

Knobbe Martens

Orthopedic IP Litigation Webinar

Presented by Knobbe Martens

August 26, 2021

Webinar Topics

1. ConforMIS suits and status
2. “Claim Construction” Limits Patent Scope
3. Small Company Derives Licensing Revenue
4. Trade Secret Issues Arise at Industry Meetings
5. Doctor Inventors File Patents and Sometimes Get Aggressive
6. IP Disputes Outside the United States – Destruction of Goods as a Remedy?
7. Countersuit Strategy – Poking the Bear

Presenters on ConforMIS



Sabing Lee
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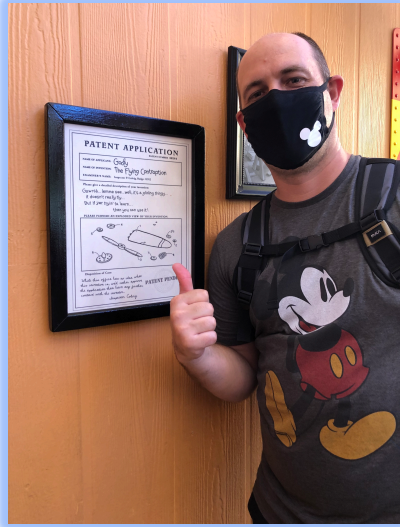
*Introduction to ConforMIS
claims types*



Christy Lea
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*ConforMIS litigation
efforts and updates*

Presenters on Recent Cases



Michael Christensen
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*OUS patent litigation
Doctor inventors
Are preliminary injunctions still possible?*



Jessica Achtsam
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Deriving licensing revenue



Kregg Koch
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Claims are not always as they appear to be



Andrew Douglas
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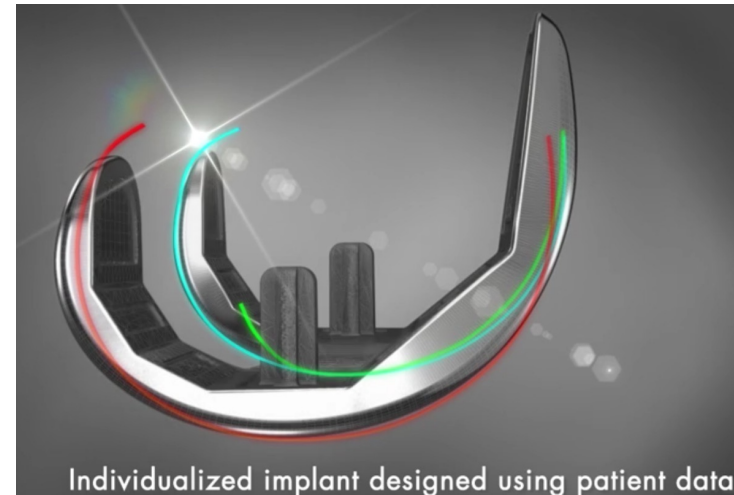
Trade secret dispute prompting patent infringement suit?



v.



- Designs and manufactures patient-specific implants and instruments for knees and hips
- Over 200 patents granted worldwide
- Earliest patents filed in 2001, will begin to expire in 2022
- Patents asserted 2013-2021 and challenged via reexamination and inter partes review



First
provisional
group filed
May 2001-
May 2003

Second
provisional
group filed
Feb. 2006 -
Sept. 2007

First non-provisional filed May 2002
Multiple continuations and CIPs
Over 100 US patents
~27 EP patents
Expires ~2022 or ~2027 and later

Many more provisionals filed through 2014,
with patents expiring up until ~2035

“In any of the embodiments and aspects described herein, the joint can be a knee, shoulder, hip, vertebrae, elbow, ankle, etc.”

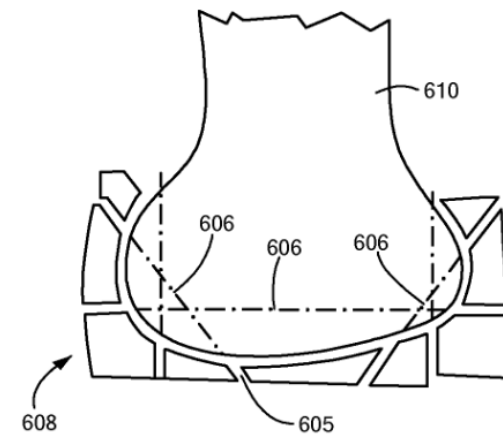


FIG. 65C

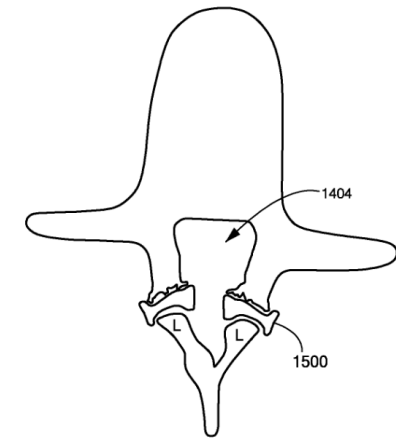
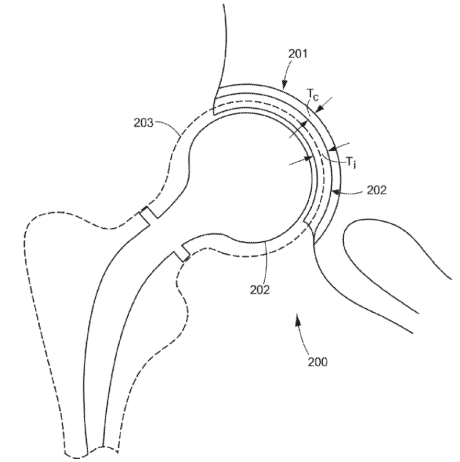


FIG. 15

Surgical Instrument Claim

1. A **surgical instrument** for the repair of a diseased articular joint surface of a joint, comprising:
 - an inner surface having a curvature or shape based on information from image data of the diseased articular joint surface; and
 - a slit defining a cutting path through at least a portion of the joint when the inner surface is applied to the diseased articular joint surface.

U.S. Patent No. 9,055,953

Priority date: May 25, 2001
Expiration date: March 24, 2023

Claims held unpatentable in IPR

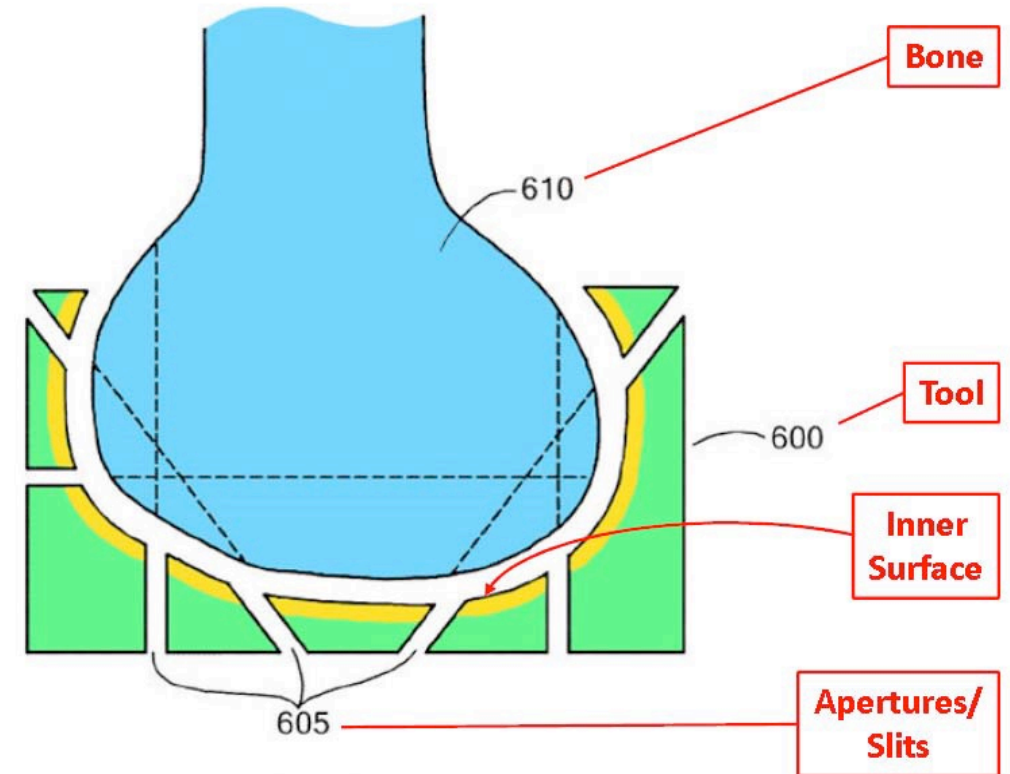


FIG. 15

System Claim with Generic Implant

1. A joint arthroplasty system for repairing a diseased or damaged joint of a patient comprising:

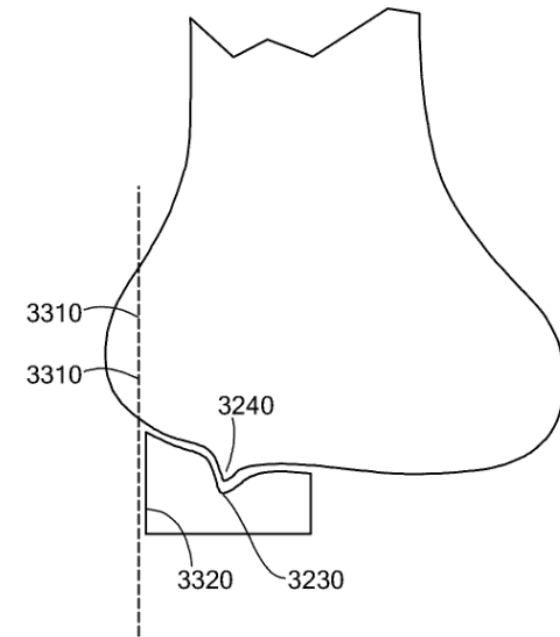
an implant; and

a patient-specific surgical instrument ...comprising:

a patient-specific surface for engaging a corresponding portion of the diseased or damaged joint, ... wherein the corresponding portion of the diseased or damaged joint includes an osteophyte, **wherein the patient-specific surface references the osteophyte** when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint; and

a guide sized and shaped to accommodate a surgical tool, wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool.

