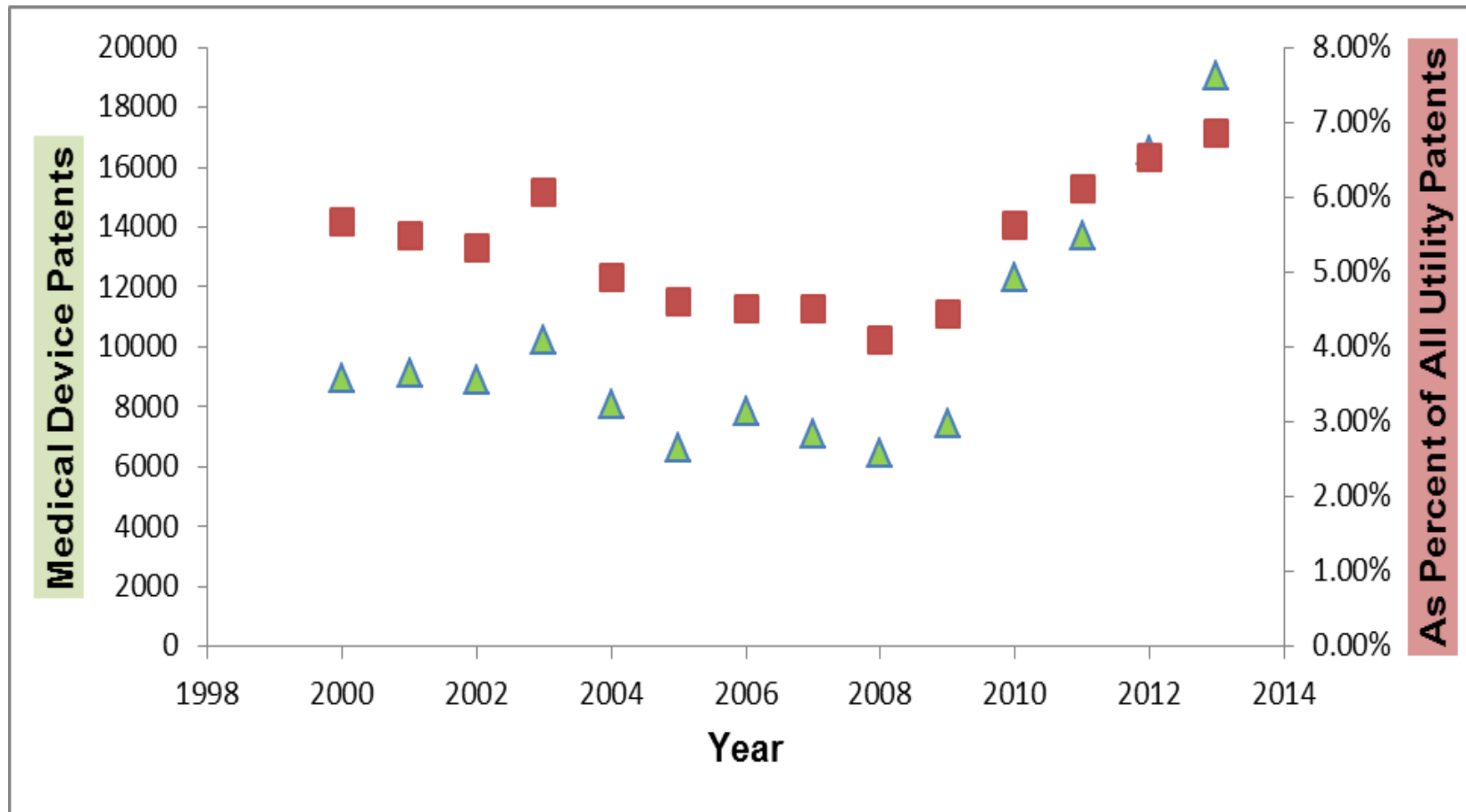
MEDICAL DEVICE PATENT STATISTICS AND CASES

