

No. 17-

IN THE
Supreme Court of the United States

IN RE: STEVEN C. CHUDIK,

Petitioner.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED
STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Was the petitioner, an applicant for a patent, denied a patent without due process of law, contrary to the doctrine of stare decisis and contrary to the deprivation of property provision in the United States Constitution's Fifth Amendment

(1) when the United States Patent and Trademark Office and the Court of Appeals for the Federal Circuit held that a prior development described in a French patent application was capable of being modified, and thus corresponded to and vitiated the petitioner's claims to his invention, despite directly contrary holdings in *Topliff v. Topliff*, 145 U.S. 156, 12 S. Ct. 825, 36 L.Ed. 658 (1892), *In re Wells*, 53 F.2d 537 (C.C.P.A., 1931) and *In re Chudik*, 851 F.3d 1365 (Fed. Cir., March 27, 2017), and

(2) when the Court of Appeals also, in rejecting the claims in the petitioner's patent application, relied upon a paragraph of the application describing a different invention and thus departed from the holding in *In re Man Mach. Interface Tech. LLC*, 822 F.3d 1282 (Fed. Cir. 2016) that the terms in an inventor's patent claims should not be construed in a manner which contradicts the detailed description of the claimed invention in the inventor's written specification, and

(3) when the Court of Appeals also, in rejecting the claims in the petitioner's patent application, relied upon an irrelevant portion of its opinion in *Catalina Marketing International, Inc. v. Coolsaving.com*, 289 F.3d 801, 809, 810-811 (Fed. Cir. 2002), instead of following the relevant portion which approved the form of the petitioner's claims, and

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(4) no reason was given for disregarding these authorities?

PARTIES TO THE PROCEEDINGS

The only party in the proceedings below was Steven C. Chudik, and he is the only party now.

RULE 29.6 DISCLOSURE STATEMENT

The petitioner, Steven C. Chudik, is an individual, the named inventor in the patent application in issue. He resides in Western Springs, Illinois. He owns the entire interest in this application and its subject matter.

There is no publicly held or privately owned company which has any interest in the application or its subject matter.

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Steven C. Chudik respectfully petitions this Court for a writ of certiorari to review the judgment of the Court of Appeals for the Federal Circuit in Appeal No. 2016-2673 rendered on August 25, 2017.

OPINIONS BELOW

The Federal Circuit's nonprecedential opinion (App. 1a) appears in Fastcase as *In re Chudik*, Appeal No. 2016-2673, August 25, 2017 (Fed. Cir., 2017) but is not otherwise reported. The Federal Circuit's order denying rehearing and rehearing en banc without opinion (App. 17a) is unreported. The opinion of the United States Patent and Trademark Office Patent Trial and Appeal Board (App. 6a) is not reported but may be found on the Patent and Trademark Office's website under Public PAIR for Patent Application Ser. No. 13/068,309. The Patent and Trademark Office Examiner's Final Office Action rejecting Dr. Chudik's patent application (App. 19a) appears only in Public PAIR .

JURISDICTION

The Federal Circuit entered judgment on August 25, 2017, and denied rehearing and rehearing en banc on November 6, 2017. This Court has jurisdiction pursuant to 28 U.S.C §1254(1).

CONSTITUTIONAL PROVISION INVOLVED

Amendment V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a grand jury, except in cases arising in

the land or naval forces, or in the militia, when in actual service in time of war or public danger; nor shall any person be subject for the same offense to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

STATUTE INVOLVED

35 U.S.C. Sec. 102 (Pre-AIA)

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for a patent in the United States.

STATEMENT OF THE CASE

When Dr. Chudik filed a nonprovisional patent application in August 2004 entitled “Devices and Methods Used for Shoulder Replacement,” he incorporated several provisional applications which he had filed during the preceding twelve months. His nonprovisional application became Serial No. 10/917,266. It contained 161 proposed patent claims. The Patent Office Examiner’s first response identified fifteen groups of those claims and required Dr. Chudik to elect one. Dr. Chudik elected Group XIV, drawn to a method of repairing a rotator cuff. The other groups were held in abeyance. Of those, the Group II claims were for a humeral implant, and those in Group III were for a glenoid implant.

While the method claim was being prosecuted in '266, Dr. Chudik filed divisions of the parent case. They contained the same written specification and drawings as '266 but different claims. One, containing the claims for the humeral implant, received Serial No. 11/525,629. Another, containing the claims for the glenoid implant, received Serial No. 11/525,631.

In the '629 application, the Examiner modified his earlier thinking and required further restriction, stating in an Office Action that the application contained claims directed to

“...the following distinct species:

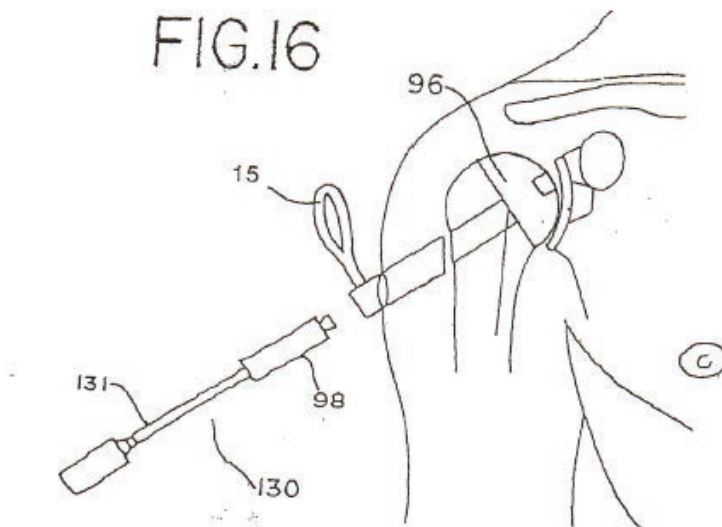
Specie I: stem included humeral implant.

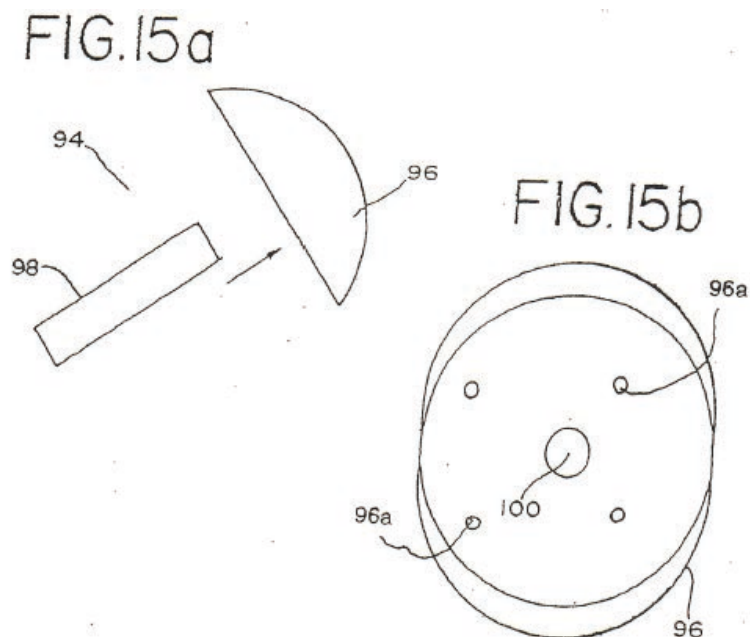
Specie II: stemless humeral implant.”