U.S. Patent No. 9,295,482



Priority date: May 25, 2001
Expiration date: December 12, 2024

Patent avoided IPR and reexamination

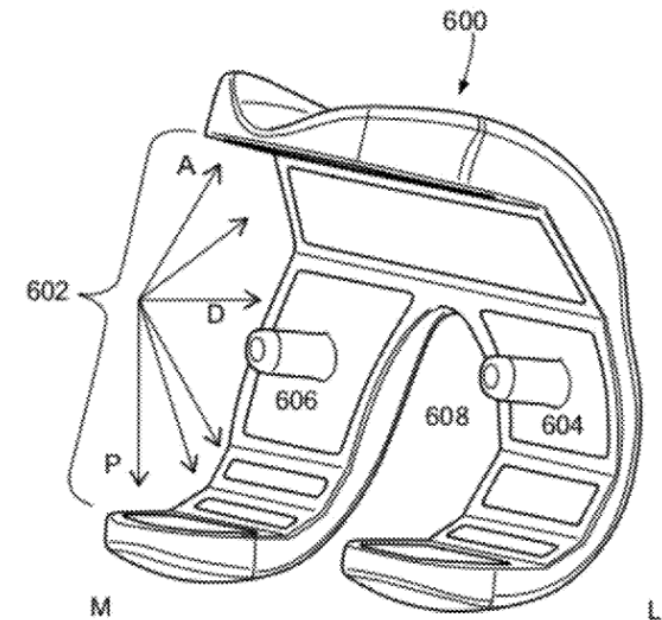
Patient-Specific *Implant* Claim

1. An implant for correcting an articular surface wear pattern of a joint of a patient, comprising

an implant body having a characteristic topography, an interior surface, and an outer surface,

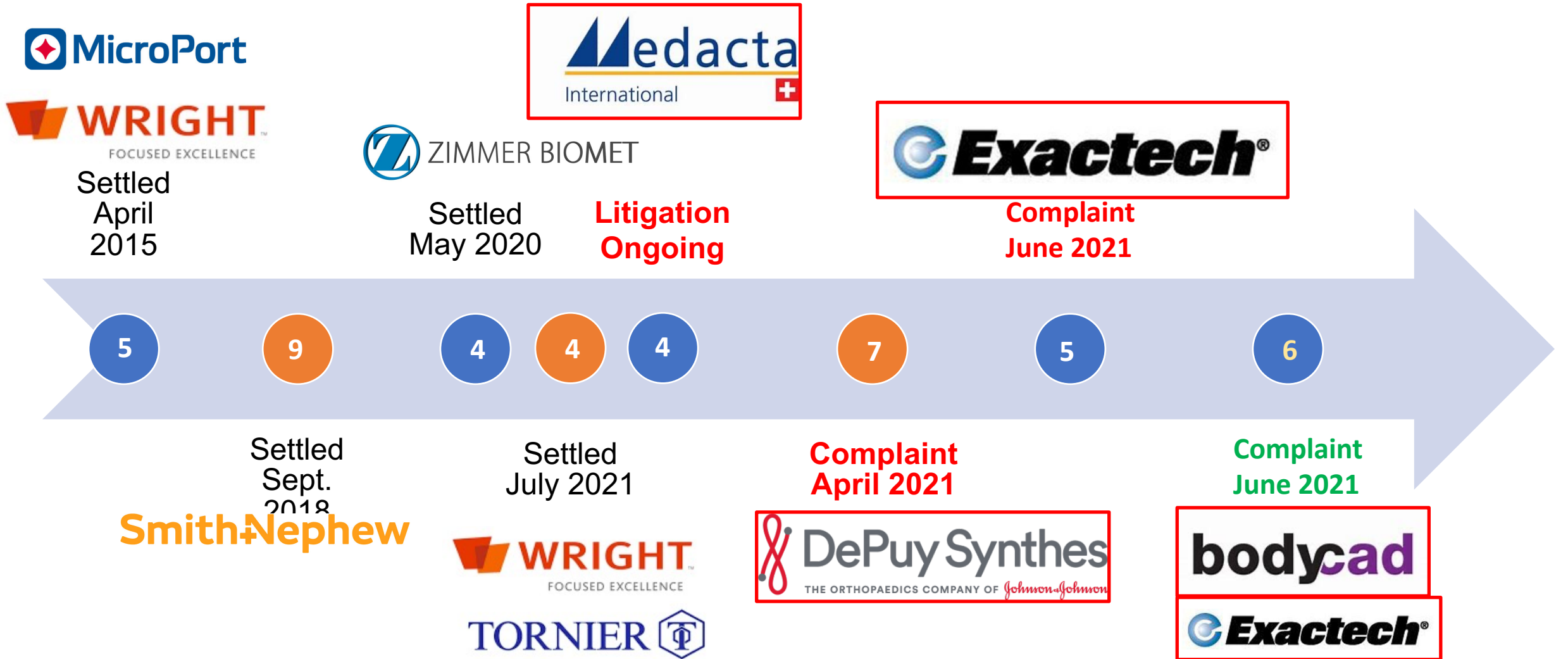
where the characteristic topography is derived from a wear pattern of the articular surface and is ***configured to alter the wear pattern*** of the articular surface to a revised wear pattern.

U.S. Patent No. 9,180,015



Priority date: March 5, 2008
Expiration date: **March 5, 2029**

Conformis Monetization of Patents



Wright - \$5.5M
S&N - \$10.5M
Zimmer - \$9.6M
Wright (Stryker) - \$15M
Total = \$40.6M
(and counting)

CONFORMIS

v.



smith&nephew

- 3 patents included “implant” limitation \$
- **S&N filed 16 IPRs on 9 patents**
- Challenged broadest patent first
- Litigation stayed pending IPR
- PTAB held key patents unpatentable
- Settled September 2018 (after 2.5 years)



Smith & Nephew Challenged Broadest Claim First

1. A surgical instrument for the repair of a diseased articular joint surface of a joint, comprising:

an **inner surface** having a curvature or shape based on information from image data of the diseased **articular joint surface**; and

a **slit defining a cutting path** through at least a portion of the joint when the inner surface is applied to the diseased articular joint surface.