Applications Filed and Patents Granted Per Year



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

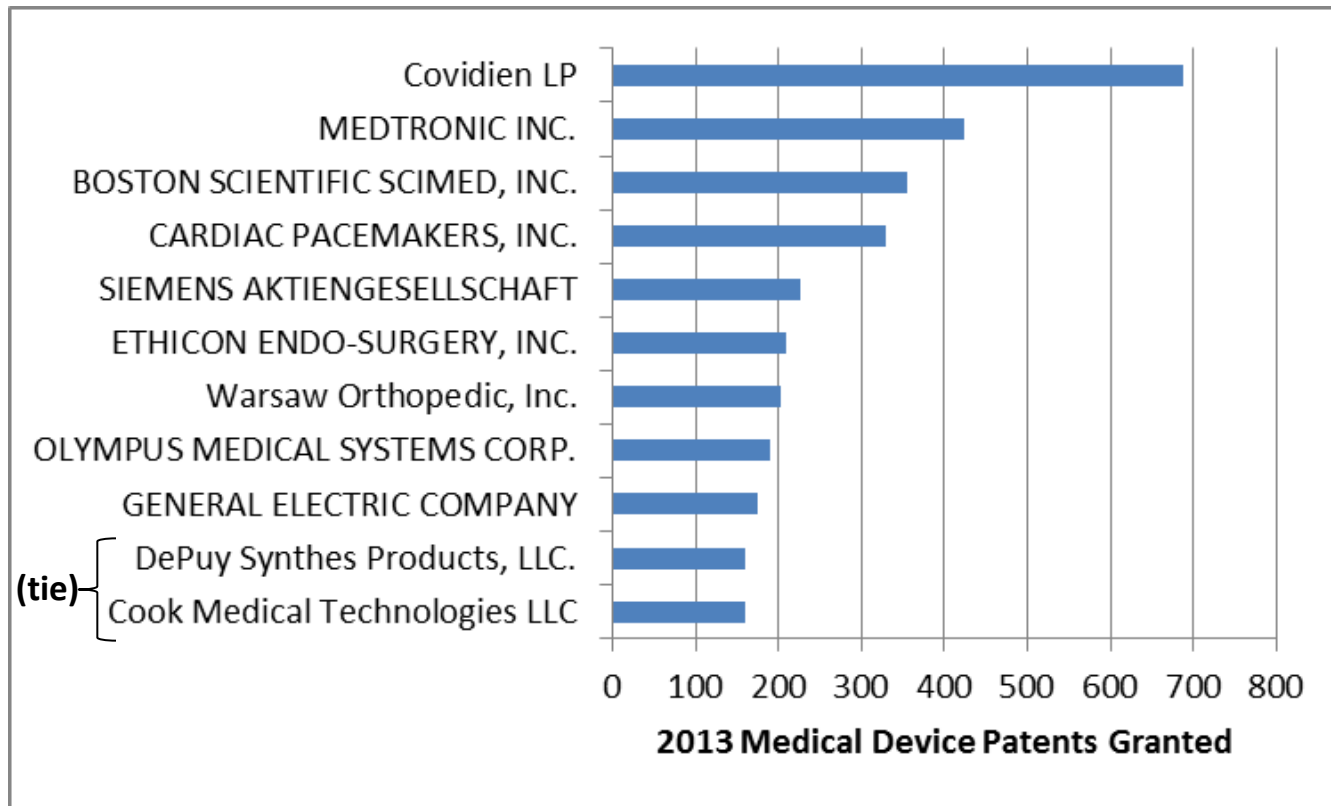
Medical Device Patents Granted



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

2013 Medical Device Patent Owners

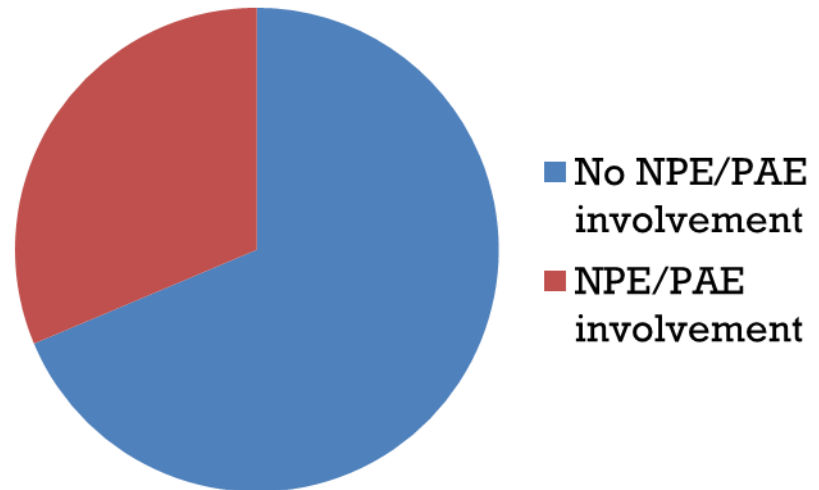
TOP TEN



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

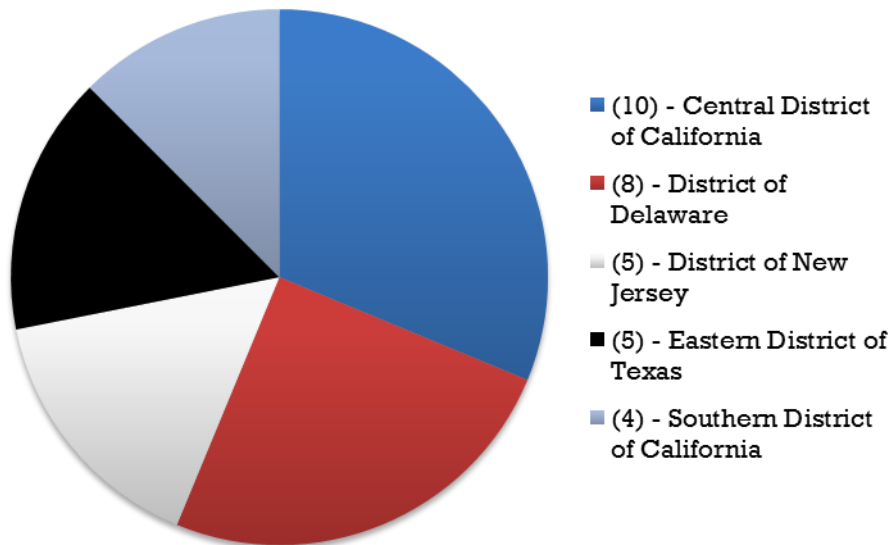
Medical Device Litigation Overview

- 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

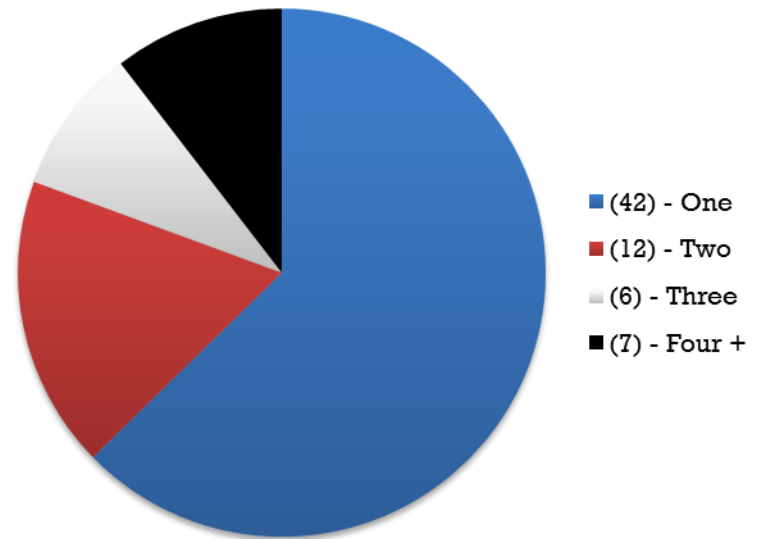


Medical Device Litigation Statistics (cont'd)

