United States Court of Appeals for the Federal Circuit

SMITH & NEPHEW, INC.,
Appellant,

v.

TERESA STANEK REA, Acting Director, United States Patent and Trademark Office,
Appellee,

AND

SYNTHES (U.S.A.)
Appellee.

2012-1343

Appeal from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences in Reexamination Nos. 95/000,465 and 90/009,377.

Decided: July 9, 2013

JOSEPH R. RE, Knobbe, Martens, Olson, & Bear, LLP, of Irvine, California, argued for appellant. With him on the brief was CHRISTY G. LEA. Of counsel on the brief were ROBERT A. KING and DAVID A. KELLY, Hunton & Williams, LLP, of Atlanta, Georgia; and BRADLEY T.

LENNIE, RODGER L. TATE, and JEFFREY B. VOCKRODT, of Washington, DC.

KRISTI L. R. SAWERT, Associate Solicitor, United States Patent and Trademark Office, of Alexandria, Virginia, argued for appellee, United States Patent and Trademark Office. With her on the brief was BRIAN T. RACILLA, Associate Solicitor. Of counsel was Nathan K. Kelley, Deputy Solicitor.

DAVID R. BAILEY, Woodcock Washburn LLP, of Philadelphia, Pennsylvania, argued for appellee, Synthes (U.S.A.). With him on the brief were WILLIAM F. SMITH and JOHN F. MURPHY.

Before DYK, BRYSON, and WALLACH, *Circuit Judges.*

BRYSON, *Circuit Judge.*

Appellant Smith & Nephew, Inc., seeks review of a decision of the Board of Patent Appeals and Interferences (now known as the Patent Trial and Appeal Board). Reversing the decision of a patent examiner, the Board held that certain claims of a patent owned by appellee Synthes (U.S.A.) would not have been obvious and therefore were not invalid. Both Synthes and the Acting Director of the Patent and Trademark Office have filed briefs supporting the Board's decision. While the "substantial evidence" standard of review for the Board's factual findings makes Smith & Nephew's burden on appeal a heavy one, we are satisfied, after careful review, that Smith & Nephew has met that burden and has shown that the claims at issue would have been obvious. We therefore reverse the decision of the Board.

I

Synthes owns U.S. Patent No. 7,128,744 ("the '744 patent"). The patent was issued in 2006, and it claims priority to a provisional application filed on September 13, 1999. The patent is directed to a system for using plates to repair bone fractures in long bones, such as the femur. The bone plate that is the subject of the patent runs along the outside of the fractured bone and is attached by bone anchors (typically, bone screws) that are inserted through predrilled holes in the plate and then into the bone. The dispute in this case focuses on the structure of the holes in the plate through which the screws are inserted.

In 2009, Smith & Nephew requested reexamination of the '744 patent, and the Patent and Trademark Office granted the request. After reviewing detailed evidentiary submissions, the examiner rejected all 55 claims of the '744 patent as obvious based on a number of prior art references. Synthes appealed the rejections to the Board of Patent Appeals and Interferences, which upheld the rejections of 31 of the claims (claims 24–31 and 33–55), but reversed the rejections of 24 of the claims (claims 1–23 and 32). Smith & Nephew appeals from the Board's decision with respect to the 24 claims on which the Board reversed the rejections.

A

The parties have treated claim 1 as representative of the 24 claims of the '744 patent that survived the reexamination, and we do the same. Claim 1 recites a bone plating system for improving the stability of a bone fracture in a long bone, comprising a bone plate having a shaft portion that is configured to run along a portion of the bone and a head portion that flares out from the shaft portion so as to accommodate the wider portion of the bone near a joint. The head portion has at least three bone anchor holes, all of which are conically tapered from

the top surface of the plate to the bottom surface.[1] All of the holes in the head portion are at least partially threaded to engage the threads on the head of a "locking" bone anchor (or screw). The shaft portion of the claimed plate has a plurality of holes in which at least a portion of the hole is threaded. The central issue in this case is whether it would have been obvious at the time of the invention to design a bone plate in which all of the holes in the plate's head portion were conically tapered and at least partially threaded to engage threaded "locking" screws.