U.S. Patent No. 9,055,953

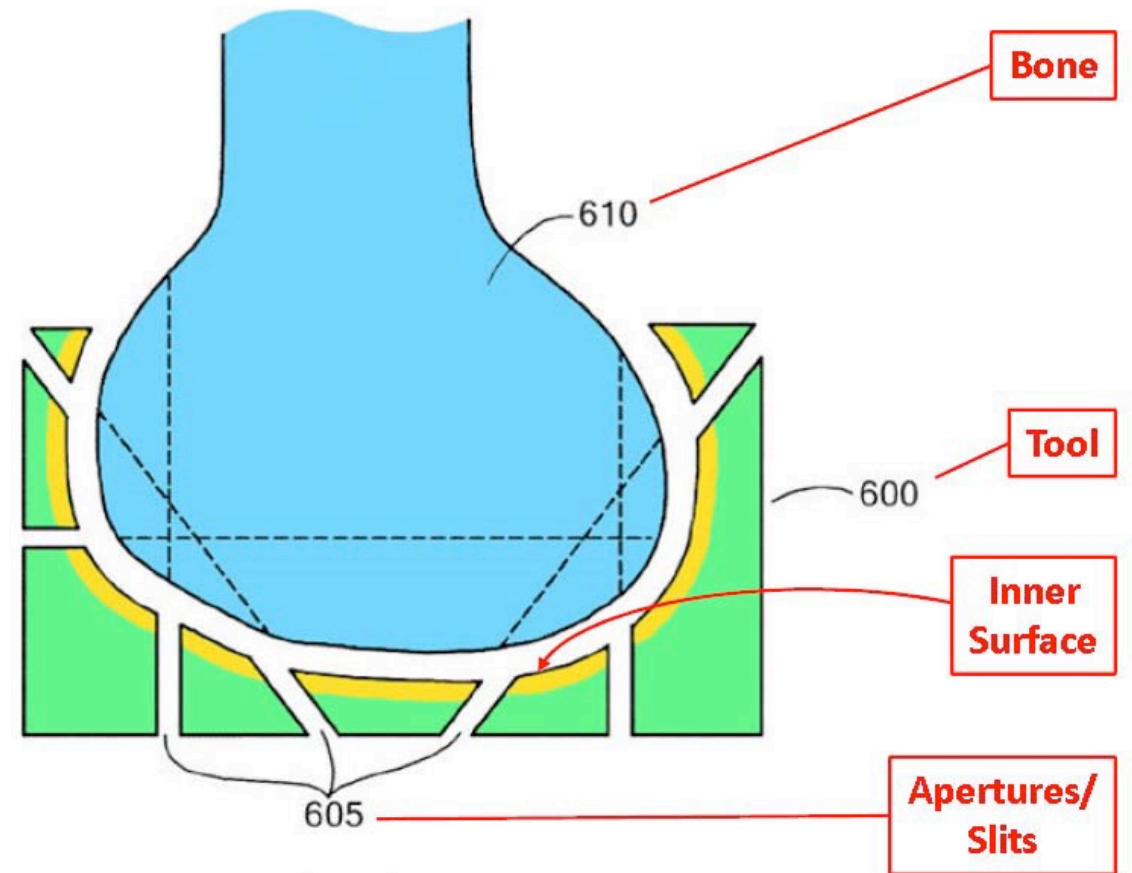
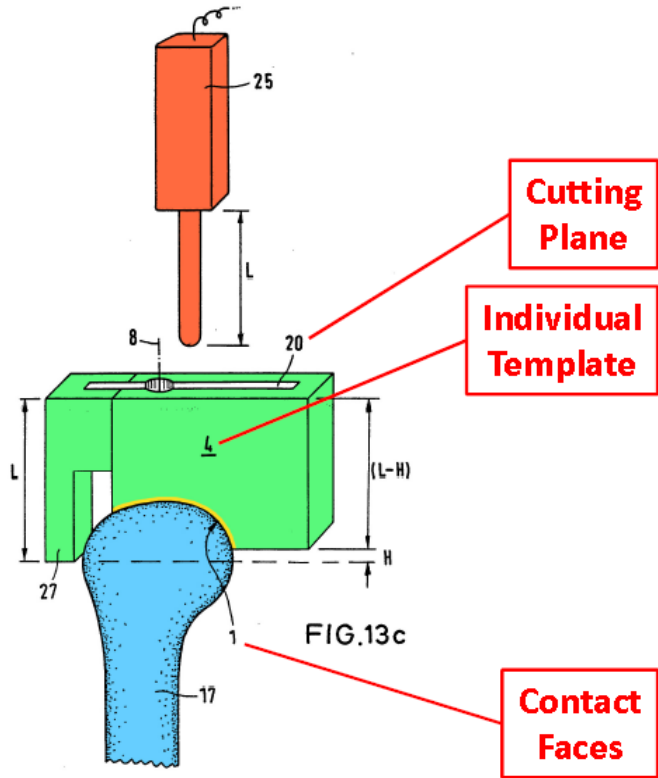
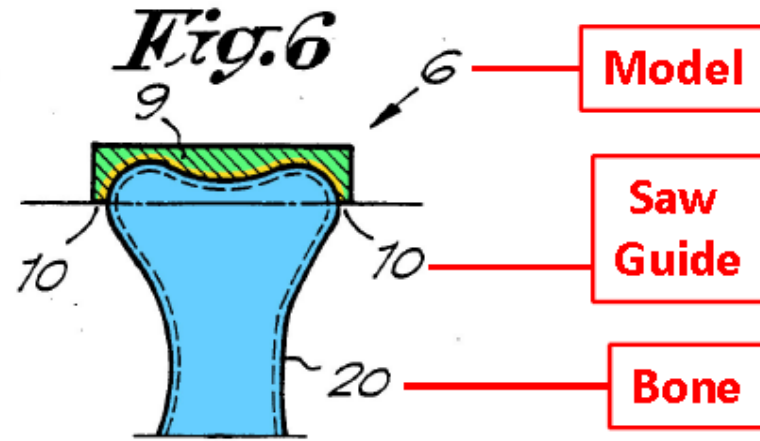