Top 5 Forums



Number of Patents Asserted

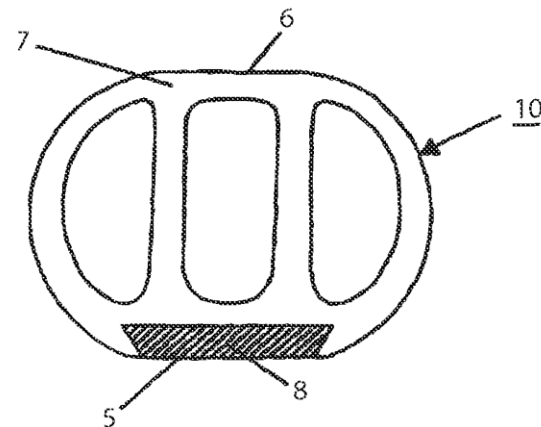
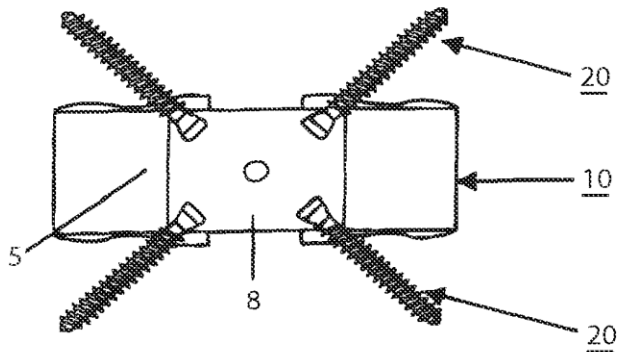


Permanent Injunction – Legal Standard

- 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’s patents valid and infringed



7,875,076 “Intervertebral Implant”

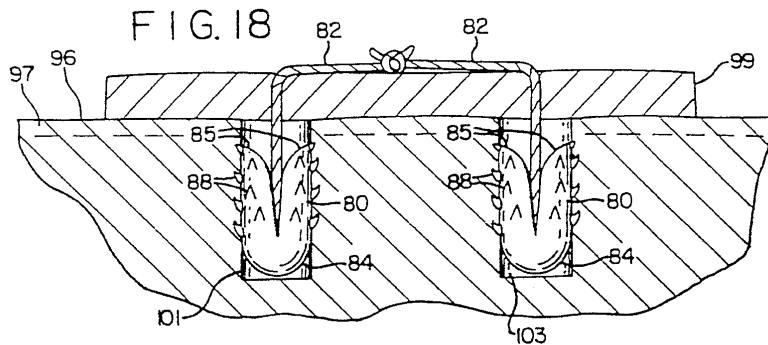
DePuy Synthes Products v. Globus

- 1) Suffered irreparable injury - NO
 - Globus offered evidence showing consumers use their (infringing) products for reasons other than the patented features
 - Lost sales alone are insufficient to prove irreparable harm
 - Also rejected argument that patented products are “door openers” to other new products
 - No basis to conclude Globus would not be able to pay the more than \$16 million reasonable royalty damages
 - Thus, Synthes will be adequately compensated
- 2) 3) and 4)
 - Court did not address Factors 2-4 because factor 1) was not met

Smith & Nephew v. Arthrex

- 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 v. Arthrex – Factors

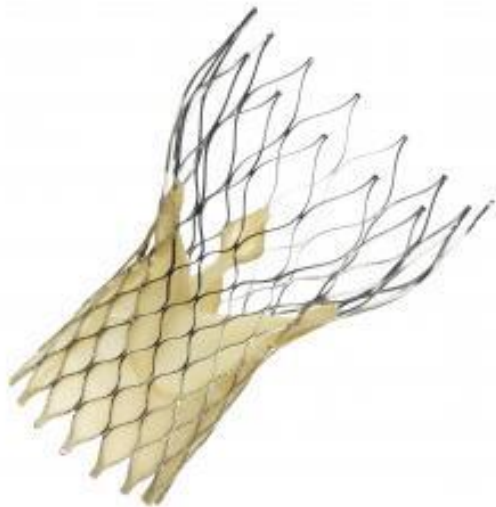
- **Irreparable Harm: Yes** – Directly compete in a portion of the market that Smith & Nephew created and that Arthrex took over through its infringement
- **Adequate Monetary Relief: No** – Difficult to quantify damages. Does not typically license.
- **Balance Hardships – SNN** – Willful infringement, Arthrex sells other products, won't go out of business
- **Public Interest – SNN** – Substantial public interest in enforcing valid patents. Acceptable alternatives on the market to meet health needs.