The Examiner further opined, “The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species.” Thereafter, pursuant to the second requirement for restriction, Dr. Chudik elected to prosecute the claims to Specie I in the '629 application. However, he also filed another division with claims to Specie II, the “stemless humeral implant” identified by the Examiner. The latter received Serial No. 13/068,309. That is the application which is under discussion in this Petition, having been rejected by the Examiner, the Patent Trial and Appeal Board and the Court of Appeals. The main ground for those rejections has been a French patent publication to Leonard et al. which is directed to a *glenoid* implant.

The humerus is the large bone in a person's upper arm joining the person's arm to his body at his shoulder. At that junction an enlarged portion of the humerus, the humeral head, articulates with another bone, the scapula, in the person's shoulder so that the person can move his arm. The humeral head is disposed near the outer end of the scapula in a formation called a glenoid cavity, a somewhat cup-shaped formation which faces outwardly from the scapula. The joint between the humerus and the glenoid cavity, called a glenohumeral joint, often requires repair. Sometimes the repair is accomplished by installing an implant on the humeral head, i.e., a humeral implant, to rebuild a portion of the head, a procedure that may or may not be accompanied by having a cooperative implant, i.e., a glenoid implant, installed in the glenoid cavity.

Fig. 16 of Dr. Chudik's '309 patent application, shown below, illustrates both humeral and glenoid implants installed in a shoulder. Figs. 15a and 15b of the application, also shown below, illustrate the humeral implant's components.





The cup-shaped component 96 of Dr. Chudik's humeral implant is fixed on the head of the humerus (see the drawing above). Element 98, the stem, is shown outside the patient's shoulder. It may be joined to 96, if the surgeon chooses to use a stem, through a passageway in the humeral head leading to a junction with 96 located on the non-articulating side of 96. The other side of 96, which faces the scapula (the articulating side of 96), contacts a concave outwardly facing surface of the glenoid implant.

The humeral surfacing component 96 and the stem 98 are discussed at length in Dr. Chudik's application, notably at paragraphs numbered 00149 through 00157 (see Public PAIR). In his discussion of the humeral implant form which he prefers, which has a stem, Dr. Chudik also states, "[a]lternatively, a novel humeral surface implant that

includes only a humeral surface 96, with no stem 98 may be used.” He advises that 96 has “a coronal radius of curvature and an axial radius of curvature.” It can be “spherical in shape.” Preferably, the component “can be more anatomic being spherical, with equal coronal and axial radii of curvature, in the center and elliptical, with larger coronal than axial radii of curvature, at the periphery.” The component “also has a depth and thickness.” It may be “spherically shaped or more of an elliptical shape which better approximates the anatomy of a natural humeral head.” It may also have “fins, spikes or other protuberances 96a on its concave, non-articular surface to enhance rotational stability.” It can be “cemented or press-fit to the prepared humeral surface.” Dr. Chudik’s specification further advises, “A bony ingrowth material allows the bone to which the implant is attached to grow into the implant and aids in attaining long-lasting fixation of the implant.” Its non-articular surface on the humerus is contrasted with the smooth surface of the side articulating with the glenoid implant, and continues: “In addition, the radius of curvature of the superior-inferior axis of the glenoid surface is greater than the coronal radius of curvature of the humeral surface of the humeral implant with which the glenoid implant articulates.” An articulating joint is the only joint described. There is no context suggesting installation of either the humeral implant or a glenoid implant in a joint which does not articulate.

The Chudik application claims his humeral implant in these terms:

“5. A humeral implant comprising a humeral surface component having a non-articular surface configured for long-lasting fixation of

Fig. 1

Fig. 1

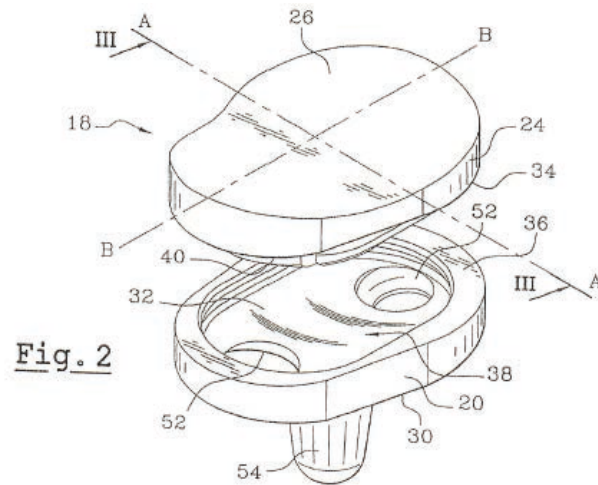


Fig. 2

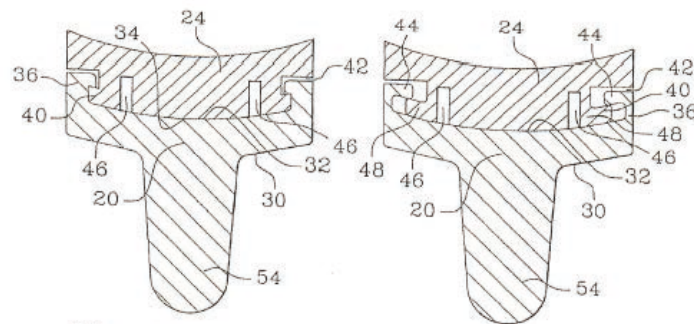


Fig. 3A

Fig. 3B

These figures show that the gradually curved surface 26, located on Leonard et al.'s mobile element 24 of glenoid prosthesis 18, provides a sliding contact surface on its articulating side for engaging humeral head 12. Further, Leonard et al.'s opening lines provide:

“The present invention relates to a...prosthetic glenoid mobile bearing capable of being attached to the glenoid cavity of the scapula and to receive the head of the humerus, or a humeral implant.

* * * *

It is also known from EP-776 636, FR-2683,142, FR-2696.313 and EP-963 742 of glenoid prostheses in two parts, comprising a base fixed to the shoulder blade and a fixed contact piece relative to the base, having a *sliding* surface adapted to receive the head of the humerus.” (emphasis added)

The drawings above also show that the non-articulating side of element 24 includes a protruding portion 40 extending into base 20. There it is grasped in an enclosed track or recess on base 20. The base, in turn, is embedded in the scapula.

FACTS AND PROCEEDINGS BELOW

In his Office Action marked “Final” rejecting Dr. Chudik’s claim 5, the Examiner explained “[I]n regards to statements of intended use and other functional statements (e.g., configured for long-lasting fixation) does not impose any structural limitations on the claims distinguishable over the device of Leonard, which is capable of being used as claimed if one so desires to do so (citing cases).” The Patent Trial and Appeal Board agreed:

“Accordingly, while the Appellant may be correct that Leonard does not disclose using platen 24 as a humeral implant, the absence of such disclosure does not defeat a finding of anticipation. To avoid anticipation, an apparatus claim (i.e., independent claim 5) must be distinguished from prior art in terms of structure. ‘If the prior art structure is capable of performing the intended use [i.e., serving as a humeral implant], then it meets the claim,’ (citing and quoting *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) in a footnote).”