The '744 patent describes two basic types of screws that were used in prior art bone plates. First are non-locking compression screws, which have threaded shafts but unthreaded heads and which typically pass through unthreaded holes in the plate. Upon being tightened, the compression screws draw the bone and plate together. Second are locking screws, which have threaded heads as well as threaded shafts. The threads on the heads of the locking screws engage with corresponding threads on the interior of the anchor holes in the plate, which results in fixing the screws to the plate.

The two types of screws perform different functions: compression (non-locking) screws draw the bone and the plate together for fracture reduction and quicker healing, while locking screws fix the relative position of the plate and bone so that the plate does not move relative to the bone. See '744 patent, col. 1, line 64–col. 2, line 7. The latter feature is especially important when the bone is a weight-bearing bone that is subject to pressure that can loosen the connection between the screws and the plate if

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[1] Smith & Nephew argues that the Board erred in construing the claim to require that all of the holes in the head be conically tapered. It is unnecessary to decide that issue to resolve the invalidity contention, so for present purposes we accept the Board's construction of the claim.

only conventional compression screws are used to attach the plate to the bone.

Several commercial bone plates, as well as articles and descriptions of bone plates, are acknowledged to be prior art to the '744 patent. First is a condylar buttress plate that Synthes marketed in the 1990s. Designed for fractures in the femur near the knee, the Synthes plate had a shaft and head portion, both of which contained unthreaded holes designed for compression screws.

A 1997 article by Kenneth Koval described a modified version of the Synthes condylar buttress plate. In the Koval plate, threaded nuts were welded onto the top of four of the six holes in the head portion of the plate, enabling the use of locking screws in those holes.

In a 1998 prior art submission to the Food and Drug Administration, referred to as the K982222 application, Synthes sought permission to market a plate having four threaded holes and two unthreaded holes in the head portion of the plate. That device, like the Koval plate, allowed locking screws to be used in the head portion. The Koval plate and the K982222 application followed the suggestion in a 1996 article by Brett R. Bolhofner (one of the inventors of the '744 patent) and others, which noted a means of solving the problem that screws "can angulate . . . and are not fixed in a constant relationship" to the plate by "selective locking of the screws to the plate."

In 1997, N.P. Haas published an article describing a version of the Synthes plate that used only conically tapered, threaded holes in the shaft and head portions of the plate. Unlike other prior art plates, this one merely stabilized the femur and did not compress or even contact bone fragments directly.

The prior art background also included plates for fractures not involving the femur. During the 1990s Synthes marketed a Distal Radius Plate ("DRP") for wrist frac-

tures. The anchor holes of the DRP were all partially threaded and, importantly, were specifically designed for use with either locking screws or non-locking, compression screws. In 1997 Synthes marketed another device, known as the Locking Reconstruction Plate ("LRP"), which was designed to serve as an internal fixation plate for a lower jaw fracture. That plate, and a patent application for a similar device that ultimately issued as U.S. Patent No. 5,709,686 ("the '686 patent"), featured anchor holes that were all partially threaded and were intended to accommodate either locking screws or compression screws.[2] The screw holes in the LRP had a threaded lower portion and an unthreaded, conically flared upper portion that enabled the screws to be countersunk so that the heads of the screws did not extend above the surface of the plate.

At the conclusion of the reexamination, the examiner rejected all of the claims of the '744 patent. He rejected the claims at issue in this appeal based on three separate combinations of prior art references: the K982222 application and the Haas article; the Koval and Haas articles; and the Synthes device and the Haas article. In the examiner's view, combining any of the bone plates in the prior art with the conically tapered, threaded holes used in the Haas reference taught all the limitations of the claims in dispute. As for the motivation to combine features in the prior art, the examiner adopted Smith & Nephew's argument that the claimed configuration was an attractive option because using locking screws would maximize the stability of the head of the plate, and using threaded screw holes would give the surgeon the option during surgery to use either locking screws or compression screws in the threaded holes, depending on whether

[2] The '686 patent does not specify what fractures the invention was intended to mend.

compression or stabilization was preferred at the particular position of each of the plate holes.