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

- Desire for infringing product driven by patented features?
 - DePuy: disconnect affirmatively shown by Globus
 - 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
- Patentee bears burden of proving entitlement to injunction

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
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
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 v. MDT/CoreValve - Settlement

MDT will pay EW:

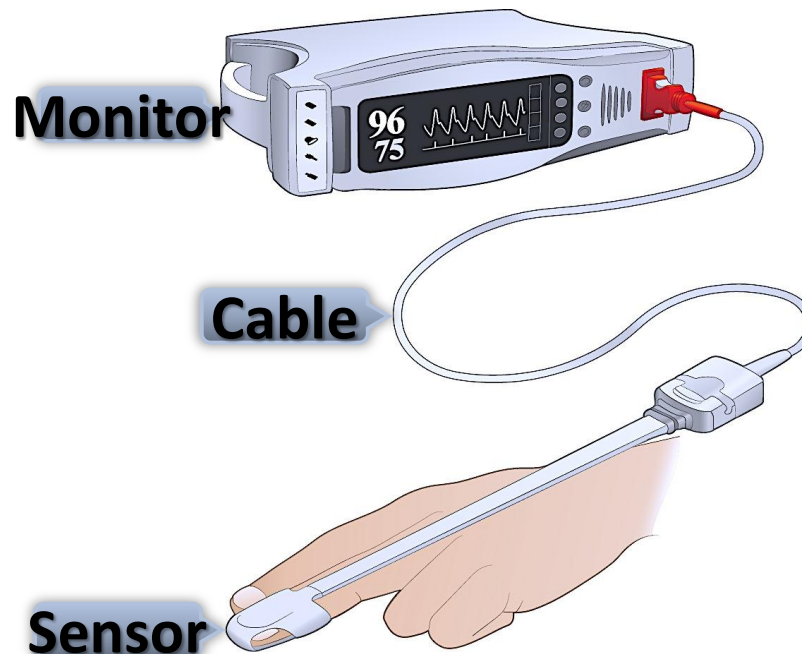
- A one-time payment of \$750 million
- Royalties through April 2022, not less than \$40 million annually

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 (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



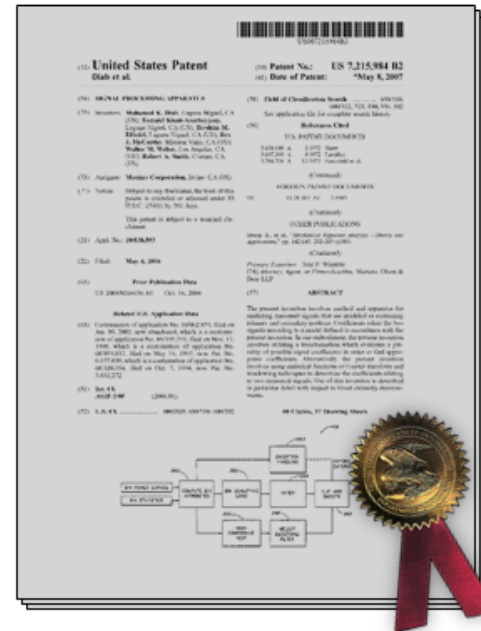
Masimo v. Philips (Del.) – Trial

- 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.) – Verdict

- Jury found Masimo's patents valid and awarded damages

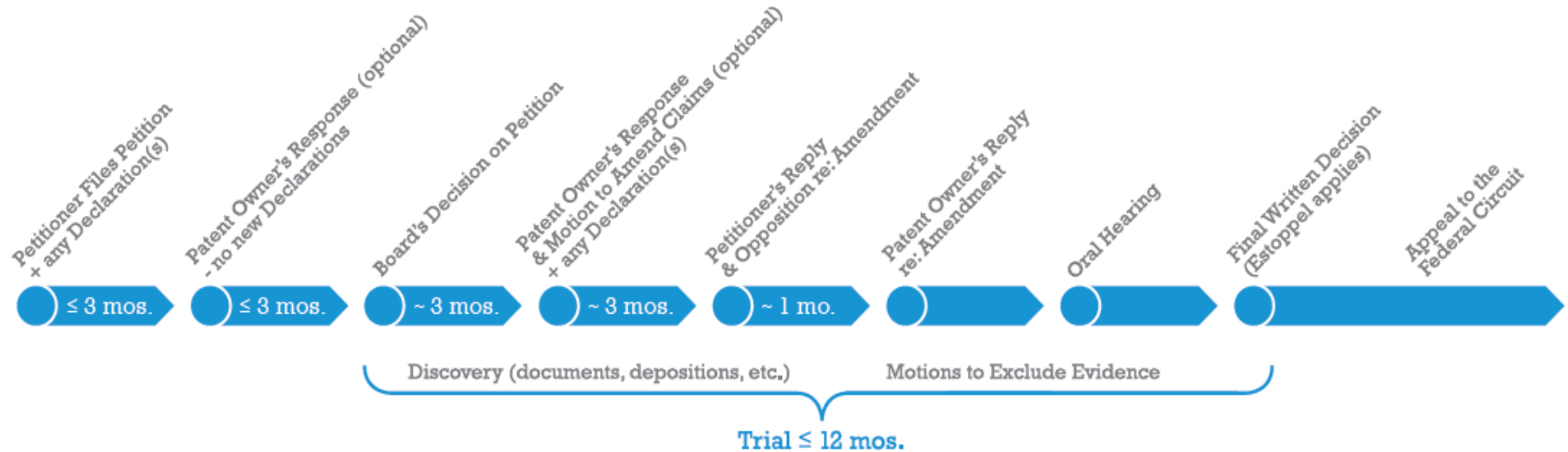
7. What is the total amount of damages to which Masimo is entitled as compensation for Philips' infringement of the '222 Patent and/or the '984 Patent?