The Court of Appeals also agreed, holding (1) that Leonard et al.’s glenoid surface 26 which faces the humeral head is capable of being fixed on the humeral head, (2) that Leonard et al.’s glenoid implant element 24 has no stem, and (3) that Leonard et al.’s prior art glenoid implant is simply being put to a new use by Dr. Chudik. Dr. Chudik petitioned for a panel rehearing or a rehearing en banc, but the petition was denied.

REASONS FOR GRANTING THE PETITION

If all it takes to invalidate a claim to an invention is locating a prior art structure which can be modified (i.e., finding one that is “capable” of becoming what the claim calls for), then an unimaginable number of today’s patents are in jeopardy. Over 100 years of precedent established by this Court in 1892, and followed, will be erased. Such a course rejects *stare decisis* and deprives an inventor of his property in a summary and arbitrary way. Moreover, as is already apparent, designating an opinion as “nonprecedential” does not diminish its importance.

The Federal Circuit's Rule 32.1(c) provides that opinions so marked are citable nevertheless: "Parties are not prohibited or restricted from citing nonprecedential dispositions issued after January 1, 2007." And, in fact, the Federal Circuit's opinion in this case has already been noticed among members of the patent bar in New York and Chicago, *See* "Fed. Cir. Affirms PTAB Nix Of Shoulder Implant," Law 360, New York, August 25, 2017, and "Rejection of Claims Containing Functional Language and a Negative Limitation Affirmed by Federal Circuit," The Chicago Bar Association, September 8, 2017.

A "humeral implant" which has a "humeral surface component" affixed on a "humeral head," the terminology in Dr. Chudik's claim 5, can only refer to a glenohumeral joint. That joint articulates. The Leonard et al. glenohumeral joint containing the Leonard et al. glenoid implant articulates, too. But modifying that glenoid implant to create a long-lasting fixation of the humeral head to it utterly destroys the Leonard et al. joint's articulation. The humeral head would also be fixed on the glenoid implant. Both of these are structural changes.

The Board and the Court of Appeals perceived the issue of anticipation as being simply whether the glenoid surface component could be affixed to the humeral head. They both concluded that a long-lasting fixation could be achieved because the glenoid implant's surface in Leonard et al. facing the head of a humerus was "capable" of being fastened there. As stated in the Board's Decision:

"Thus, we understand the Examiner to be saying that the humeral-side of Leonard's platen 24 is configured for (i.e., capable of)

long-lasting fixation on the removed section of humeral head 12.

* * * * *

“We agree with the Appellant that the recital of ‘configured for long-lasting fixation’ may impose structural limitations...but, due to the breadth of independent claim 5, Leonard meets such structural limitations. ‘[I]f someone such as a surgeon or orthopedic doctor desired to use bone cement and secure the implant to the bone, it is capable of being done and would establish the implant as “long lasting.”’”

Sustaining the Board, the Court of Appeals brushed aside claim 5’s requirement that it is for an implant in a joint which articulates. The Court of Appeals merely stated:

“Contrary to Dr. Chudik’s argument, claim 5 requires only a non-articular surface that is *configured for* long-lasting fixation. As a result, whether Leonard discusses a sliding contact is not relevant to whether Leonard is capable of long-lasting fixation. * * * He [Dr. Chudik] also argues that using screws and cements to achieve long-lasting fixation would result in a joint with a limited range of motion – but claim 5 contains no limitation regarding range of motion.” (emphasis original)

Both of the Court of Appeals’ reasons for sustaining the Board’s conclusion, namely (1) that sliding contact is

irrelevant, and (2) that there is no limitation in Dr. Chudik's claim 5 regarding range of motion, are clearly wrong. Both fail to recognize that the joint is an articulating joint (which the Examiner admits), and when that foundation fact is recognized, "sliding contact" is relevant, and so is range of motion. It is indisputable that cementing Leonard et al.'s glenoid surface 26 to the head of humerus 12 would be disastrous. Both sides, the humerus and the glenoid, would be fused to each other, quite contrary to Leonard et al.'s disclosure. A glenohumeral joint modified in this manner just would not work.

The proper basis for a decision in the case at bar was expressed to the Court of Appeals in Dr. Chudik's opening brief, namely that this Court's decision in *Topliff v. Topliff*, 145 U.S. 156, 12 S.Ct. 825, 36 L.Ed 658 (1892) should be followed. That was also done in Dr. Chudik's reply brief and again in Dr. Chudik's petition for rehearing. But neither *Topliff* nor any of the cases which have followed it were followed, or acknowledged. No reason was ever given for those omissions.

It is hard to understand why. The Court of Appeals had itself followed *Topliff*, only five months earlier, in a precedential decision entitled *In re Chudik*, 851 F.3d 1365 (Fed. Cir. March 27, 2017). The case concerned the claims to Dr. Chudik's glenoid implant, the Group III case. It involved the same set of patent application drawings, the same written description, the same shoulder joint, even the same "capability" theory of anticipation. However, the Court of Appeals held that there was no anticipation there, specifically spelling out the proper legal criteria (851 F.3d at 1372):

“A patent claim is invalid for anticipation under 35 U.S.C. §102 when a prior art reference describes each and every claim limitation and enable[s] one of skill in the art to practice an embodiment of the claimed invention without undue experimentation.’ *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1344 (Fed. Cir. 2012).... Simply put, an anticipated invention ‘is not new.’ *Skvorecz*, 580 F.3d at 1266. By contrast, a prior art reference that “must be distorted from its obvious design” does not anticipate a patent claim. *In re Wells*, 53 F.2d 537, 539 (C.C.P.A. 1931) (quoting *Block v. Nathan Ankle Support Co.*, 9 F.2d 311, 312 (2d Cir. 1925); accord *Topliff v. Topliff*, 145 U.S. 156, 161, 12 S.Ct. 825, 36 L.Ed. 658 (1892) (“It is not sufficient to constitute an anticipation that the device relied upon might, *by modification*, be made to accomplish the function performed by the patent in question, if it were not designed by its maker, nor adapted, nor actually used, for the performance of such functions.”) (emphasis added))”

Then the Court of Appeals made it plain why the rule of *Topliff* and *Wells* applied (851 F.3d at 1373-1374):

“Claim 1 is indeed an apparatus claim, and the ‘arranged to engage’ language could imply that the protruding surface on the flat side need not always actually engage the glenoid cavity surface. However, it must be at least capable of doing so. Here, element 27b’s protruding surface (in the Rambert prior art reference) cannot be

‘arranged to engage’ the glenoid cavity surface without removing element 27a. Prior art that ‘must be distorted from its obvious design’ does not anticipate a new invention. *Wells*, 53 F.2d at 539; *see also Topliff*, 145 U.S. at 161, 12 S.Ct. 825 (prior art that must be modified ‘to accomplish the function performed by the patent in question’ does not anticipate).”

Adopting a simple “capable of” standard for applying the law of anticipation under 35 U.S.C. 102(b) would be a drastic change in the law. The *Topliff* standard has existed for over a century. There was no change in this standard even when Section 102 was extensively remodeled in the America Invents Act of 2011.

But changing to a “capable of” standard is not the only point of concern in present matter.

