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# Developing Effective Patent Strategies for Personalized Medical Devices in Europe and the US

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# **Personalised Medical Devices**

 Medical devices intended for a particular individual which could be custom-made, adaptable or patient-specific

### - Examples:

- Implants and prostheses produced by 3D printing;
- Assemblies and systems built according to a patient's anatomical parameters
- Surgical implants adapted to be thermoformed during the surgical procedure

# Growth in Applications directed to Medical Devices

PCT applications published by Year



Data obtained using PatBase<sup>™</sup> \*2020 data omitted as incomplete **Exemplary Claim types covering Medical Devices** 

A medical device comprising...

Treatment system comprising the medical device...

Method of manufacturing the medical device...

Methods relating to how the medical device is used....



# Hypothetical Case Study – Med Device Europe

- Med Device Europe have developed a customized, implantable therapy device with additional features X and Y
- The device facilitates healing following surgery by delivering electrical impulses to the surrounding tissue
- It can be used as an independent unit or as an ancillary component to a standard surgical implant

 The R&D team at Med Device Europe have also identified a new process for manufacturing the device

hgf.com

# Hypothetical Case Study – Med Device Europe

- Med Device Europe learn that legislation will soon be introduced that limits the power output of all electrical therapy devices
- The inventors identify a means of calibrating the unit prior to use that ensures a power threshold is not exceeded
- Many competitors of Med Device Europe are exploring similar solutions prompted by the impending change in legislation
- High global demand is anticipated for the therapy device with the greatest sales volumes expected in Europe and the US
- Instructions are issued to file a new patent application to secure protection ASAP in their main commercial territories



Exemplary claims in a PCT application filed by Med Device Europe

- 1. An implantable therapy unit comprising features X and/or Y.
- 2. A system for delivering therapy comprising a surgical device and the implantable therapy unit of claim 1.
- 3. A method of manufacturing the implantable therapy unit of claim 1 comprising processes A and B.
- 4. A method of calibrating an implantable therapy unit prior to implantation within a human or animal body, the method comprising steps 1, 2 and 3.
- 5. A method of delivering therapy to a tissue site, wherein therapy is delivered to the tissue site by the implantable therapy unit of claim 1.



# Case Study – Examination in Europe

#### Claims

- 1. An implantable therapy unit comprising features X and/or Y.
- 2. A system for delivering therapy comprising a surgical device and the implantable therapy unit of claim 1.

Claims 1 and 2 found to lack novelty over prior art reference D1 which discloses feature X. D1 does not however disclose feature Y.

- 3. A method of manufacturing the implantable therapy unit of claim 1 comprising processes A and B.
- 4. A method of calibrating an implantable therapy unit prior to implantation within a human or animal body, the method comprising steps 1, 2 and 3.

None of the prior art references disclose the methods of claim 3 or claim 4. The European Examiner also considers that the subject matter of these claims is inventive.

5. A method of delivering therapy to a tissue site, wherein therapy is delivered to the tissue site by the implantable therapy unit of claim 1.

The Examiner notes that claim 5 relates to a method of treatment by surgery or therapy and is excluded from patentability in Europe by Article 53 (c) EPC.

# **Exceptions to Patentability in Europe**

Article 53(c) EPC

European patents shall not be granted in respect of:

• • • •

(c) methods for treatment of the human or animal body <u>by surgery or therapy</u> and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.



Methods for treatment of the human or animal body by surgery or therapy

 Principle of the Article 53(c) EPC exclusion is so medical practitioners have freedom to use best available treatments to the benefit of their patients without worry that some treatment might be covered by a patent

Legal rationale discussed at length in G1/07 and G1/04



# Methods concerning operation of the medical device

- Methods only concerned with the operating of a device without any functional link between the claimed method and the effects produced by the device on the body are not excluded from patentability by Article 53(c) EPC
- T1731/12 concerned a case relating to a device for the desynchronization of pathologically active brain areas
- Claim 1 of the patent essentially required control means to emit stimuli causing the activity of regions in the brain to change
- It was found that the functional limitation in claim 1 could only be met once electrodes emitting stimuli had been implanted
- Board of Appeal determined that the device was defined by a feature that could only be produced by a surgical or therapeutic step and was exempt from patentability under Article 53(c) EPC



# Case Study – Allowable Claims

#### Claims

- 1. An implantable therapy unit comprising features X and/or Y. </
- 2. A system for delivering therapy comprising a surgical device and the implantable therapy unit of claim 1. 🗸

Claims 1 and 2 novel and inventive over D1 which does not disclose feature Y.