\$ 466,774,783.00

Brent Babcock

USPTO POST-GRANT PROCEEDINGS: LESSONS LEARNED AFTER 2 YEARS

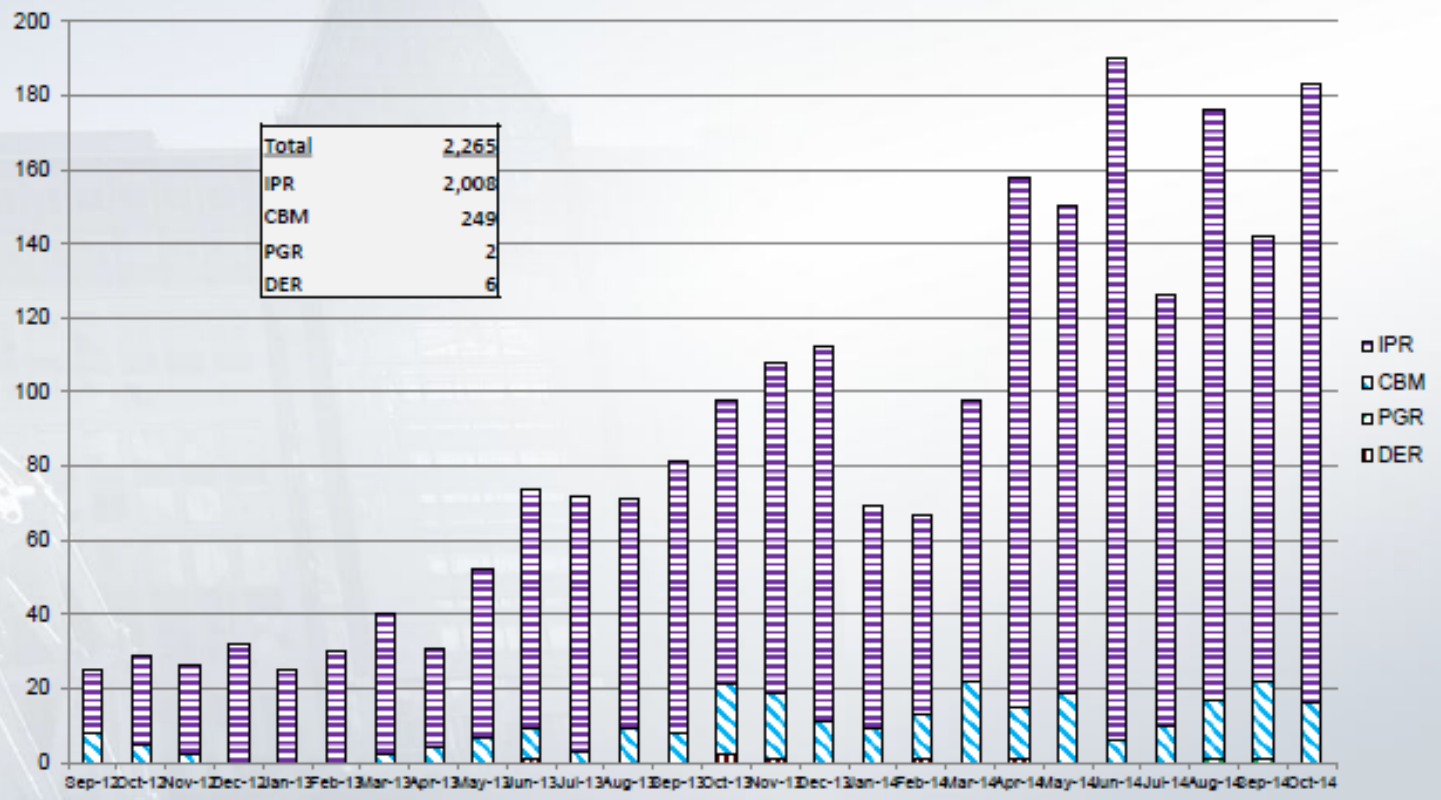
IPR Timeline





AIA Progress (as of October 30, 2014)