The Court of Appeals’ lack of concern for precedent in the case at bar shows up also in its interpretation of the term “no stem” in Dr. Chudik’s claim. The Examiner had thought in the early days that the term “no stem,” meant “stemless.” He thought that that was a distinct “species” with “mutually exclusive characteristics.” The Court of Appeals, however, thought that the term meant a “separate component,” and thus that the protrusion 40 extending from the underside of Leonard et al.’s platen 24 was not a stem because it was still attached to 24. Accordingly, since the protrusion was not a “stem,” Leonard et al.’s implant met the “no stem” terminology of claim 5 and was an anticipation.

Just the words “no stem” by themselves would seem to be absolute and exclusive. Alone, they do not suggest any reservation, and Dr. Chudik’s claim 5 has no words tying “no stem” to another element which might or might not be associated with the humeral implant after, before or during the implant’s use. The Court of Appeals, however, without citing any specific passage, adopted a strained reading of Dr. Chudik’s detailed specification which limited “no stem” to a structure which includes a stem somewhere close by but unattached to the implant’s surface component. Not only is the Court’s reading tortured in itself, and contrary to the basis on which the “stemless” application was filed in the first place, it is also specifically contradicted in Dr. Chudik’s text. At paragraph 00150 the specification of the application states:

“The novel humeral implant 94 in accordance with the present invention is modular and includes a humeral surface 96 component, a roughly hemispheric shaped surface with a short central mating device 100, and a transhumeral stem 98 which fills the transhumeral portal 30 (Figure 15a-b). *Alternatively, a novel humeral surface 96, with no stem 98 may be used when warranted. Preferably, however, a novel humeral implant with two components 96, 98 is used.*” (emphasis added)

The same Court of Appeals has also recently held, in *In re Man Mach. Interface Tech. LLC*, 822 F.3d 1282 (Fed. Cir. 2016), that patent claims cannot be interpreted so broadly that the interpretation brings in a feature expressly *disclaimed* by the inventor:

“The broadest reasonable interpretation of a claim term cannot be so broad as to include a configuration expressly disclaimed in the specification.

* * * *

This court’s cases on BRI make clear that the proper BRI construction is not just the broadest construction, but rather the broadest reasonable construction in light of the specification. *Proxyconn*, 789 F.3d at 1298 (‘A construction that is unreasonably broad and which does not reasonably reflect the plain language and disclosure will not pass muster.’ (internal quotation marks and citations omitted)).”

The opinion in the present case cannot pass this test. Just looking at Leonard et al.’s extension 40 on the lower side of the platen 24 says, in everyday language, that extension 40 is a stem. Yet the Court of Appeals ruled that “the Board did not err in finding that Leonard discloses the ‘no stem’ limitation of claim 5.” No reason is given for such a departure. In fact, *Man Mach.* and its rule are not even mentioned.

Similarly, the Court of Appeals has not dealt with the rule which it followed previously in *Catalina Marketing International, Inc v. Coolsavings, Inc.*, 289 F.3d 801 (Fed. Cir. 2002). That is a precedential decision. Its holding was that a limiting term had to be observed when that term appeared in both the claim’s preamble and the body of the claim. Specifically, the prior decision held (289 F.3d at 810-811):

“While the phrase ‘located at predetermined sites such as consumer stores’ appears only in the preamble of Claim 1, this language appears in both the preamble and body of Claim 25. Hence, the applicants specifically included this language in the claim not once, but twice. By virtue of its inclusion in the body of Claim 25, this phrase limits claim 25. The court, therefore, must determine whether the district court’s construction of the disputed phrase is correct as a matter of law.”

Dr. Chudik’s claim 5 specifies a “humeral” implant in its preamble, and then continues using that term in the body of the claim, i.e., “a humeral surface component” and “fixation of the implant on a humeral head.” Yet the Court of Appeals dismisses distinguishing the Leonard et al.’s glenoid implant, saying that “The patentability of an apparatus claim ‘depends on the claimed structure, not on the use or purpose of that structure.’ *Catalina Mktg Int’l v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002);...” That is not what *Catalina* says (see above). Nevertheless, the Court of Appeals concludes, saying merely, “Thus, Dr. Chudik’s contention that his apparatus will be used in a humeral, as opposed to a glenoid, implant is not a patentable distinction, and cannot prevent Leonard from anticipating the claim.”

In sum, the Court of Appeals simply rejects *Topliff* and its progeny, blithely states that a structure which is clearly a stem is not a stem, and cites the wrong rule of claim construction from its earlier case, all without expressing any reason for not following the rules of stare decisis evident in the cases cited by Dr. Chudik.

The importance of the stare decisis doctrine has been repeatedly emphasized by this Court.

In *Payne v. Tennessee*, 501 U.S. 808, 828, 111 S.Ct. 2597, 115 L.Ed.2d 720 (1991) the doctrine is reviewed:

“*Stare decisis* is the preferred course because it promotes the evenhanded, predictable, and consistent development of legal principles, fosters reliance on judicial decisions, and contributes to the actual and perceived integrity of the judicial process. See *Vasquez v. Hillery*, 474 U.S. 254, 265-266, 106 S.Ct. 617, 624-625, 88 L.Ed.2d 598 (1986).

* * * * *

Considerations in favor of stare decisis are at their acme in cases involving property and contract rights, where reliance interests are involved. (citing cases)”

Justice Marshall, dissenting in *Payne*, nevertheless emphasized the doctrine too (501 U.S. at 848-849):

“Although the doctrine of stare decisis is not an ‘inexorable command,’ *Burnet v. Coronado Oil & Gas Co.*, 285 U.S. 393, 405, 52 S.Ct. 443, 446-447, 76 L.Ed. 815 (1932) (Brandeis, J., dissenting), this Court has repeatedly stressed that fidelity to precedent is fundamental to ‘a society governed by the rule of law’ (citing cases).

* * * * *

Appeal of Concerned Corporators of Portsmouth Savings Bank, 129 N.H. 183, 227, 525 A.2d 671, 701 (1987) (Souter, J., dissenting) (“[S]tare decisis...’is essential if case-by-case judicial decision-making is to be reconciled with the principle of the rule of law, for when governing legal standards are open to revision in every case, deciding cases becomes a mere exercise of judicial will, with arbitrary and unpredictable results” quoting *Thornburgh v. American College of Obstetricians and Gynecologists*, 476 U.S. 747, 786-787, 106 S.Ct. 2169, 2192-2193, 90 L.Ed.2d 779 (1986) (White, J., dissenting))

Consequently, this Court has never departed from precedent without ‘special justification.’ *Arizona v. Rumsey*, 467 U.S. 203, 212, 104 S.Ct. 2305, 2310-2311, 81 L.Ed.2d 164 (1984).”

See also, *Pearson v. Callahan*, 555 U.S. 223, 233, 129 S.Ct. 808, 172 L.Ed.2d 565 (2009), and similar emphasis in *Alleyne v. United States*, 133 S.Ct. 2151, 2164, 186 L.Ed.2d 314, 81 USLW 4444 (2013) (Sotomayor, J., concurring, joined by Ginsburg, J. and Kagan, J.):

“While stare decisis is not an ‘inexorable command,’ *Hohn v. United States*, 524 U.S. 236, 251, 118 S.Ct. 1969, 141 L.Ed.2d 242 (1998) (internal quotation marks omitted), it is “a basic self-governing principle within the Judicial Branch, which is entrusted with the sensitive and difficult task of fashioning and

preserving a jurisprudential system that is not based upon ‘an arbitrary discretion,’ *Patterson v. McLean Credit Union*, 491 U.S. 164, 172, 109 S.Ct. 2363, 105 L.Ed.2d 132 (1989) (quoting The Federalist, No. 78, p. 490 (H. Lodge ed. 1888) (A. Hamilton)). *** To protect these important values, we require a ‘special justification’ when departing from precedent. *Dickerson v. United States*, 530 U.S. 428, 443, 120 S.Ct. 2326, 147 L.Ed.2d 405 (2000).”