- 3. A method of manufacturing the implantable therapy unit of claim 1 comprising processes A and B.  $\checkmark$
- 4. A method of calibrating an implantable therapy unit prior to implantation within a human or animal body, the method comprising steps 1, 2 and 3.

None of the prior art references disclose or suggest the methods of claim 3 or claim 4.

5. A method of delivering therapy to a tissue site, wherein therapy is delivered to the tissue site by the implantable therapy unit of claim 1.

Claim 5 deleted to overcome the objection under Article 53(c) EPC.



European Prosecution – Considerations prior to grant

Inclusion of commercially useful dependent claims

Less flexible approach than US to claim amendments

- Implications of EP prosecution history and file wrapper estoppel

Filing strategies for divisional applications



# Maximizing protection for medical devices across Europe

Strategic and economic considerations of where to validate:

Sales volumes;

Where are devices manufactured;

Location of competitors;

Translation costs/London Agreement

Tactical filing of divisional applications



CONFORMIS

- Founded in 2004, headquartered in Massachusetts
- 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 enforced against multiple large medical device companies (Depuy Synthes, Wright Medical, Tornier, MicroPort, Smith & Nephew, Zimmer, Bodycad, Exactech)
- Patents challenged via reexamination and inter partes review





#### **Complex Patent Families and a Variety of Disclosures**



First non-provisional filed May 2002 Multiple continuations and CIPs Over 100 US patents ~27 EP patents Expirations ~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."









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#### Personalized Medicine – Surgical Instrument Claim

A surgical instrument for the repair of a 1. 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





Art Unit 3773 – Medical & Surgical Instruments, Treatment Devices, Surgery and Surgical Supplies

**Greater damages potential for** personalized medical devices compared to reusable medical devices

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#### Personalized Medicine – System Claim

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



System claim provides potential for damages for implants sold with instruments, even if implants are not patient-specific

#### Personalized Medicine – 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





"Configured to" language is common in device claims but can face difficulties in examination

Include structural details in narrower claims/specification to distinguish what may be inherent in the prior art

#### Personalized Medicine – Method of Use Claim

32. A method for *implanting* a knee implant in a patient's knee joint, the method comprising the steps of:

(a) *preparing a proximal end of a tibia* to receive an implant including at least one tibial implant; and

(b) *inserting the at least one tibial implant onto the prepared proximal end of the tibia* such that a first articular surface of the at least one tibial implant engages a first articular surface of a femoral implant and a second articular surface of the at least one tibial implant engages a second articular surface of the femoral implant;

wherein the first articular surface is higher than the second articular surface relative to an anatomical axis of the tibia, wherein the first articular surface, or the second articular surface, or both, includes patient-adapted sagittal radii or curvature.

U.S. Patent No. 8,771,365





Estimated expiration 27 March 2030



Infringer in the U.S. is the medical device manufacturer (look to IFUs)

Draft specifications with surgical methods in mind (e.g., flow charts, sequence drawings, how does the implant interact with the body)

Beware of mixing manufacture and surgical steps

#### Personalized Medicine – Method for Designing an Implant

1. A method for *designing* an implant for repairing a joint of a patient comprising the following steps:

obtaining data for the joint;

*fusing* at least two imaging planes from the image data for the joint; *segmenting* image data of one or more meniscal surfaces of the joint; and *converting* the segmented image data into a patient-specific surface of the implant.

U.S. Patent No. 8,077,950

Method of manufacture claims can be more difficult to prove infringement, but may be easier with software

Who/what is the infringer? (method of making, method of designing, etc.)

