

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

_____)	
HOWMEDICA OSTEONICS CORP.,)	
)	
) Plaintiff,)	
)	
v.)	Civil Action No. 00-1167 (GEB)
)	
WRIGHT MEDICAL TECHNOLOGY,)	MEMORANDUM OPINION
INC.)	
)	
) Defendants.)	
_____)	

BROWN, Chief Judge

This matter comes before the Court upon the following three motions:

(1) the motion for summary judgment of defendant Wright Medical Technology, Inc. (“Wright”) (Dkt. No. 131); (2) the cross-motion for summary judgment of plaintiff Howmedica Osteonics Corp. (“Howmedica”) (Dkt. No. 132); and (3) Wright’s motion to strike the allegedly untimely expert declaration of Stephen D. Cook and the declaration of Alfred Zarnowski. (Dkt. No. 139).

Each party opposes its adversary’s motion for summary judgment, and Howmedica opposes Wright’s motion to strike. For the reasons that follow, Wright’s motion for summary judgment is granted, Howmedica’s motion for summary judgment is denied, and Wright’s motion to strike is denied.

I. Background

A. Facts

Howmedica and Wright are competitors in the prosthetic knee implant industry.

Howmedica originally filed this case in 2000, asserting that certain of Wright's prosthetic knee implants infringe claims 15 and 18 of U.S. Patent No. 5,824,100 (the '100 patent). Wright moves for summary judgment claiming that the '100 patent is invalid in light of a prior art patent issued to Dr. Anne Hollister as U.S. Patent No. 5,133,758 (the "'758 patent" or the "Hollister patent").

1. Background of the '100 patent

The '100 patent is directed to artificial knee prosthesis or implants for restructuring the knee joint. The "total knee replacement" of the '100 patent includes a femoral component 22 to be attached to the femur (*i.e.*, thigh bone) and a tibial component 24, which is attached to the tibia (*i.e.*, shin bone). The femoral component 22 includes an articular surface 26 at its lower edge which is designed to engage with a corresponding articular surface 28 on the tibial component 24. As explained in the specification of the '100 patent, the articular surface 26 of the femoral component 22 has a region 92 in which the radius of curvature 90 (about the center of curvature 94) is constant, *i.e.*, a circular arc. ('100 patent col. 3 ll. 52-55).

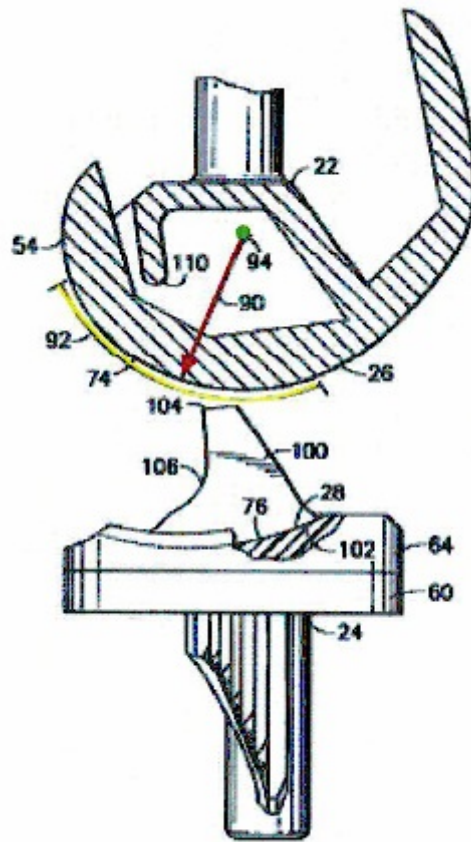


FIG.3

The natural human knee, which faces both front (anterior) and back (posterior), actually bends in both directions. (Pl.'s Br. at 3). When we sit on a chair or crouch in anticipation of jumping, we perform a modest degree of knee articulation in the “posterior” direction. If we attempt to touch our toes when crouching, we ask our knees to “hyperextend” in the “anterior” or “distal” direction. (*Id.*) An essential aspect of the invention of the '100 patent is described in the following portion of the specification:

As best seen in FIG. 3, anterior-posterior surface profile contour 74 of knee prosthesis 20 includes an essentially constant anterior-posterior articular radius 90 throughout a region 92 of each condylar element 54. The regions 92 include those portions of the articular surfaces 26 of the condylar elements 54 which contact the bearing member 64 during articulation throughout a portion of the full range of flexion of the knee prosthesis 20, between hyperextension and full flexion, the portion of the full range being the primary range of flexion between a hyperextended position and a flexed position, defining the portion of the full range of flexion within which most normal activities occur. Thus, the primary range of flexion, as depicted

in FIGS. 4 through 7, is from a hyperextended position of about -15°, as seen in FIG. 5, to a flexed position of about 75°, as seen in FIG. 7.