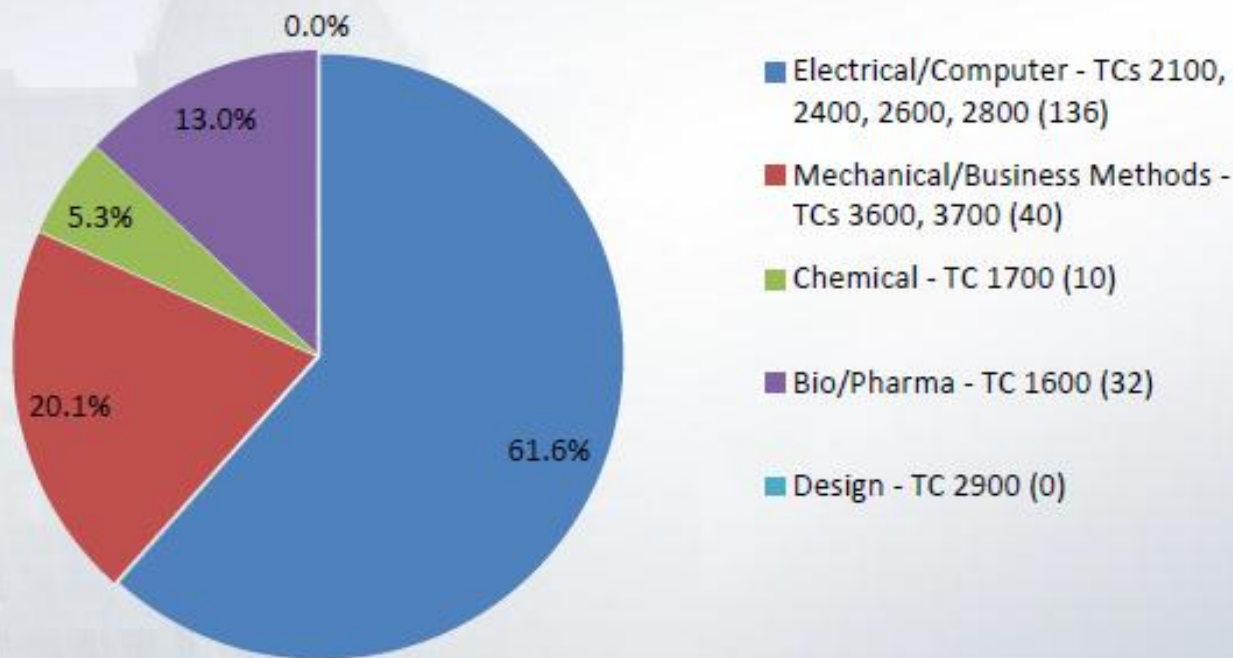
• AIA Monthly Filings



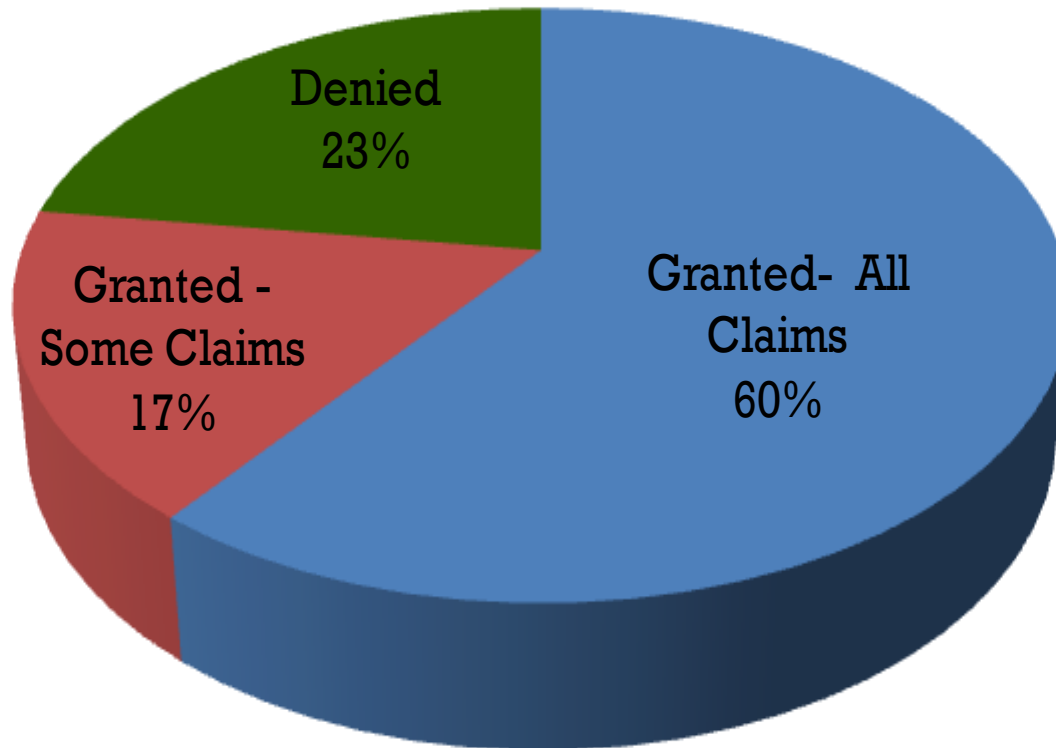


AIA Progress (for FY15 through October 30, 2014)