Software limitations or manufacturing techniques may provide more patentable aspects



2666 - Digital Cameras; Image Analysis; Applications; Pattern Recognition; Color and Compression; Enhancement and Transformation

2624 – Selective Visual Display Systems 1747 – Plastics Shaping and Molding

#### Even Earlier Personalized Medicine Patents Are Expiring

1. A computer implemented method of obtaining data for determining a *3-dimensional shape* of a medical device, the method comprising:

(a) **obtaining computer readable image data of a target tissue** wherein the target tissue comprises two portions, a portion with a defect and a portion without a defect;

(b) *rendering* from the image data a computergenerated 3-dimensional representation of the target tissue;

(c) *superimposing* a three-dimensional template onto the 3-dimensional representation, wherein the threedimensional template represents a normative shape of an anatomical surface of the target tissue; and

(d) *deforming* the three-dimensional template to the computer-generated 3-dimensional representation *to determine the 3-dimensional shape of the medical device*.

U.S. Patent No. 9,330,206 (Osteoplastics LLC)



Expired patents may provide opportunities for new entrants into the market

Old prior art (even in different fields) may be relevant to patentability

Emphasize technical challenges that were overcome to argue for patentability

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## History of Litigations (2013-2021)



# **Smith**<br/> **Nephew**







bodycad





# WRIGHT. MicroPort

#### FOCUSED EXCELLENCE

- Complaint filed September 2013 in District of Massachusetts
- 5 patents asserted against • **PROPHECY** patient specific instruments for knee and ankle surgery

302

Settled April 2015 

263



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- Complaint filed February 2016 in District of Massachusetts
- 9 patents asserted against VISIONARE
  patient specific instruments for knee surgery
- 3 patents included "implant" limitation
- S&N filed 16 IPRs on 9 patents
- ConforMIS voluntarily dismissed 2 patents
- Litigation stayed pending IPR
- PTAB held key patents unpatentable
- Settled September 2018



#### 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.

5. The surgical instrument of claim 1, wherein the inner surface matches a curvature of diseased cartilage of the diseased articular joint surface.

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



#### Numerous Prior Art References



# **ConforMIS Contracted with Prior Art Author**

# PROFESSOR KLAUS RADERMACHER JOINS CONFORMIS

ELIZABETH HOFHEINZ, M.P.H., M.ED. • THU, APRIL 28TH, 2011



**E**very serious scientific entity needs an expert named "Klaus"...Now, ConforMIS, Inc. has said expert. Professor Klaus Radermacher, heralded for his contributions to image-guided surgery, surgical navigation, and medical robotics, has now joined the ConforMIS Scientific Advisory Board. Professor Radermacher is Chair of Medical Engineering at the Helmholtz-Institute for Biomedical Engineering, RWTH Aachen University, Aachen, Germany.

#### Inter Partes Review Timeline: Patent Trial and Appeal Board ("PTAB")

District court litigation often stayed pending IPR



#### Patent Litigation Timeline: District Court



#### Smith & Nephew Road to Successful Resolution











#### Institution Rates By **Petition**

• Rates of institution have declined over time



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

#### Institution Rates by **Patent**



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







- Complaints filed August 2019 in District of Delaware
- 4 patents asserted against patient specific instruments for knee, shoulder, and hip surgery
- Consolidated for pretrial
- May 2020 Zimmer settled
- March 2021 Markman ruling
- Trials February 2022

# 129 avoided IPR 304 WM suit 161



V.

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- Complaint filed April 2020 in District of Delaware
- 4 patents asserted against patient specific instruments for shoulder
- Early written discovery
- No schedule



**DePuy Synthes** CONFORMIS V. THE ORTHOPAEDICS COMPANY OF Johnson 129 482 **TRUMATCH®** avoided Complaint filed April implant Personalized Solutions **IPR** 2021 in District of Shoulder System Delaware Surgical Technique 304 7 patents asserted 161 WM1 against TRUMATCH Zim/Med WM2 patient specific instruments for knee and shoulder surgery 745 Pleading stage () DePuy Synthes 026 780 WM2 **WM2** 



- Complaint filed June 3, 2021 in Middle District of Florida
- 5 patents asserted against VANTAGE patient specific instruments for ankle surgery





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



#### Key Takeaways



Patent and litigation activity involving personalized medical devices remains high

File provisionals early and often Pursue multiple claim types Aggressively file continuations and new applications





Beware of continuations-in-part and their effect on patent term

Conduct freedom-to-operate searches and watch for litigation risk Know how to challenge patents



# Thank you

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