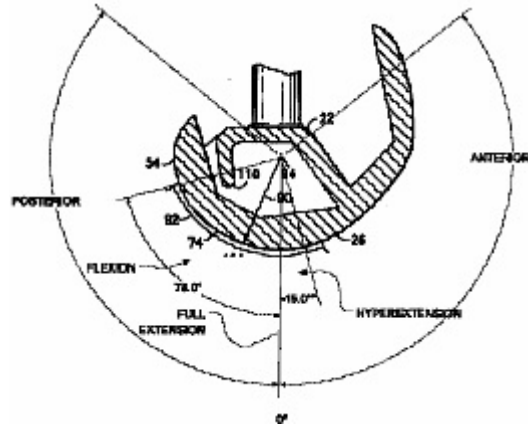
(’100 Patent col.3 ll.52-67 (emphasis added).) The emphasized portions describe a feature that Howmedica alleges that the prior art lacks: a surface of constant radius (*i.e.*, circular) on *both* the anterior and posterior portions of the femoral component.

The only independent claim of the ’100 Patent at issue is Claim 15, which reads as follows:

15. In a knee prosthesis for replacing the natural knee, the knee prosthesis having a femoral component and a tibial component, the tibial component including a bearing member and the femoral component including at least one condylar element for confronting and engaging the bearing member to accomplish articulation of the knee prosthesis throughout a range of flexion, including a primary range of flexion between a hyperextended position and a flexed position, the engagement between the condylar element of the femoral component and the bearing member of the tibial component ordinarily taking place at a contact area along articular surface areas of the condylar element and the bearing member, the improvement comprising:

anterior-posterior surface profile contours along the condylar element and the bearing member, the anterior-posterior surface profile contour along the condylar element having an essentially constant anterior-posterior articular radius throughout the articular surface area of the condylar element which contacts the bearing member during articulation throughout the primary range of flexion [-15° of hyperextension to +75° of flexion], the anterior-posterior articular radius having an origin lying generally along a line extending laterally between the medial and lateral collateral ligament attachment points on the femur of the natural knee.

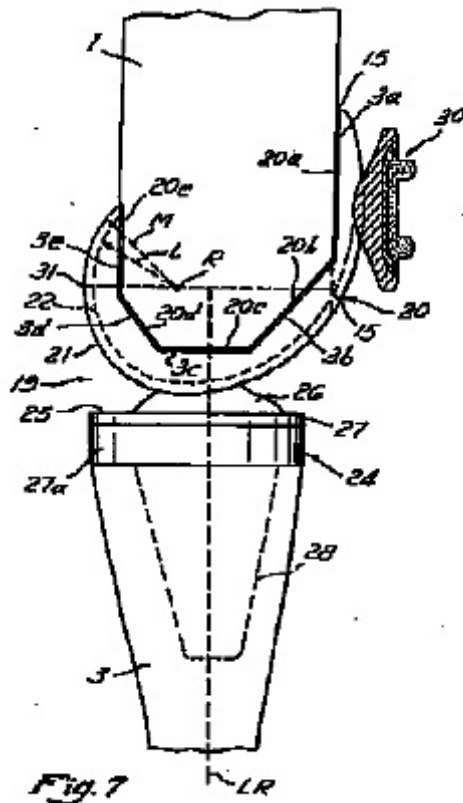
The Court has previously construed the term “primary range of flexion” as used in the ’100 patent to mean “-15° of hyperextension to +75° of flexion.” (Dkt. No. 98, at 12). As described and claimed in the ’100 Patent, the invention is concerned with the surface geometry of the prosthesis in both the posterior and anterior portions of the implant, and that surface contour of the “condylar element” must have “an essentially constant . . . articular radius . . . throughout the primary range of flexion [*i.e.*, -15° of hyperextension to +75° of flexion].”



It is Howmedica's contention that the prior art Hollister patent does not disclose a constant radius in the anterior region where hyperextension takes place. (Pl.'s Br. at 11-13).

2. *Background of the Hollister Patent*

Wright alleges that the '100 patent is invalid in view of the Hollister patent, which will be discussed in detail here. The parties agree that the Hollister patent is prior art to the '100 patent. (Final Pretrial Order at 12, ¶ 40). Like figure 3 of the '100 patent, figure 7 of the Hollister patent is a cross-section illustration showing the surface at issue:



There are three relevant features that the Hollister patent discloses. First, the Hollister patent teaches that the lower portion of the femoral component has a circular exterior surface across the area that contacts the tibial component. The Hollister patent explains that “[t]he radii of curvature of the posterior part of the two condyles are circular, when viewed perpendicularly to the FE axis, through a sweep of approximately 135 degrees.” (’759 Patent col.4 ll.2-5) (emphasis added).