The identical point was made in *Johnson v. United States*, 135 S.Ct. 2551, 2575, 192 L.Ed.2d 569 (2015) (Alito, J., dissenting): “There must be good reasons for overruling a precedent, and there is none here.”

These views all call for review of the Court of Appeals’ dismissal of Dr. Chudik’s patent application.

CONCLUSION

Dr. Chudik’s claim 5 accurately describes the humeral implant without a stem which he invented. In rejecting that claim, the Court of Appeals admits that the claim does not literally describe the Leonard et al. glenoid implant, because the glenoid implant’s surface on which a humeral head slides is not immediately configured for long-lasting humeral head fixation there. However, the Court of Appeals finds that it is capable of being affixed to the humeral head, and then turns a blind eye to what changes such a fixation will cause throughout Leonard et al.’s glenoid implant. The *Topliff* decision forbids finding an identity to Dr. Chudik’s claim in those circumstances, but the Court of Appeals has turned aside from that decision.

The Court of Appeals has unreasonably found that Claim 5's "no stem" requirement is met by the glenoid implant illustrated by Leonard et al., noticeably contrary to the Patent Office Examiner's initial reading. Moreover, Dr. Chudik's specification actually contradicts adding any stem to the claimed implant.

Plus, the Court of Appeals has also found that claim 5 covers both a humeral implant and a glenoid implant, despite its earlier directions that a claim formulated as claim 5 is should not be read with an ambivalent preamble.

All of these conclusions defy the doctrine of stare decisis as it applies to the prosecution of Dr. Chudik's patent application, and the Court of Appeals offers no excuse. Looking beyond Dr. Chudik's immediate situation, denying a patent application using the criteria illustrated by the decision below endangers new applications and even existing patents. The practice should not be allowed to expand. Dr. Chudik respectfully petitions this Court for a writ of certiorari to correct it.

Respectfully submitted,

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APPENDIX

**APPENDIX A — OPINION OF THE UNITED
STATES COURT OF APPEALS FOR THE
FEDERAL CIRCUIT, DATED AUGUST 25, 2017**

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

NOTE: This disposition is nonprecedential.

2016-2673

IN RE: STEVEN C. CHUDIK,

Appellant

Appeal from the United States Patent and Trademark
Office, Patent Trial and Appeal Board in No. 13/068,309.

Decided: August 25, 2017

Before LOURIE, MOORE, and HUGHES, *Circuit Judges*.
HUGHES, *Circuit Judge*.

Dr. Steven Chudik appeals from the Patent Trial and
Appeal Board's determination that claims 5-15 of U.S.
Patent Application 13/068,309 are not patentable over
the prior art. Because substantial evidence supports the
Board's determination, we affirm.

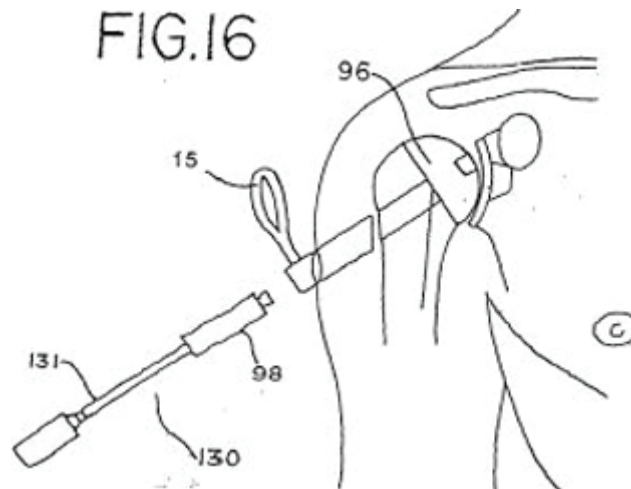
I

The '309 application is directed to a humeral implant
used in shoulder replacement surgery. The specification,
as shown in Figure 16 below, discloses a humeral implant
having a humeral surface 96 that is shaped to match the

2a

Appendix A

anatomy of the humeral head, while stem 98 engages the side facing away from the glenoid cavity.



Independent claim 5 reads as follows:

5. A humeral implant comprising a humeral surface component having a non-articular surface configured for long-lasting fixation of the implant on a humeral head and no stem.

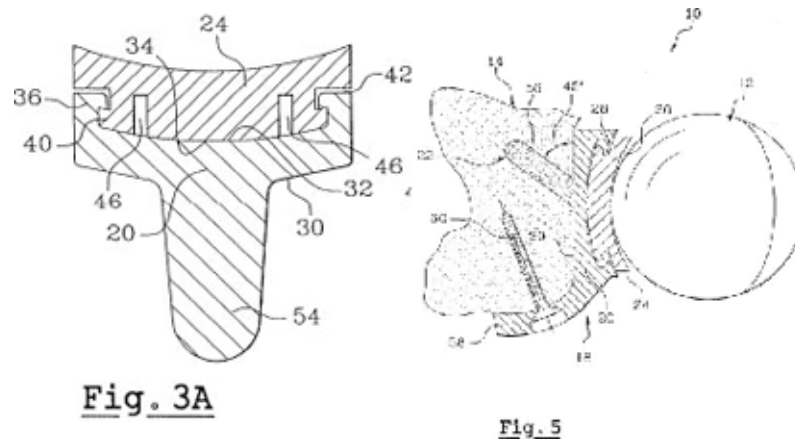
The Examiner rejected claim 5 under 35 U.S.C. § 102(b) as anticipated by Leonard (French Patent Pub. No. 2825263), and the Board affirmed the Examiner. Dr. Chudik appeals from the Board's decision. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

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Appendix A

II

Because Dr. Chudik’s arguments for the patentability of dependent claims 6-15 depends on claim 5, we address only claim 5. We review the Board’s legal conclusions de novo and its factual findings for substantial evidence. *Rambus Inc. v. Rea*, 731 F.3d 1248, 1251 (Fed. Cir. 2013). Dr. Chudik first challenges the Board’s finding that Leonard discloses the “no stem” limitation of claim 5. Leonard discloses shoulder implants for attachment in the glenoid cavity. In one embodiment, as depicted in Figures 3A and 5 below, the implant comprises a platen 24 with portion 40 that is placed between a base 20 and the head of the humerus 12.



According to Dr. Chudik, portion 40 in Leonard is a “stem” because it extends away from the main body of platen 24. We disagree. The ‘309 specification describes the stem as a physically distinct and separate component from the

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implant. J.A. 249 ¶ 155. In Leonard, portion 40 is a part of and not separate from platen 24. Therefore, the Board did not err in finding that Leonard discloses the “no stem” limitation of claim 5.