FIG. 15

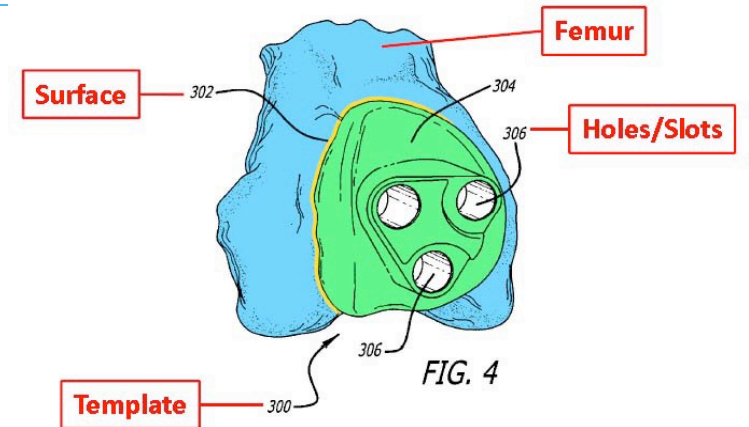
Numerous Prior Art References



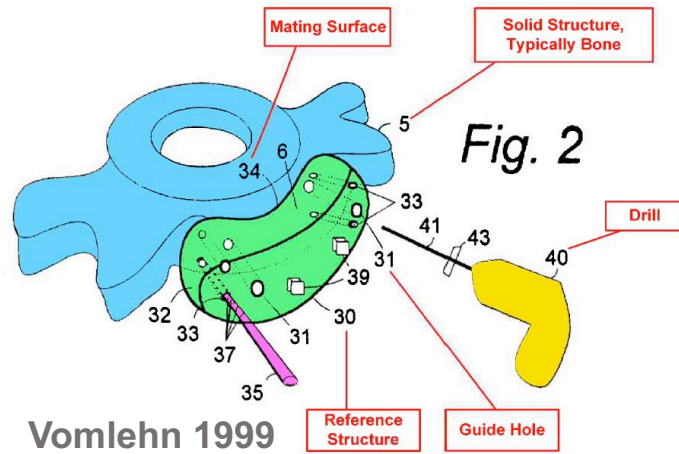
Radermacher 1993



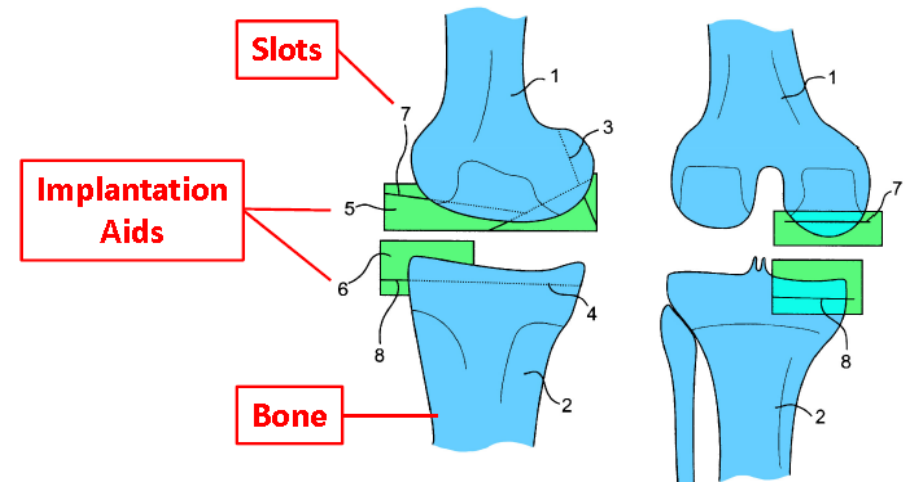
Swaelens 1995



Carignan 2000



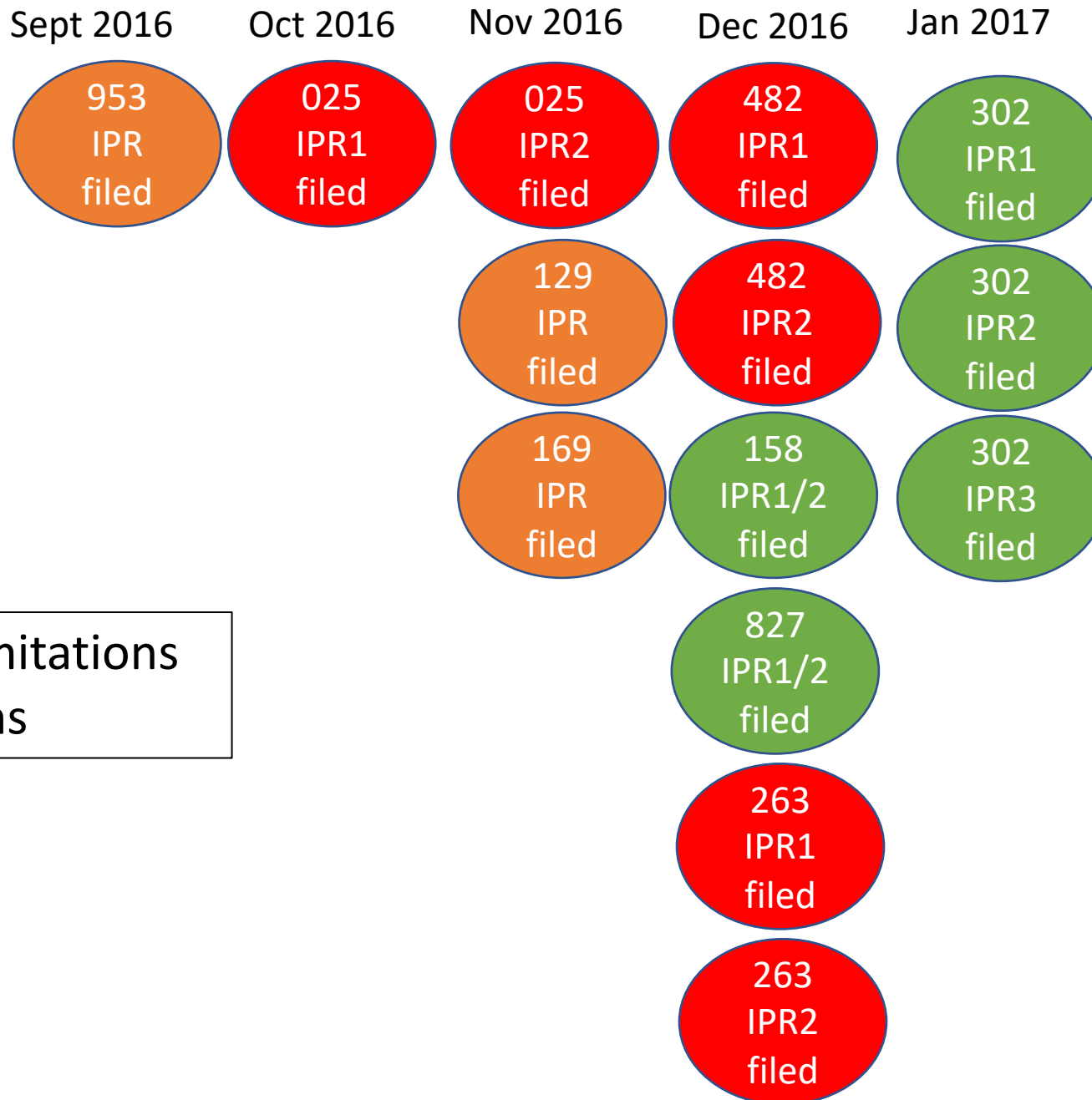
Vomlehn 1999



Schuster 2000

FIG. 2

A Very Busy Five Months

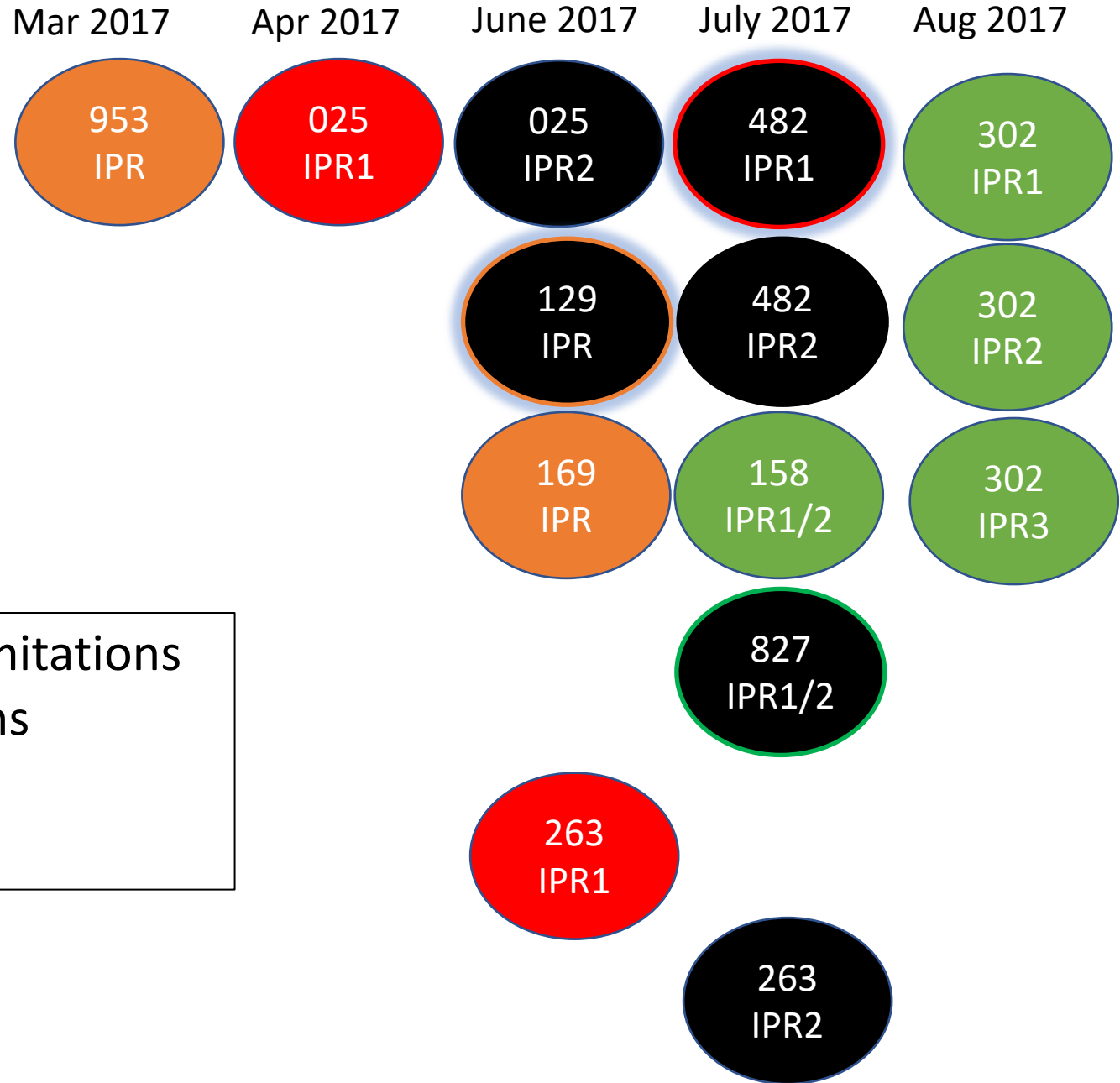


Red – Patents with implant limitations
Green – High number of claims

Win Some, Lose Some

Six months later

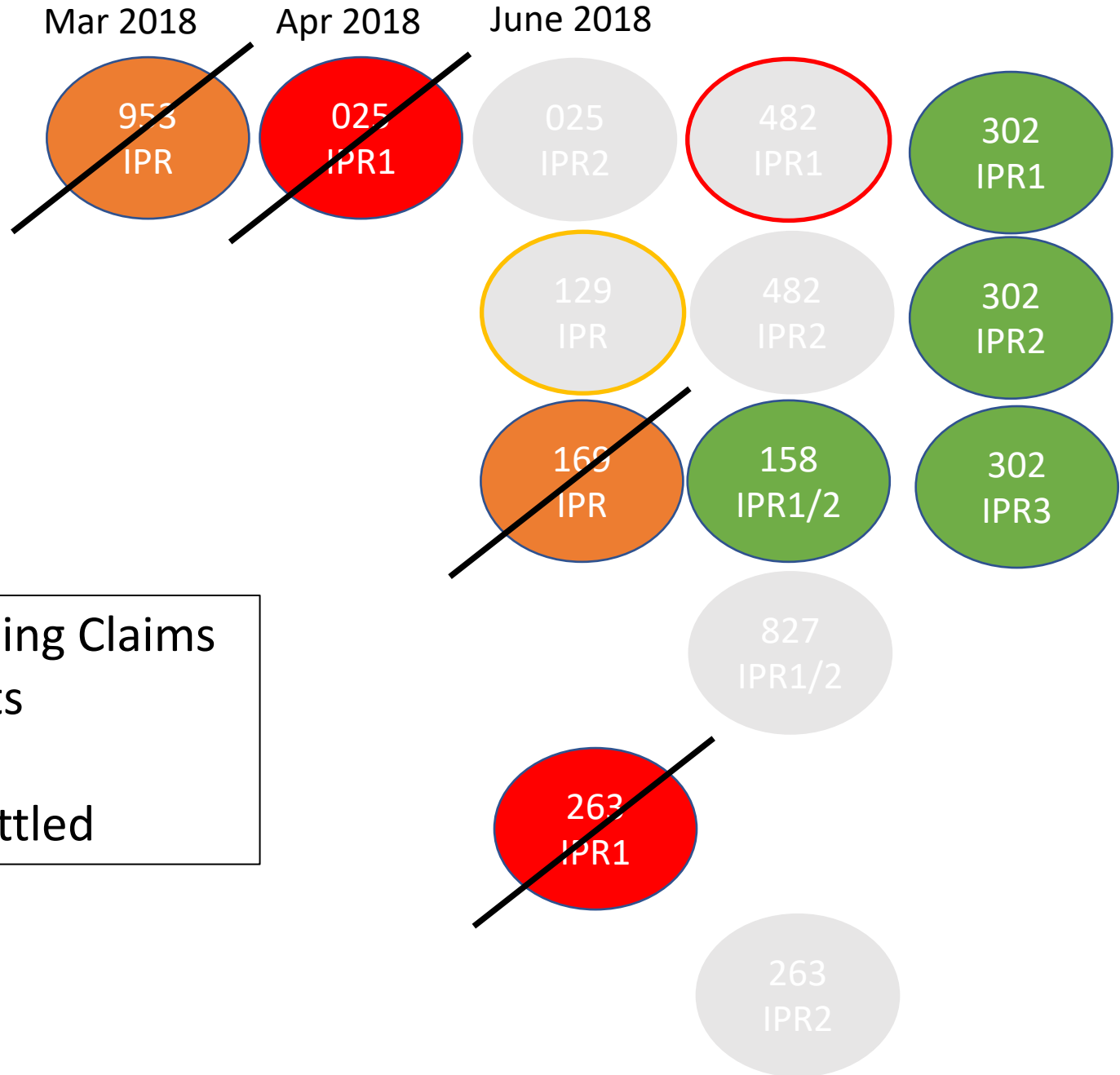
Red – Patents with implant limitations
Green – High number of claims
Black – denied institution



Big Win

One year later...