Second, the Hollister patent teaches that the axis of the constant radius is found on a horizontal line that could be drawn between the points of attachment of the MCL and LCL to the femur of the natural knee, as follows:

In the natural human knee, this fixed axis of flexion-extension, (hereinafter “FE”)

axis is directed from anterior-superior on the medial condyle of the distal femur to posterior-inferior on the lateral condyle and passes through the origins of the medial and lateral collateral ligaments.

(*Id.* at col. 2 ll. 52-57) (emphasis added).

Third and finally, the Hollister patent explains that the constant radius extends to “all” degrees of flexion the natural knee can accomplish. It reads:

The radii of curvature of the posterior and distal portions of the medial condyle portion M and the posterior and distal portions of the lateral condyle portion L are circular through a sweep of over 120 degrees, and ideally a sweep of approximately 135 degrees. Thus, the natural movement of the anatomic knee is mimicked in the instant prosthetic knee.

(*Id.* at col. 7 ll. 52-59) (emphasis added). The Hollister patent discloses that the surface of the femoral component is “circular” (*i.e.*, of a constant radius) within a sweep of 120 degrees, mimicking the movement of the natural knee. (*Id.*) Howmedica stipulated in the Final Pretrial Order that “[t]he femoral component disclosed in the ’758 patent includes a primary range of flexion *between a hyperextended position and a flexed position.*” (Final Pretrial Order at 13, ¶ 44) (emphasis added).¹ In the same pretrial order, Howmedica also confirmed that it understood “the primary range of flexion” to mean “the region where most normal activities of daily living occur.” (*Id.* at 17, ¶ 5).

B. Procedural History

On November 29, 2005, this Court issued a *Markman* Order construing certain disputed terms in claims 15 and 18 of the ’100 patent. In particular, the Court construed one term in a manner that narrowed the scope of the asserted claims. Following the *Markman* Order,

¹ Stipulations in the Pre-Trial Order, like other concessions in pleadings, are judicial admissions that bind the party who makes them. *Berckley Inv. Group, Ltd. v. Colkitt*, 455 F.3d 195, 211 (3d Cir. 2006).

Howmedica stipulated that Wright did not infringe the '100 patent based upon the Court's interpretation of that term. On appeal, the United States Court of Appeals for the Federal Circuit subsequently reversed this Court's construction of that claim term, ruling that the claims should be interpreted more broadly, and remanded the case. *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337 (Fed. Cir. 2008).

On February 6, 2009, Wright filed the instant motion for summary judgment alleging that the '100 patent is invalid in light of the Hollister patent. On March 27, 2009, Howmedica cross moved for summary judgment on the grounds that the '100 patent is not anticipated. Wright filed a motion to strike a portion of the factual record that was submitted with Howmedica's motion, and all matters were fully briefed by June 26, 2009.

II. Discussion

A. Legal Standard

A party seeking summary judgment must “show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Hersh v. Allen Prods. Co. Inc.*, 789 F.2d 230, 232 (3d Cir. 1986). The threshold inquiry is whether there are “any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (noting that no issue for trial exists unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict in its favor). In deciding whether triable issues of fact exist, the court must view the underlying facts and draw all reasonable inferences in favor of the non-moving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587

(1986); *Pa. Coal Ass'n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995); *Hancock Indus. v. Schaeffer*, 811 F.2d 225, 231 (3d Cir. 1987).

B. Application

Wright alleges that the '100 patent is invalid because it is anticipated by the Hollister patent. Howmedica disputes this, and argues that it is entitled to summary judgment declaring that the '100 patent is valid.

To anticipate the claims of a patent, and thereby render them invalid, a single prior art reference must include each and every limitation of the claim. *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003); *see also* 35 U.S.C. § 102. Anticipation is a question of fact, including whether an element is inherent in the prior art. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006). A prior art reference is anticipatory regardless of the specific words used, as long as it discloses the substance of each element of the claimed invention. *In re Bond*, 910 F.2d 831, 832-33 (Fed. Cir. 1990) (the elements need not satisfy “an *ipsissimis verbis* test” to be expressly anticipating.) Further, a prior art reference can inherently anticipate a patent, if a person of skill in the art would understand the limitations are implicitly disclosed. *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1347 (Fed. Cir. 2000).