Next, Dr. Chudik argues that Leonard does not disclose a “non-articular surface configured for long-lasting fixation” as required by claim 5. Dr. Chudik contends that Leonard discloses a sliding contact between the humeral head and the platen, and that using screws and cements to achieve “long-lasting fixation” would change the structure of Leonard. Contrary to Dr. Chudik’s argument, claim 5 requires only a non-articular surface that is *configured for* long-lasting fixation. As a result, whether Leonard discusses a sliding contact is not relevant to whether Leonard is capable of long-lasting fixation. Dr. Chudik has not pointed to any evidence in the record that Leonard is incapable of long-lasting fixation. He also argues that using screws and cements to achieve long-lasting fixation would result in a joint with a limited range of motion—but claim 5 contains no limitation regarding range of motion. Therefore, substantial evidence supports the Board’s conclusion.

Finally, Dr. Chudik argues that Leonard does not disclose the “humeral implant” limitation of claim 5 because Leonard is directed to a glenoid implant and not a humeral implant. The patentability of an apparatus claim “depends on the claimed structure, not on the use or purpose of that structure.” *Catalina Mktg. Int’l v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002); *see also In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997)

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(“It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.”) Thus, Dr. Chudik’s contention that his apparatus will be used in a humeral, as opposed to a glenoid, implant is not a patentable distinction, and cannot prevent Leonard from anticipating the claim.

We have considered Dr. Chudik’s remaining arguments but find them unpersuasive. Because the Board applied the correct law and because its decision is supported by substantial evidence, we affirm the Board’s decision.

AFFIRMED

No costs.

**APPENDIX B — DECISION OF THE UNITED
STATES PATENT AND TRADEMARK OFFICE,
FILED MAY 9, 2016**

UNITED STATES PATENT
AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEVEN C. CHUDIK

Appeal 2014-003518
Application 13/068,309
Technology Center 3700

Before PHILIP J. HOFFMANN, CYNTHIA L. MURPHY,
and KENNETH G. SCHOPFER, *Administrative Patent
Judges*.

MURPHY, *Administrative Patent Judge*.

DECISION ON APPEAL

The Appellant (Steven C. Chudik) appeals under 35 U.S.C. § 134 from the Examiner's rejections of claims 5–15. We have jurisdiction over this appeal under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

The Appellant's invention relates to “implants for orthopedic surgery and, more specifically, to rotator cuff

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sparing procedures and associated devices for shoulder replacement surgery.” (Spec ¶ 2.)

*Illustrative Claim*¹

5. A humeral implant comprising a humeral surface component having a non-articular surface configured for long-lasting fixation of the implant on a humeral head and no stem.

References

Arcand	US 6,368,353 B1	Apr. 9, 2002
Wiley	US 2004/0122519 A1	June 24, 2004
Maroney	US 2004/0193276 A1	Sept. 30, 2004
Cyprien	US 2004/0230311 A1	Nov. 18, 2004
Winslow	US 7,585,327 B2	Sept. 8, 2009
Leonard	FR 2825263	Dec. 6, 2002

Rejections

I. The Examiner rejects claims 5–15 under 35 U.S.C. § 112, second paragraph, as indefinite. (Final Action 3.)

II. The Examiner rejects claim 5 under 35 U.S.C. § 102(b) as anticipated by Leonard. (*Id.* at 5.)

1. This illustrative claim is quoted from the Claims Appendix (“Claims App.”) set forth on pages 24- 25 of the Appeal Brief.

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III. The Examiner rejects claims 6–9 under 35 U.S.C. § 103(a) as unpatentable over Leonard in view of Cyprien. (*Id.*)

IV. The Examiner rejects claim 10 under 35 U.S.C. § 103(a) as unpatentable over Leonard in view of Arcand. (*Id.* at 6.)

V. The Examiner rejects claim 11 under 35 U.S. C. § 103(a) as unpatentable over Leonard in view of Winslow. (*Id.*)

VI. The Examiner rejects claims 12, 13, and 15 under 35 U.S.C. § 103(a) as unpatentable over Leonard in view of Wiley. (*Id.* at 7.)

VII. The Examiner rejects claim 14 under 35 U.S.C. § 103(a) as unpatentable over Leonard in view of Maroney. (*Id.*)

ANALYSIS

Claim 5 is the sole independent claim on appeal, with the rest of the claims on appeal (i.e., claims 2- 15) depending therefrom. (*See* Claims App.) Independent claim 5 is directed to “[a] humeral implant” comprising “a humeral surface component.” (*Id.*)

Rejection I

Independent claim 5 recites that the humeral surface component, and thus, the implant, has “a non-articular

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surface.” (Claims App.) However, independent claim 5 does not recite an “articular surface.” (*Id.*) According to the Examiner, “to recite that the implant is a ‘humeral implant’ and have no structure to define such an articulating surface is indefinite and contrary to the choice of terminology.” (Final Action 4.)

The Appellant argues that the Examiner has failed “to point to any statement in the [S]pecification saying that ‘the articular surface and its structure’ are essential elements of the invention recited in claim 5.” (Appeal Br. 17.) We agree with the Appellant’s position that the Examiner has not established that a structure must comprise an articular surface in order to be considered a “humeral implant.” Independent claim 5 is indeed broad enough to cover a structure without an articular surface, for example, a structure used in conjunction with another humeral implant (or other separate element) having an articular surface. However, this is a matter of breadth, not indefiniteness.²

Independent claim 5 also recites that the non-articular surface is “configured for long-lasting fixation of the implant on a humeral head.” (Claims App.) According to the Examiner, “[t]he phrase ‘long-lasting’ in claim 5 is relative terminology which renders the claim indefinite.” (Final Action 4.) The Examiner implicates that one of ordinary skill in the art would not understand whether “long-lasting” is measured in “weeks, months, years, etc.” (*Id.*)

2. See *In re Johnson* , 558 F.2d 1008, 1016 n. 17 (CCPA 1977) (Even “undue breadth is not indefiniteness”).

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The Appellant argues that one of ordinary skill in the art “would not find the term indefinite.” (Appeal Br. 18.) We are persuaded by the Appellant’s position because one of ordinary skill in the art would understand the bounds of the term “long lasting” in light of the Specification.³ One of ordinary skill in the art would understand that, in the context of shoulder-replacement implants, “long lasting” would be measured in years after completion of the surgery as opposed to, for example, trial implants inserted during the surgery. (*See e.g.*, Spec. ¶ 132.)

The Examiner also maintains that independent claim 5 “fails to define how some vague structural **surface** render[s] the implant long-lasting.” (Final Action 4.) However, as pointed out by the Appellant, independent claim 5 does not recite that the implant is “long-lasting” (*see* Appeal Br. 18); independent claim 5 only recites that the non-articular surface is “configured for long-lasting fixation of the implant on a humeral head.” (Claims App.) This claim is indeed broad enough to encompass a structure that requires additional fixation elements (e.g., screws and/or cement) for long-lasting fixation of the implant on a humeral head. However, again, this is a matter of breadth, not indefiniteness.

Thus, we do not sustain the Examiner’s rejection of independent claim 5, and claims 2-15 depending therefrom, under 35 U.S.C. § 112, second paragraph.

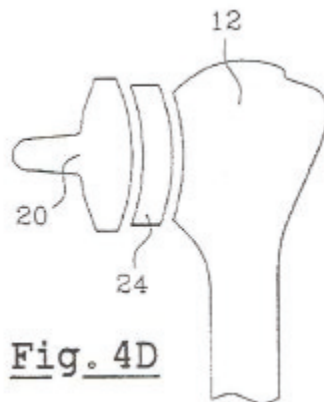
3. *See Miles Labs, Inc. v. Shandon, Inc.* 997 F.2d 870, 875 (Fed. Circ. 1993) (“The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification”).