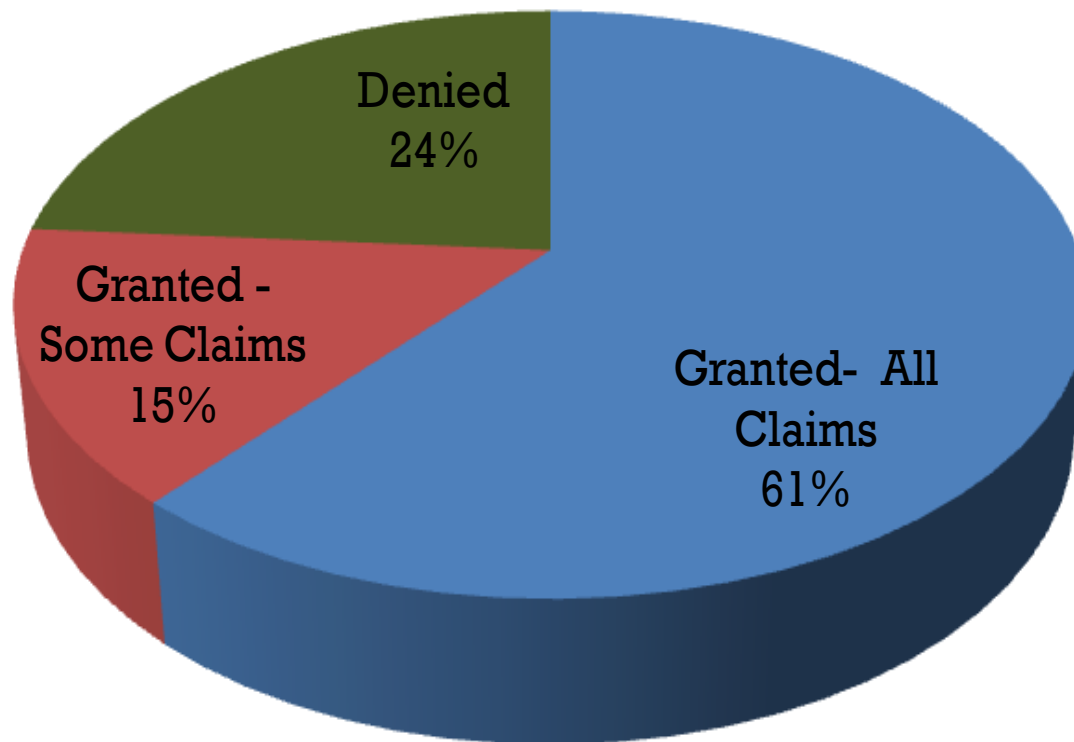
• AIA Petition Technology Breakdown



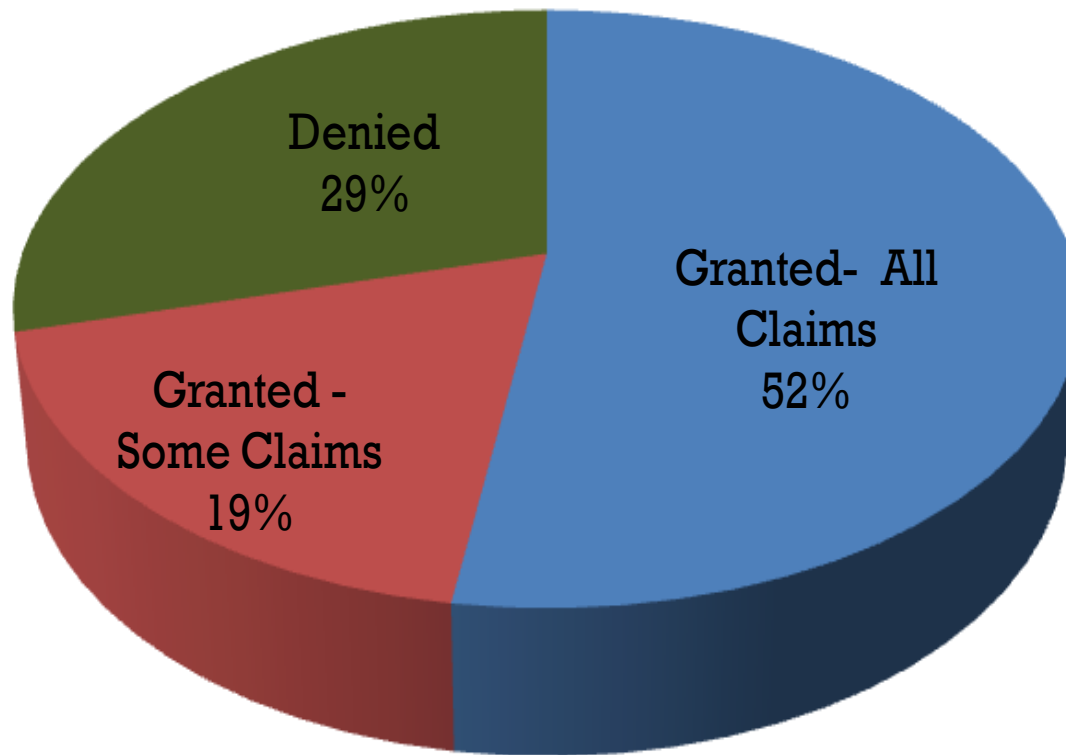
Trials Institutions Overall



Trial Institutions for Sep. & Oct. 2014



Trial Institutions for Sep. & Oct. 2014 (excluding 38 Zond decisions)



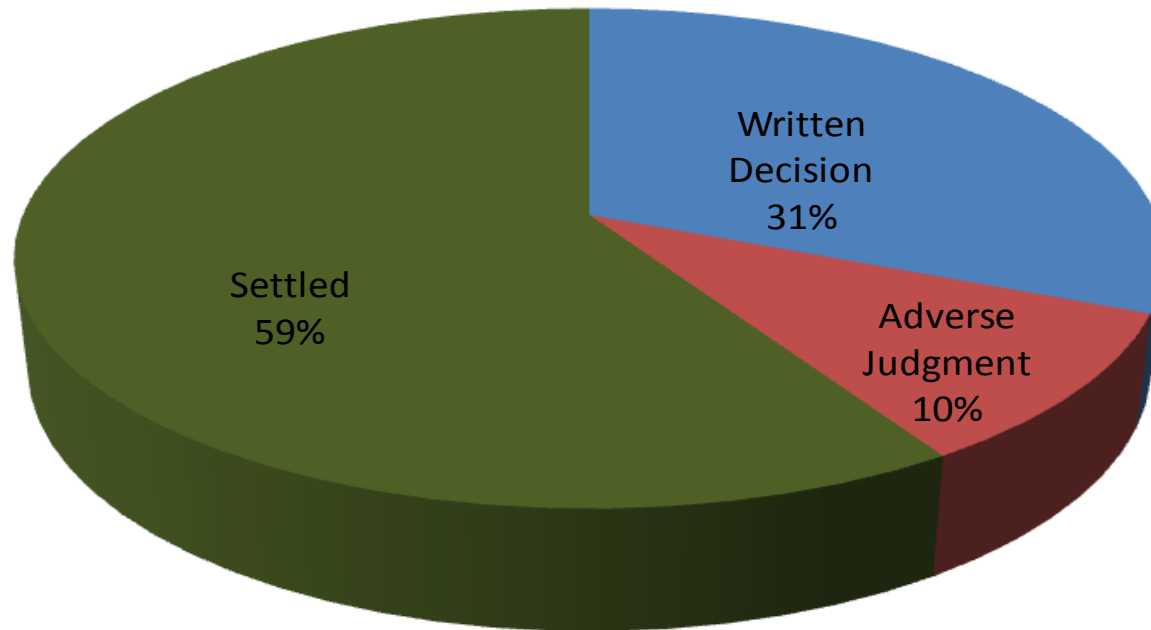
Rationales for Denial of Petition

- Missing element
- Insufficient showing of inherency
- No reason to combine
- No expert declaration or insufficient reasoning in expert declaration
- Failure to establish reference as prior art
- Publication not established
- § 102(e) basis not sufficiently supported