Final Written Decisions Holding Claims Unpatentable in Four Patents
September 2018: Parties settled

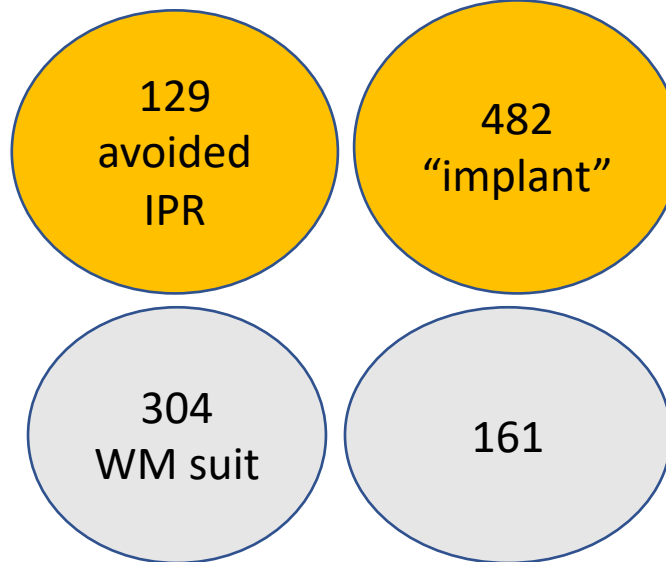




v.



- Complaint filed August 2019 in District of Delaware
- 4 patents
- patient specific instruments for knee, shoulder, and hip surgery
- Trial February 28, 2022

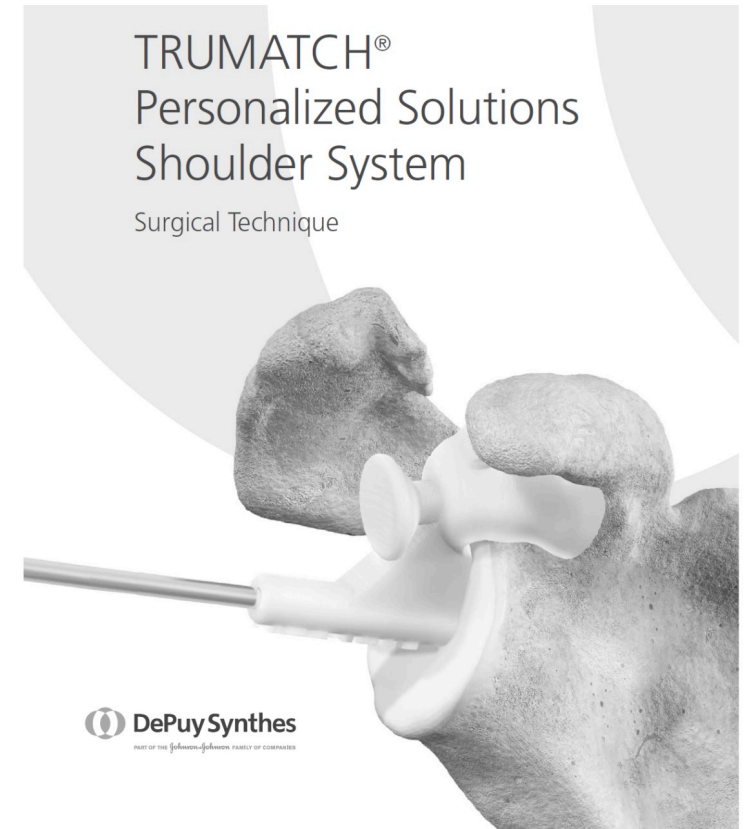
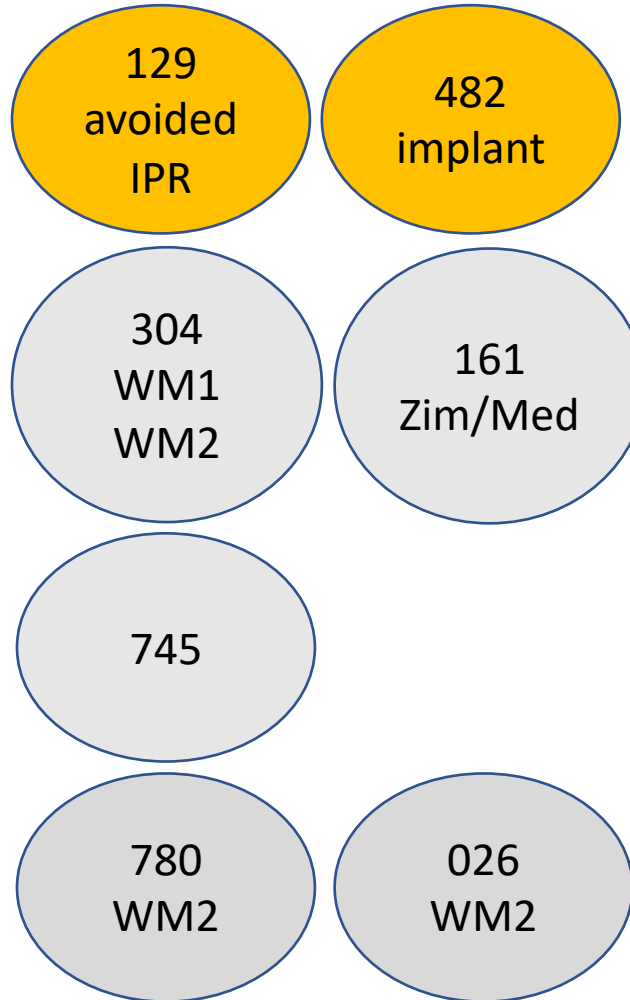




v.



- Complaint filed April 2021 in District of Delaware
- 7 patents
- patient specific instruments for knee and shoulder surgery
- Third extension on Answer (due Sept. 24, 2021)

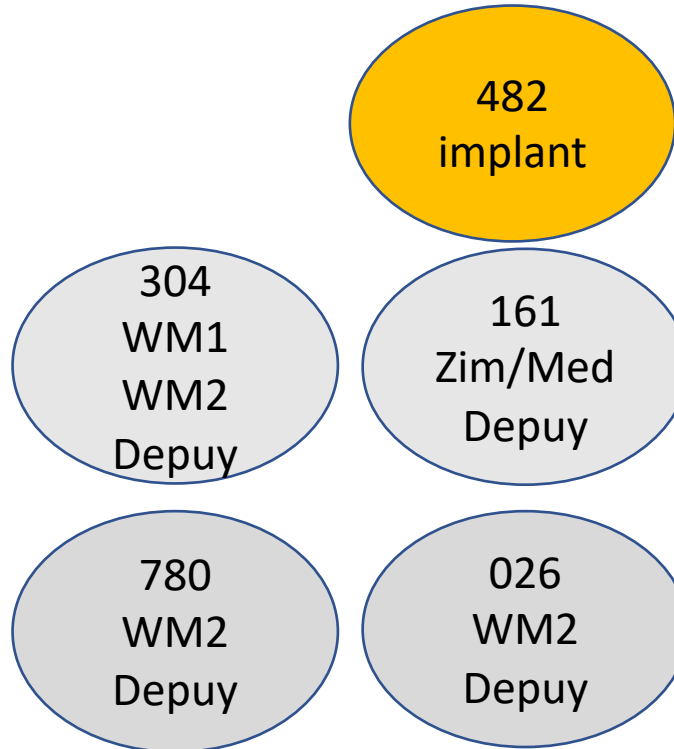




v.



- Complaint filed June 3, 2021 in Middle District of Florida
- 5 patents
- patient specific instruments for ankle surgery
- Stipulated trial date April 2023

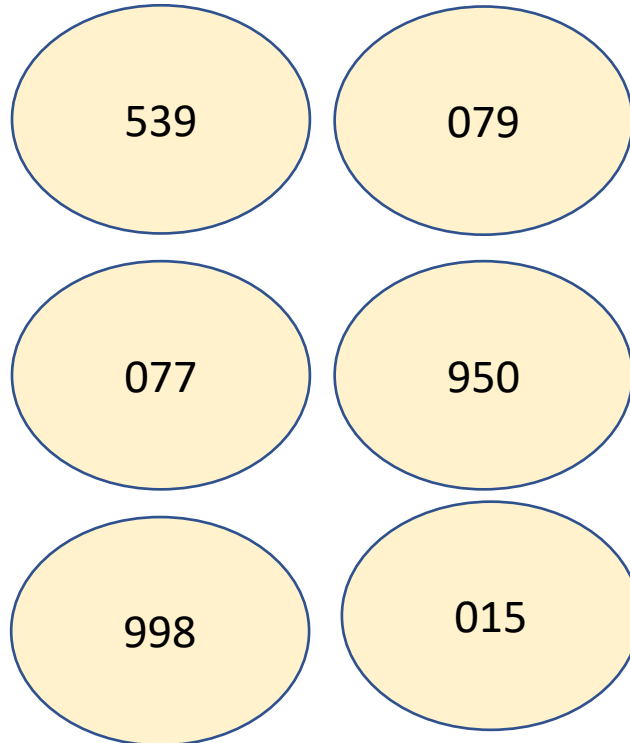




v.