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Rejection II

As indicated above, independent claim 5 is directed to a humeral implant comprising “a humeral surface component” having “a non-articular surface configured for long-lasting fixation of the implant on a humeral head.” (Claims App.) The Examiner finds that Leonard shows, in Figure 4D (reproduced below), “a humeral implant having a humeral surface component 24.” (Final Action 5.)



Leonard’s Figure 4D shows a platen 24 having a convex surface matching a concave profile in the head of a humerus 12. This figure and other drawings in Leonard show that platen 24 is connected to a separate base 20 having a stem 54, which is screwed to the glenoid cavity 14. (*See e.g.* Leonard, Figs. 1, 3A and 3B.)

The Appellant argues all of Leonard’s drawings “show a glenoid implant,” and “there is no showing anywhere” that Leonard’s platen 24 is a humeral implant. (Appeal

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Br. 19.) According to the Appellant, if the Examiner's use of the term "humeral surface component" is meant "to suggest that element 24 is implanted on the humerus," this "is not accurate." (*Id.* at 19-20.) The Appellant appears to be asserting that the recitation of a "humeral implant" requires the actual "implantation" of the claimed component on a humeral head. (*See* Reply Br. 5.)

We are not persuaded by this argument because independent claim 5 does not require the actual implantation of the claimed component on a humeral head. Such an interpretation would not be not be consistent with the Specification, which conveys that a structure is considered an "implant" prior to its implantation in a patient's body. For example, the Specification calls the device a "humeral implant" prior to its insertion into the patient's shoulder. (*See e.g.* Spec. ¶¶ 113, 118, 120.)

Accordingly, while the Appellant may be correct that Leonard does not disclose using platen 24 as a humeral implant, the absence of such disclosure does not defeat a finding of anticipation. To avoid anticipation, an apparatus claim (i.e., independent claim 5) must be distinguished from the prior art in terms of structure. "If the prior art structure is capable of performing the intended use [i.e., serving as a humeral implant], then it meets the claim." (Answer 10.)⁴

4. *See In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). In *Schreiber*, the Appellant argued that its claim called for a dispensing top that could dispense popcorn from an open-ended popcorn container, and the prior art reference did not disclose that its dispensing top could do so. *Id.* at 14 77. The Federal

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The Appellant argues that the Examiner is saying “that the nonarticulating side of [Leonard’s platen 24], the side with the ‘portion 40’ [i.e., the glenoid side] is capable of being affixed to the head of a humerus.” (Reply Br. 8.) However, the Examiner states that “it is common knowledge to surgeons, that if a diseased or deteriorating head needs to be resurfaced, it can be prepared as such as the humerus head shown for the humeral surface component (24) is able to replace that section of the head removed in the embodiment shown in Fig. 4D of Leonard.” (Answer 13.) Thus, we understand the Examiner to be saying that the humeral-side of Leonard’s platen 24 is configured for (i.e., capable of) long-lasting fixation on the removed section of humeral head 12.⁵

The Appellant argues that the concept of Leonard’s platen 24 having a side capable of fixation on humeral head “is speculative and has no record support in this application.” (Reply Br. 8.) However, the Examiner explains that Leonard shows that “[s]crews and cements are well known means” that can be used to “fix” a component on a surface of bone. (Answer 14.) The Appellant does not adequately address why Leonard’s platen 24 is not capable of being affixed (e.g., via cement) to a humeral head with

Circuit held that “[a]lthough Schreiber is correct that [the prior art reference] did not address the use of the disclosed structure to dispense popcorn,” the absence of such disclosure “does not defeat” a finding of anticipation. *Id.*

5. That being said, it appears that a humeral head could instead be resurfaced into a shape complementary to that of the glenoid side of Leonard’s platen 24. (See e.g., Leonard Figs. 4A, 4B, and 4E.)

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complementary resurfacing. We agree with the Appellant that the recital of “configured for long-lasting fixation” may impose structural limitations (*see* Appeal Br. 22) but, due to the breadth of independent claim 5, Leonard meets such structural limitations. “[I]f someone such as a surgeon or orthopedic doctor desired to use bone cement and secure the implant to the bone, it is capable of being done and would establish the implant as ‘longlasting.’” (Final Action 2.)

The Appellant argues that Leonard’s platen 24 has “feet” which are “grasped by the rest of the glenoid mounting members to fix element 24 in the glenoid.” (Appeal Br. 19.) Again, while this may augment the Appellant’s position that Leonard does not disclose using platen 24 as a humeral implant, it does not distinguish the prior art in terms of structure. The Appellant does not, for example, assert that these feet somehow render Leonard’s platen 24 structurally incapable of performing as a humeral implant and/or humeral surface component.

Independent claim 5 also recites that the humeral surface component has “no stem.” (Claims App.) The Appellant argues that, in all of Leonard’s drawings, “there is a stem.” (Appeal Br. 19.) As discussed above, Leonard does indeed show that platen 24 is connected to a base 20 having a stem 54. (*See e.g.*, Leonard Fig. 1.) However, as explained by the Examiner, independent claim 5 only requires the humeral surface component (i.e., platen 24) to not have a stem. (*See* Answer 10–11.) Independent claim 5 does not preclude the humeral implant from having another component with a stem and/or preclude

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the humeral implant from being used in conjunction with another humeral implant (or other separate element) having a stem.

More succinctly, as discussed above in our indefiniteness analysis, independent claim 5 is broad enough to cover a stem-less implant structure with a surface requiring fixation elements (e.g., screws and/or cement) for long-lasting fixation of the implant on a humeral head. The Examiner finds that Leonard's platen 24 is a stem-less implant structure having such a surface (*see* Final Action 2-3, 5; Answer 10-14); and the Appellant's arguments do not address why this finding by the Examiner is flawed (*see* Appeal Br. 19-22; Reply Br. 5-8).

Thus, we sustain the Examiner's rejection of independent claim 5 under 35 U.S.C. § 102(b) as anticipated by Leonard.

Rejections III-VII

Claims 6-15 depend from independent claim 5 and recite additional features of the humeral surface component, and particularly its non-articular surface. (*See* Claims App.) The Examiner determines that the humeral implants recited in the dependent claims would have been obvious over Leonard in combination with other prior art references. (*See* Final Action 5-7.) As discussed above, Leonard's failure to teach using platen 24 as a humeral implant and/or as a humeral surface component does not defeat an anticipation rejection. But this non-teaching could factor into whether it would have been obvious to

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incorporate features of the humeral surface component shown in the secondary references into Leonard's platen 24.

Here, however, the Appellant argues only that Leonard's component "has a stem to hold it in place, the Examiner has already held that such a construction is 'patentably distinct.'" (Appeal Br. 22.) As discussed in our analysis above, Leonard's component 24 does not have a stem, as the illustrated stem 54 is part of a separate base component 20. (*See e.g.*, Leonard Fig. 1.) As such, we are not persuaded by the Appellant's position that the Examiner errs in determining that humeral implant recited in dependent claims 6–15 would not have been obvious over the prior art.

Thus, we sustain the Examiner's rejections of claims 6–15 under 35 U.S.C. § 103(a) as unpatentable over Leonard in view of Cyprien, Arcand Winslow, Wiley, or Maroney.