Patents are presumed valid. 35 U.S.C. § 282. However, “[t]he presumption [of validity] is one of law, not fact, and does not constitute ‘evidence’ to be weighed against the challenger’s evidence.” *Chiron Cop v. Genentech*, 363 F.3d 1247, 1258-59 (Fed. Cir. 2004). Further, “[a]nticipation must be proved by clear and convincing evidence. . . .” *Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1052 (Fed. Cir. 1994). When the prior art at issue was

not considered by the Patent Office during prosecution, then it is easier for the moving party (Wright) to overcome the presumption of validity. *Alco Standard Corp. v. Tennessee Valley Auth.*, 808 F.2d 1490, 1497 (Fed. Cir. 1986); *American Hoist and Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984). Though the Hollister patent was in existence at the time the application that would later become the '100 patent was filed, it was not considered during prosecution. (Def.'s Br. at 11).

It is undisputed that the vast majority of claims 15 and 18 of the '100 patent are anticipated by the Hollister patent, but the parties vigorously dispute whether the extension of the constant radius “throughout the primary range of flexion” is taught by Hollister. This feature must be contained in the Hollister patent for it to anticipate and invalidate the '100 patent. *Schering*, 339 F.3d at 1377.

The crux of the instant motions is whether the Hollister patent discloses a “circular” surface or a “constant radius” into the range of hyperextension. Howmedica argues that because the prior art does not expressly state that the prosthesis travels into hyperextension, it cannot invalidate the '100 patent. (Pl.'s Br. at 7). Wright argues that because the prior art explicitly states that it “mimicks the natural movement of the human knee,” and because Howmedica does not dispute that the entire “primary range of flexion” in the '100 patent (+75° to -15°) is part of the natural motion of the human knee, it necessarily follows that Hollister discloses circularity throughout the primary range of flexion and anticipates the '100 patent. (Def.'s Reply Br. at 1). Howmedica counters by arguing that the Hollister patent only teaches *movement* in the anterior direction, not necessarily movement *along a circular surface*. (Pl.'s Br. at 11-13).

Wright argues that Hollister's multiple references to “mimicking the natural human

knee,” coupled with Howmedica’s admission that the anatomical human knee operates naturally into a region of hyperextension is clear and convincing evidence that the ’100 patent is anticipated by Hollister. (Def’s Reply Br. at 3). While Howmedica admits that the Hollister patent discloses *movement* into the hyperextension region, it vigorously argues that the Hollister patent does not disclose movement *along a surface of constant radius* into the hyperextension region. (Pl.’s Surreply Br. at 2). Hollister repeatedly discloses movement into the “distal” portions (“distal” has the same meaning as “anterior”), and expressly states a circular sweep in the “posterior and distal portions.” (’758 Patent, col. 7, ll. 52-57).

The distinction drawn by Howmedica, that the Hollister patent does not teach a constant radius into the hyperextension region, is aided by their own construction of the knee, which contains a reference line at 0°. Howmedica even goes so far as to claim that the Hollister patent teaches a circular sweep from “0° to +135°.” (Pl.’s Surreply Br. at 2). It does not. Just as Hollister does not expressly state a constant radius into the anterior region (*i.e.*, hyperextension), it also does not expressly state that the radius of the implant’s femoral portion changes at the point described as “0°.” Hollister teaches a circular movement along a sweep that mimics the natural knee, not one that stops at 0°.

In light of Hollister’s disclosures, the Court concludes that claim 15 of the ’100 patent is invalid because it is anticipated by the Hollister patent. The Hollister patent discloses all of the features of claim 15, including movement along a circular surface with a constant axis which mimics the movement of the human knee. Howmedica conceded that the “primary range of flexion” in claim 15 of the ’100 patent is synonymous with “the region where most normal activities of daily living occur.” (How’s Resp. to 56.1 Stmt. No. 26). Hollister teaches that

circularity is maintained to mimic the movement of the natural knee, and it is undisputed that the “primary range of flexion” includes “the region where most activities of daily living occur.” Therefore, to grant summary judgment requires that mimicking the natural movement of the human knee includes “the region where most activities of daily living occur.” The Hollister patent unequivocally discloses circularity “through a sweep of over 120 degrees” to mimic “the natural movement of the anatomic knee.” (’751 Patent, col. 7, ll. 52-59). The Court holds that claim 15 is anticipated as a matter of law by the Hollister patent. The Court further holds that, because claim 18 is a dependent claim of identical scope to claim 15 as explained in the *Markman* order, (Dkt. No. 98 at 11) it is also anticipated as a matter of law.

In light of the Court’s conclusions, the obviousness arguments need not be addressed at this time.

III. Conclusion

For the foregoing reasons, defendant Wright’s motion for summary judgment of invalidity (Dkt. No. 131) is GRANTED; plaintiff Howmedica’s motion for summary judgment of no anticipation (Dkt. No. 132) is DENIED; and Wright’s motion to strike (Dkt. No. 139) is DENIED. An appropriate form order is filed herewith.

Dated: November 24th, 2009

s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.