- Complaint filed June 3, 2021 in Middle District of Florida
- 5 patents
- patient specific **implants** for knee surgery
- Also asserted against Fine Osteotomy Accused System



Our implants are tailored especially for you

Other Recent IP Disputes in Orthopedics

- Complaint filed May 2018 in the DDE, asserting U.S. Patent No. 8,177,822 (the '822 patent)
 - Patent directed to a bone plate for fixing fractures and a drill guide to facilitate drilling holes

Claim 1 of '822 patent:

A combination of a bone plate for fixing fractures of a bone having a small terminal fragment and drill guide facilitating implantation of the bone plate, comprising:

a bone plate having a first region configured for placement adjacent an outer surface of a bone and a **second region configured to wrap around a terminal endpoint of the bone**, the second region having at least **two hook shaped projections** for insertion into holes in the terminal endpoint of the bone;

...

→ **No infringement:** Arthrex Volar Hook Plates do not have **hook shaped projections substantially // to the longitudinal axis of the bone**

Arthrex can continue selling

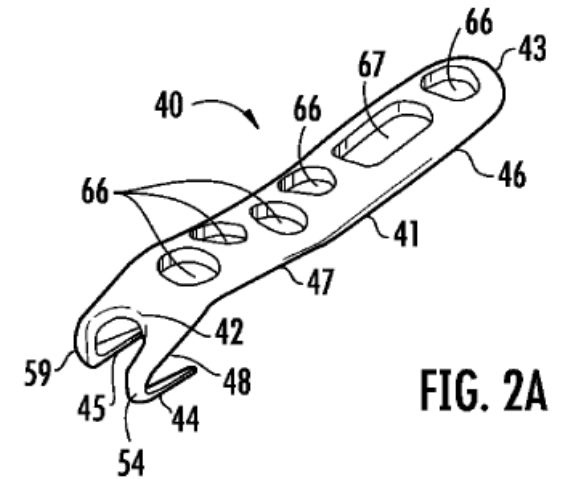


FIG. 2A



- Construction: “wrap around a terminal endpoint of the bone” requires:
 - the second region is configured to curve onto a terminal endpoint and back around such that the **hook shaped projections are substantially parallel to the longitudinal axis of the bone** at the terminal end
- Construction based on:
 - All figures and described embodiments had hook shaped projections substantially // to longitudinal axis
 - Statements characterizing the “present invention” having prongs substantially // to longitudinal axis
- Take-away points:
 - Claims can be narrowed based on language in spec. and figures
 - Include alternative designs
 - Make sure description and claims track product

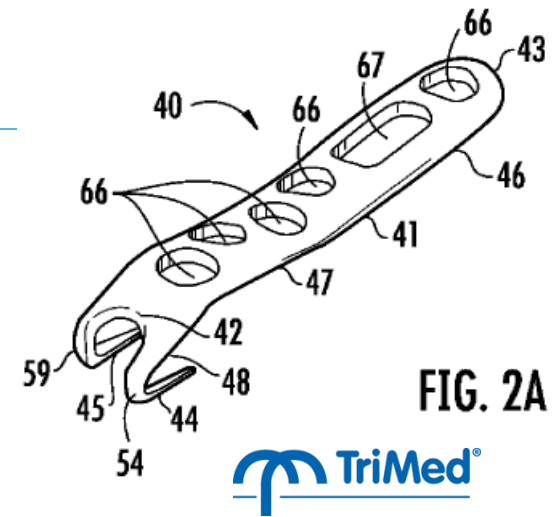


FIG. 2A

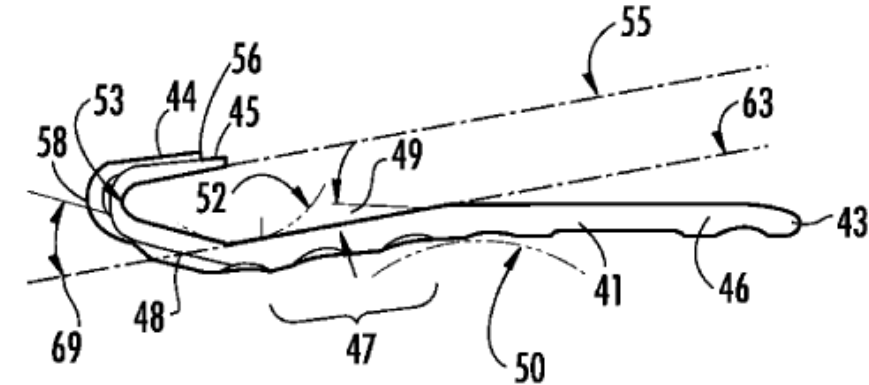
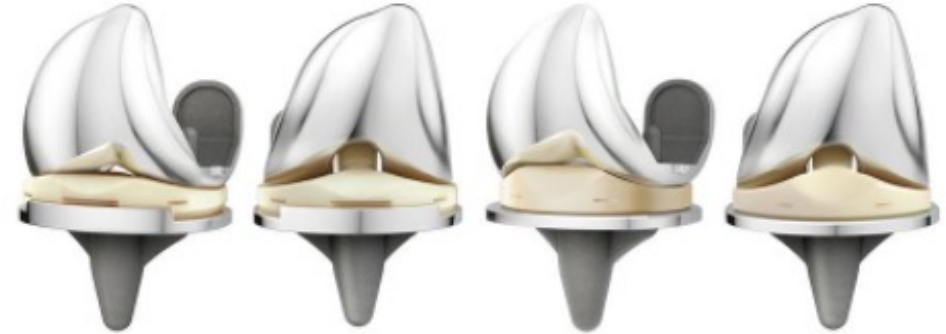


FIG. 2C



- MedIdea sued DePuy over its ATTUNE® Primary Total Knee System
 - Four patents asserted → Claim construction / IPR Proceedings → Claim 9 of U.S. Patent No. 6,558,426 (the `426 patent)



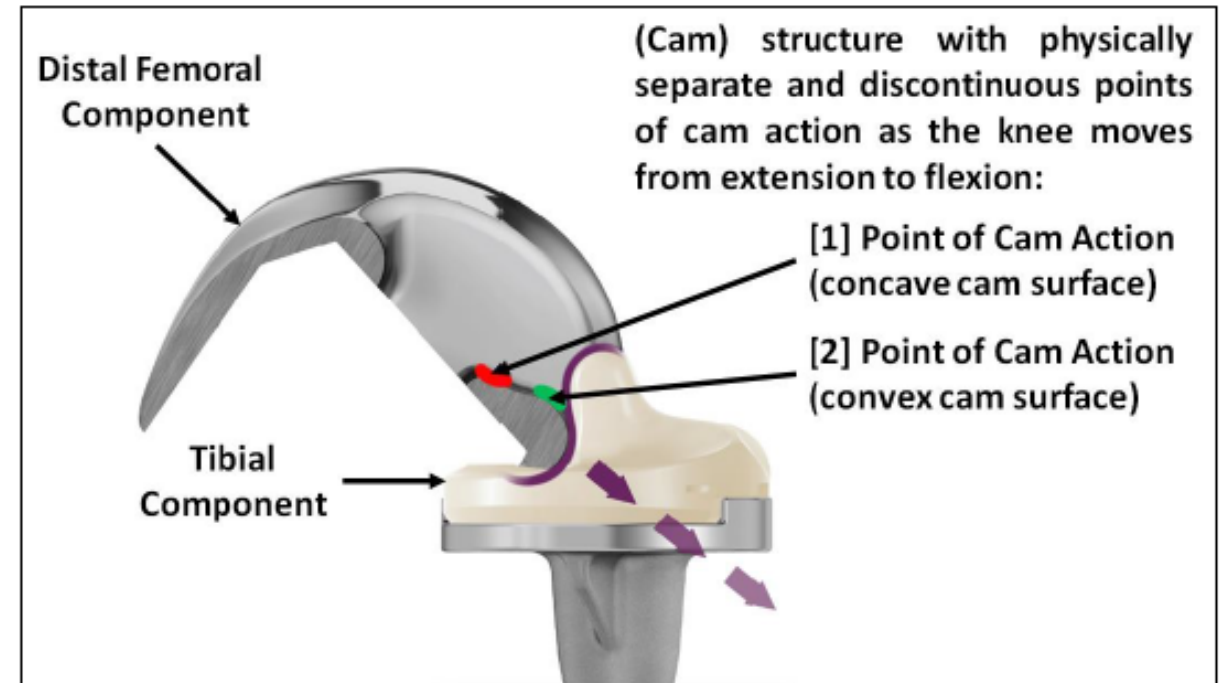
- Claim 9 of the `426 patent recites:
A distal femoral knee-replacement component ... comprising:

...

a structure providing more than one physically separate and discontinuous **points of cam action** as the knee moves from extension to flexion.