DECISION

We REVERSE the Examiner's rejection of claims 5–15 under 35 U.S.C. § 112.

We AFFIRM the Examiner's rejections of claims 5–15 under 35 U.S.C. § 102 and § 103.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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**APPENDIX C — OPINION OF THE UNITED
STATES COURT OF APPEALS FOR THE
FEDERAL CIRCUIT, FILED NOVEMBER 6, 2017**

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2016-2673

IN RE: STEVEN C. CHUDIK,

Appellant.

Appeal from the United States Patent and Trademark
Office, Patent Trial and Appeal Board in No. 13/068,309.

ON PETITION FOR PANEL REHEARING
AND REHEARING *EN BANC*

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK,
MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN,
HUGHES, and STOLL, *Circuit Judges*.

PER CURIAM.

ORDER

Appellant Steven C. Chudik filed a combined petition for panel rehearing and rehearing *en banc*. A response to the petition was invited by the court and filed by appellee Joseph Matal. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing *en banc* was referred to the circuit judges who are in regular active service.

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Appendix C

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing *en banc* is denied.

The mandate of the court will issue on November 13,
2017.

FOR THE COURT

November 6, 2017

Date

/s/ Peter R. Marksteiner

Peter R. Marksteiner

Clerk of Court

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**APPENDIX D — FINAL REJECTION, UNITED
STATES PATENT AND TRADEMARK OFFICE,
FILED DECEMBER 28, 2012**

UNITED STATES PATENT
AND TRADEMARK OFFICE

* * *

Status

1) ☒ Responsive to communication(s) filed on *26
November 2012*.

2a) ☒ This action is **FINAL**.

2b) ☐ This action is non-final.

* * *

Disposition of Claims

5) ☒ Claim(s) 5-15 is/are pending in the application.

* * *

7) ☒ Claim(s) 5-15 is/are rejected.

* * *

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 11/26/12 have been fully
considered but they are not persuasive. In response to

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applicant's argument that Leonard et al. has a humeral implant not fastened on the humeral head, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Clearly if someone such as a surgeon or orthopedic doctor desired to use bone cement and secure the implant to the bone, it is capable of being done and would establish the implant as "long-lasting". Just because the reference is silent as to whether the implant is attached to the humeral head is irrelevant to the issue of patentability of the product. Methods of use are not at issue here and must not be confused with establishing what is novel and what is not.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine any of the teaching references with Leonard since it is alleged that the prior art teachings make the Leonard device inoperable, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, if one was to provide the implant with a non-articular surface

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“configured for long-lasting fixation” it would certainly not make the device inoperable because i.e. Fig. 5 shows a component of a humeral prosthesis that is “fixed” to be “long-lasting” and thus, if one was to cement the structure or component 24 to the humeral head, this still provides an articular surface for the other component 20 to move with as seen in Fig 40. Applicant is mistaken.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S. C. 112(b):

(B) CONCLUSION.-The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S. C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-15 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. Note claims 6-15 are rejected for being dependent upon a rejected base claim.

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Claim 5 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the location and structure to define a “non-articular surface” along with the “articular surface” and its structure because a humeral joint is an articulating joint and to recite that the implant is a “humeral implant” and have no structure to define such an articulating surface is indefinite and contrary to the choice of terminology. According to Applicant’s specification (paragraph 151) the articulating surface is spherically or elliptically shaped whereas the non-articulating surface is stated to be concave.

The phrase “long-lasting” in claim 5 is relative terminology which renders the claim indefinite. The clause “long-lasting” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Is one of ordinary skill in the art to consider “long-lasting” in terms of weeks, months, years etc.? However, on a more critical note the claim also fails to define how can some vague structural **surface** render the implant long-lasting?

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Leonard et al. (FR 2825263). Fig. 40 shows a humeral implant having a humeral surface component **24** and no stem. Please note the limitation of “non-articular surface configured for long-lasting fixation of the implant” is a functional limitation because “non-articular surface” is a non-descriptive limitation of defining a feature without positively defining it. Further in regards to statements of intended use and other functional statements (e.g., configured for long-lasting fixation) does not impose any structural limitations on the claims distinguishable over the device of **Leonard**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. (FR 2825263)

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in view of Cyprien et al. (2004/230311). Leonard et al. is explained supra. However, Leonard does not explicitly state the use of biologic or autologous material with the implant. Cyprien et al. teach (paragraph 17) the use of biologic autologous material for a shoulder implant. It would have been obvious to one of ordinary skill in the art to use biologic autologous material as taught by Cyprien et al. with the humeral implant of Leonard et al. such that it enhances the stabilization of the implant in the body. Regarding claims 8,9 Leonard does not disclose the use of bony ingrowth material or cells or tissue allograft. Cyprien teaches (paragraph 11) the use of bony ingrowth material or coating that includes progenitor cells to enhance the implant stabilization. It would have been obvious to one of ordinary skill in the art to use the bony ingrowth coating that has cells as taught by Cyprien et al. with the humeral implant of Leonard et al. such that it enhances the stabilization of the implant in the body.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. (FR 2825263) in view of Winslow (7585327). Leonard et al. is explained supra. However, Leonard does not explicitly state the use of hydroxyapatite coating with the implant. Winslow teaches (col. 2, lines 40-43, col. 3, lines 39-44) the use of hydroxyapatite material on the shoulder implant. It would have been obvious to one of ordinary skill in the art to use a hydroxyapatite coating on the non-articular surface as taught by Winslow with the humeral implant of Leonard et al. such that it enhances the adhesion of the implant to the site, see Winslow.

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Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. (FR 2825263) in view of Arcand (6368353). Leonard et al. is explained supra. However, Leonard does not explicitly state the use of bone morphogenic protein with the implant. Arcand teaches (col. 8, lines 49-53) the use of bone morphogenic protein on the implant. It would have been obvious to one of ordinary skill in the art to use incorporate bone morphogenic protein as taught by Arcand with the humeral implant of Leonard et al. such that it enhances the fixation of the implant to the site and promotes ingrowth of new tissue, see Arcand.

Claims 12, 13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. (FR 2825263) in view of Wiley et al. (2004/122519). Leonard et al. is explained supra. However, Leonard does not explicitly state the use of trabecular metal or porous metal or tantalum for the implant. Wiley et al. teach (paragraph 23) the use of trabecular metal or porous metal or tantalum as a material to use with a shoulder implant for biocompatibility. It would have been obvious to one of ordinary skill in the art to use trabecular or porous metal or tantalum as taught by Wiley et al. with the humeral implant of Leonard et al. such that it enhances the body acceptance of the implant and ingrowth for stabilization.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. (FR 2825263) in view of Maroney et al. (2004/193276). Leonard et al. is explained supra. However, Leonard does not explicitly state the use of a porous metal coating for the non-articular surface of

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the implant. Maroney et al. teach (Fig. 12, paragraph 83) the use of a porous metal coating **870** on the non-articular surface **834**. It would have been obvious to one of ordinary skill in the art to use the porous metal coating as taught by Maroney et al. with the humeral implant of Leonard et al. such that it promotes bony ingrowth and enhances fixation at the site, see Maroney.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **BRIAN PELLEGRINO** whose telephone number is

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(571)272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Sweet can be reached on 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571 -273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian E Pellegrino/
Primary Examiner, Art Unit 3738