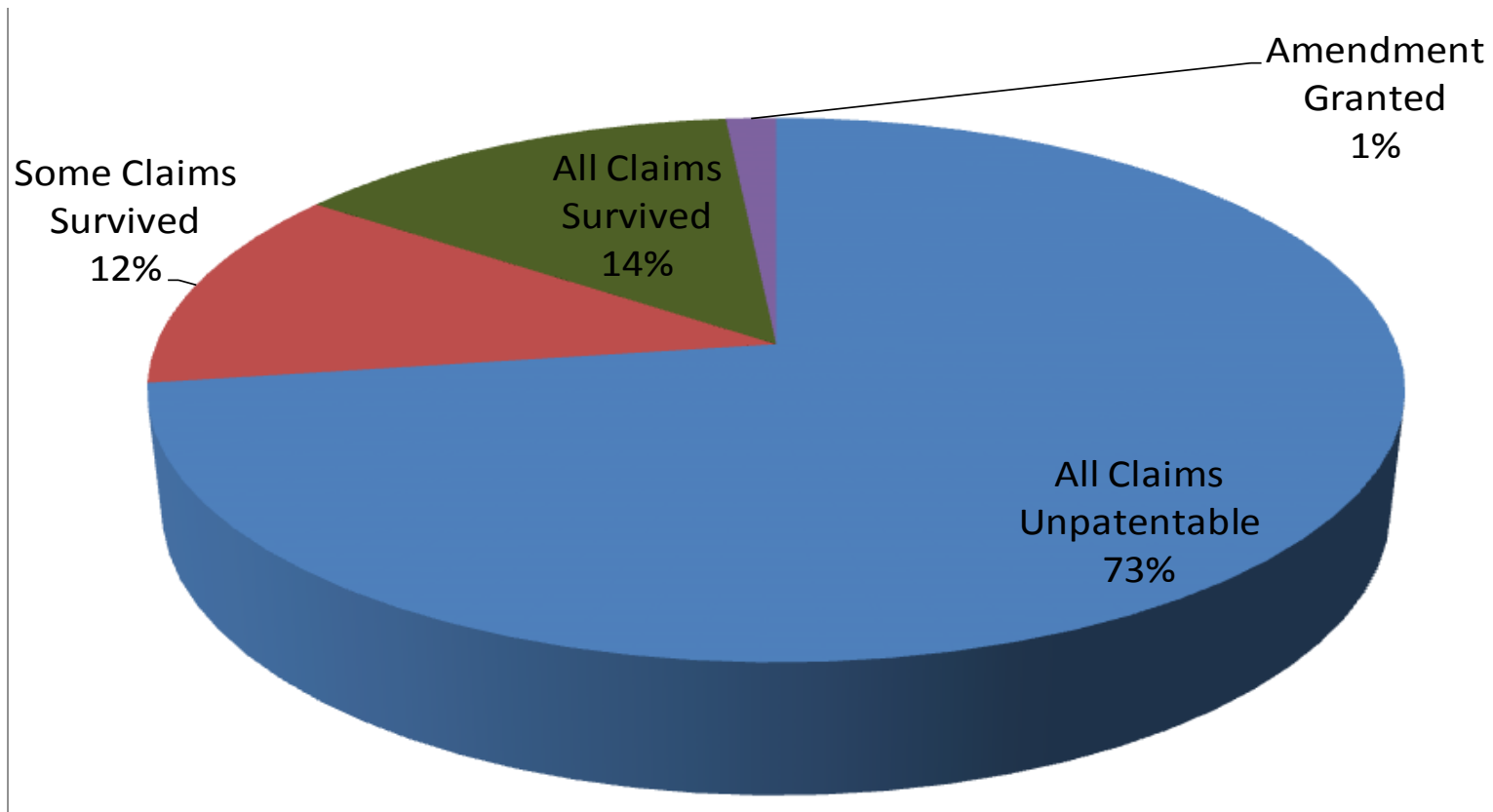
Rationales for Denial of Petition

- Procedural
 - Statutory 1-year bar from service of Complaint
 - Filed Declaratory Judgment (DJ) action first
 - Real Party-in-Interest (RPI) not identified
 - No joinder
 - Redundancy
 - § 325(d) (previously presented)
 - Discretionary
 - PTAB's invocation is on the rise

“Disposals”



Final Written Decisions



Rationales for Claims Surviving Final Decision

- Reasons provided:
 - Missing element
 - Petition argued inherency
 - No reason to combine
 - Battle of the experts
 - Reference successfully antedated
- Motion to Amend
 - Only one motion granted, and that was an unopposed Motion to Amend

Considerations for Multi-Forum Proceedings

- IPR and litigation proceeding simultaneously
 - Most IPRs/CBMs prompted by litigation
 - Stays are common, but by no means certain
- Multiple IPRs
 - Attack different claims of same patent
 - Propose different unpatentability grounds
- IPR and continuations/reissues/ex parte reexams
 - Common strategies to seek new claims

IPRs and Concurrent Litigation: Issues to Consider

- **Protective Order**
 - USPTO default Protective Order
 - Can be modified by stipulation with supporting rationale
- **Prosecution Bar**
 - Limited to participation with Motion to Amend?
 - Covers all USPTO activity?
- **Confidential Information**
 - Will be disclosed if PTAB deems necessary

IPRs and Concurrent Litigation: Issues to Consider

- Coordination with Litigation Counsel
- Coordination with Prosecution Counsel
- Discovery
 - Very limited in PTAB
- Claim Construction
 - Broadest Reasonable Interpretation (BRI) v. *Phillips*
- Expert Choice/Preparation
 - Technical background
 - Litigation experience

Thank you!

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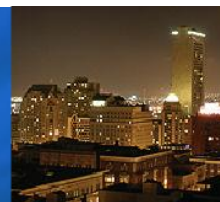
Orange County



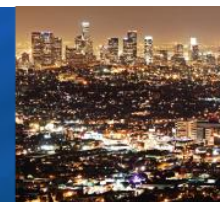
San Diego



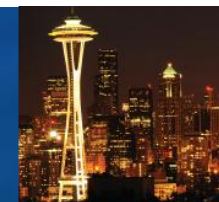
San Francisco



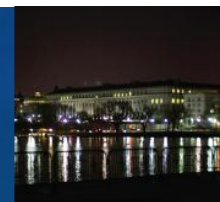
Silicon Valley



Los Angeles



Seattle



Washington
DC