→ SJ granted for DePuy (noninfringement)

- DePuy can continue selling products



- Claim construction:
 - more than one physically separate and discontinuous **points of cam action**
 - Holding: the claimed “points of cam action” are **convex**
 - Claims/specification did not expressly limit the claimed “points of cam action” to convex surfaces.
 - Basis of claim construction holding:
 - “Medldea steadfastly and repeatedly maintained that the claimed points of cam action were met by convex surfaces on the femoral component of the Attune® system.”
 - Amended complaint: ATTUNE has “a **first convex cam surface** and a **second convex cam surface ...**”
 - All examples in patent show convex surfaces
 - Prosecution: “The cam surfaces ... are the same, functionality is the same ...”
 - IPR: referred to “**convex cam action surfaces**” in its description of “the multiple points of cam action ...in **the disclosed and claimed invention**”
 - On appeal

- **Take-away points:**

- Competitor:

- Claim scope can be significantly more narrow than it appears to be
 - Search prosecution, litigation and IPR history

- Litigant:

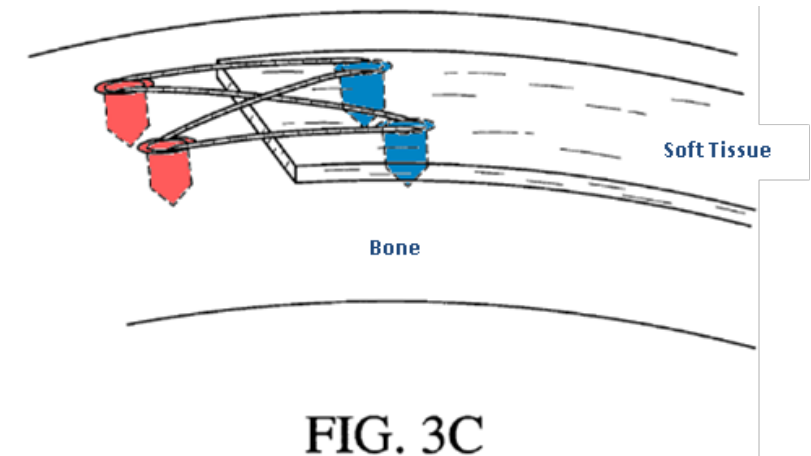
- Scrutinize arguments and pleadings (cannot change claim construction position from IPR)

- Patentee:

- Include alternative examples and scrutinize description in patent application and statements during examination

KFx Medical, LLC v. Stryker Corp.

- KFx Medical accused the **ReelX STT Soft Tissue Anchor System** of patent infringement (orthopedic suture anchors)
- KFx asserted the '311 & '287 Patents in S.D. Cal.
 - Technology involves knotless double row rotator cuff repair
- IPRs filed on both patents
 - Both were denied institution
 - With respect to the '311 Patent, the PTAB noted that the patent survived initial prosecution, a re-examination, and the Arthrex lawsuit
- The case was dismissed in June 2020



KFx Medical, LLC v. Stryker Corp.

- ‘311 patent was subject of previous lawsuits
 - KFx and Arthrex in 2011
 - KFx won more than \$35 million in damages
 - KFx and Wright Medical dismissed
 - Licensing deal with Wright
- Additional licensing agreements



KFx Medical, LLC v. Stryker Corp.

- Take-away points:
 - Interplay between IPR and pending litigation
 - Leveraging litigation for licensing agreement
 - Small companies can defend their IP

MicroPort Orthopedics v. Medacta

- MicroPort filed a lawsuit against Medacta in June 2020 alleging:
 - willful infringement of MicroPort’s patents
 - tortious interference with contract and business relations
- Technology: Microport patented procedures for minimally invasive hip replacement surgery
- “Medacta sought to take market share from MicroPort by convincing surgeons to implant Medacta implants—rather than MicroPort implants—while still using MicroPort’s Patented Procedures and instruments.”
- The case settled and motion to dismiss granted on July 21, 2021.
 - Settlement agreement: Medacta will pay to MicroPort Inc. \$7 million by five days after the signature of the agreement and \$5 million over a term of seven years



Safe Orthopaedics v. Neo Medical

- Ready-to-use pedicle screw kits
- Protected by issued patents in multiple countries
- Started with EPO opposition
- Patent infringement case in France
- In May 2021, French court ruled that Neo Medical cannot market or import its pedicle screw kit on French territory and must destroy remaining stock



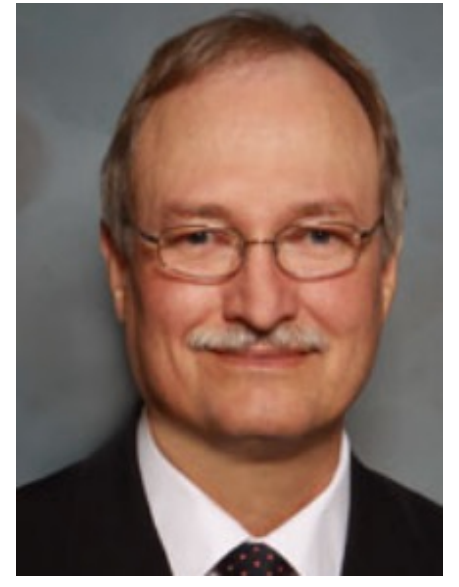
Safe Orthopaedics v. Neo Medical

- Take-away points:
 - Enforcement not just in US
 - Be aware of stock destruction possibility in France



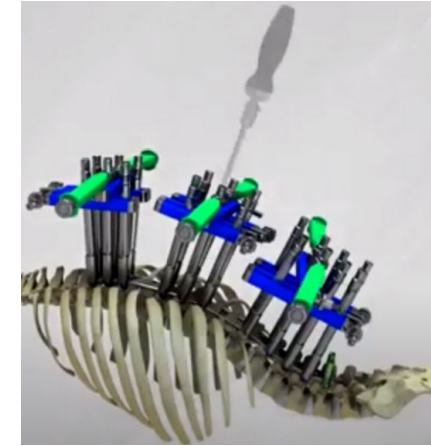
Prolific Doctor-Inventor Litigation

- Several cases recently filed by prolific orthopedic doctors
 - **Barry** v. Alphatec, SeaSpine, Stryker and others
 - **Jackson** v. NuVasive and SeaSpine
 - **Moskowitz** Family LLC v. Globus Medical
 - RSB Spine (**Bray**) v. DePuy Synthes, Life Spine, others
 - Arthrodesis (**Chandran**) v. Wright Medical
 - **Burkhart** v. Arthrex



Prolific Doctor-Inventor Litigation

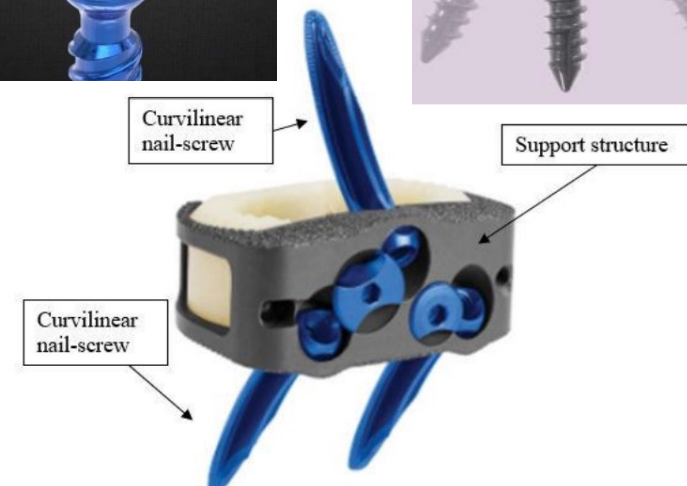
- Barry v. Alphatec, SeaSpine, Stryker and others
 - Spinal Deformity Repair (Scoliosis)



- Jackson v. NuVasive and SeaSpine
 - Spinal screw innovations



- Moskowitz Family LLC v. Globus Medical
 - Minimally invasive spinal fusion devices and insertion tools



Prolific Doctor-Inventor Litigation

- Take-away Points:
 - Be aware of the doctor-inventors and their patents
 - Solo doctors can be successful in generating revenue from patents, whether they develop the technology or not
 - Does your license include all relevant patents, now and in future?
 - Value of Large Patent Portfolios

Life Spine v. Aegis Spine



Fig. 4. ProLift PLIF/TLIF wedges.



Fig. 5. AccelFix TLIF/PLIF wedges.

- Spinal disc implant
- Breach of contract/Trade Secret violation
- Relationship started at trade show
- Reverse engineering
- Preliminary injunction issued in April 2021

Life Spine v. Aegis Spine



Fig. 4. ProLift PLIF/TLIF wedges.



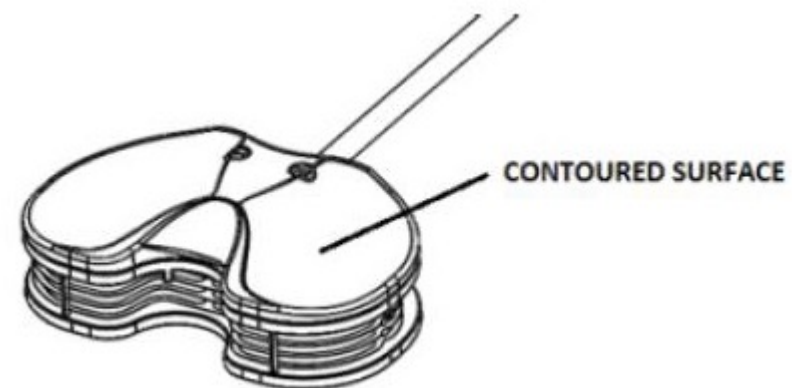
Fig. 5. AccelFix TLIF/PLIF wedges.

- Take-away points:
 - Patent infringement not the only remedy
 - Preliminary injunctions rare but still possible
 - Be protective in agreements with distributors/sales reps
 - Identification of competitor's device as predicate device can be risky

FACTUAL ALLEGATIONS IN XPANDORTHO ('XO') COMPLAINT

- 2012 – XO Founded
- 2018 – Meetings resume under amended NDA (Exclusivity; Break-up fee)
 - ORTHOsoft “Inventor C” provisional
 - LOI with XO favorable terms → Diligence (Data room)
 - FDA Materials, lab work
 - Zimmer calls off the deal after lab work
 - One month later 2 more patent apps with XO images
- 2019 – Exactech Acquires XO and thereafter patent assets publish
- 2021 – Exactech / XO file suit in Southern District of California

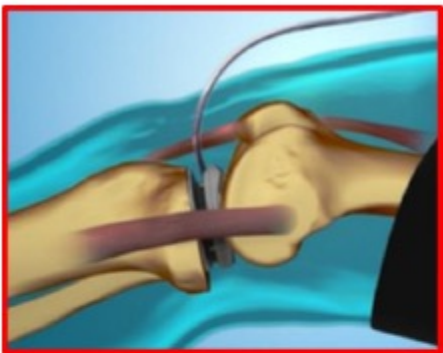
ORTHOsoft[®]
(Zimmer CAS)



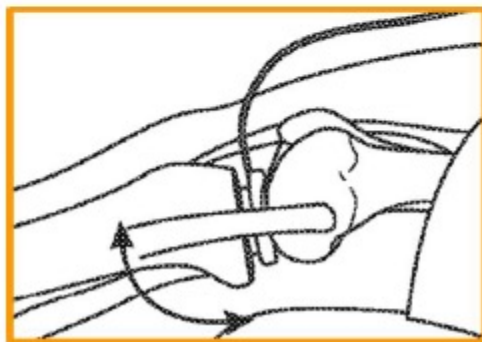
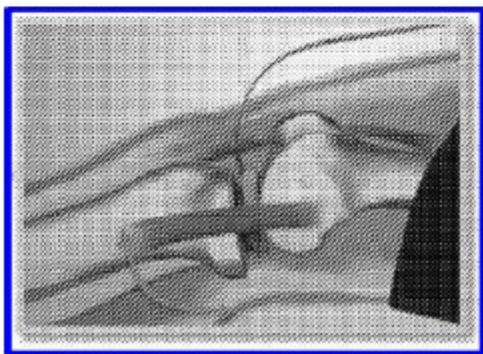
ORTHOsoft[®]

(Zimmer CAS)

XO¹ Animation



"Inventor C" Patent Assets



Zimmer Disclosure Filed One Month after Terminating Deal References XO

4. Flexion balance using Xpanse Ortho-4-in-1 holes with robotic arm

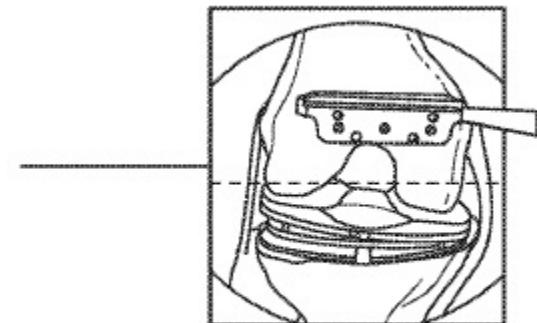


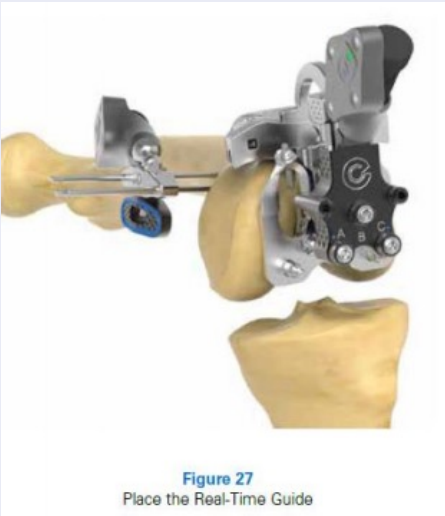
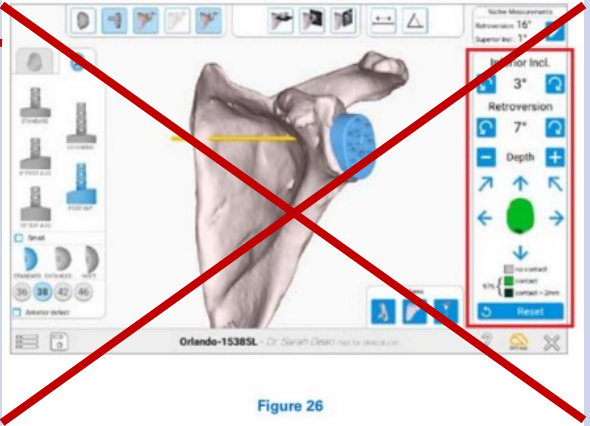

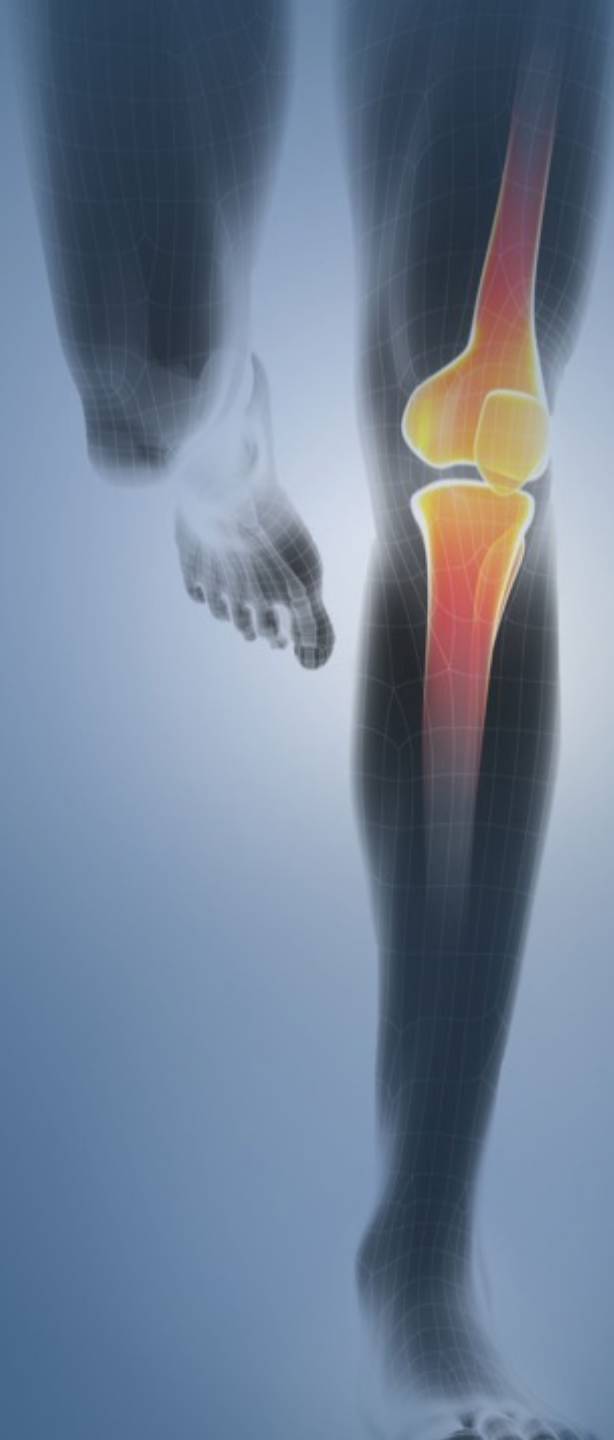


FIG. 10

| Count | Accused Product |
|-------|---|
| 1-2 | <p data-bbox="580 299 904 342">Exactech GPS</p> <div style="display: flex; justify-content: space-around;">   </div> <p data-bbox="1651 686 1842 736">Figure 11 One-Step Calibration</p> |
| 3-4 | <p data-bbox="580 775 1523 818">Exactech GPS & Trulliant Total KneeSystem</p> <div style="display: flex; justify-content: space-around;">   </div> <p data-bbox="1709 1250 1905 1286">Figure 27 Place the Real-Time Guide</p> |

| Count | Accused Product |
|-------|--|
| 5 | <p>Exactech Shoulder Planning App/Software</p>  <p>Figure 26</p> |
| 6 | <p>Optetrack Logic Revision Knee System</p>  <p>Tibial Components and Augments</p> <p>A universal tray can be used in both Logic primary and Logic CC revision procedures, providing a straightforward conversion technique when revision implants are required for complex primary arthroplasty.</p> <p>The FIT tibial tray accepts 5 and 10mm augments which are available in both 1/3 and 1/2 configurations. The tibial augments can be stacked up to 15mm if the defect requires a larger augment. The 5mm augments can be used on either side of the tray. The 10mm augments are side-specific due to the 15-degree taper designed to match the shape of the tibia and reduce overhang.</p> |



Knobbe **Martens**

Thank you!