B

On appeal, the Board reversed the rejections as to claims 1–23 and 32. The Board concluded that it would not have been obvious to modify the condylar buttress plate in the prior art by having only threaded holes in the head portions of that plate. The Board acknowledged that persons of skill in the art would have been motivated to include threaded holes for locking screws in the head portion.[3] However, the Board concluded that the prior art references suggested only that some of the holes in the head portion should be partially or wholly threaded, not that *all* of them should be partially or wholly threaded. The Board further concluded that the evidence of record was insufficient to show that inserting conventional screws in the tapered, threaded holes recited in claim 1 could impart compression between the head portion of the buttress plates and the bone, and for that reason the Board held that the examiner's obviousness analysis was not "based on adequate rational underpinnings."

The Board acknowledged that the specification of the '744 patent referred to the '686 patent, which disclosed a bone plate in which all of the holes were partially threaded, and that the specification stated that the partially threaded holes of the '686 patent "allow either non-locking or locking screws to be used." '744 patent, col. 2, ll. 17–18. However, the Board distinguished the holes described in claim 1 of the '744 patent from the holes of the '686 patent on the ground that the former were "conically tapered from the upper surface to the lower surface" of the plate,

[3] Both parties' experts agreed that a person of skill in the art would include an orthopedic surgeon with two years' experience in the design or implantation of bone plates or similar orthopedic implants.

while the holes of the '686 patent "include an unthreaded conically flaring area . . . and a separate threaded straight portion." A hole that is conically tapered from the upper surface to the lower surface, the Board stated, is disclosed in the record only by the threaded holes of the Haas prior art reference. Because the holes disclosed in Haas were not shown to accept non-locking screws that would allow for compression, the Board concluded that the evidence did not establish that partially threaded plate holes that are conically tapered from the upper surface to the lower surface were known to be suitable for use with both locking and non-locking screws.

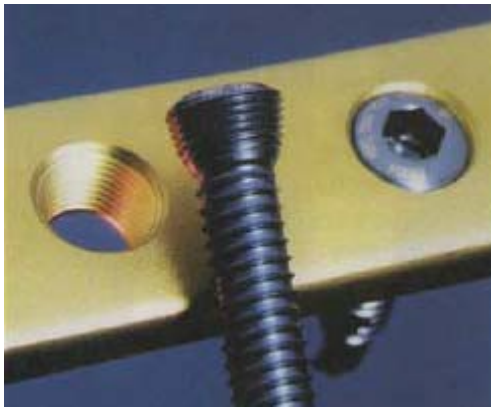
The Board rejected the argument that a person of ordinary skill in the art would have used conventional bone screws in the conical tapered holes of Haas, partly on the ground that the heads of the screws would "sit[] high atop the plate," thereby causing patient discomfort and other possible complications. The Board relied on the declaration of one of Synthes's experts, Clifford H. Turen, who stated that a conventional condylar plate screw had a "rounded-bottom head" that would stick out from a conical hole. The Board noted that the Haas plates used chamfers to countersink its screws into conical holes, but it found that the chamfering shown in Haas "is very small and shallow," and therefore could not be used to countersink conventional condylar buttress plate screws.

II

The Synthes prior art condylar buttress plate discloses most of the limitations of claim 1 of the '744 patent. It consists of a bone plate with a shaft portion having arched cut-outs on its lower surface. The head portion contains at least three screw holes. The modifications of that plate represented by the Koval and K982222 prior art references contain four holes in the head portion that are partially threaded to engage the threads on the head of a locking screw. The Haas secondary reference includes

holes in the head portion that are both conically tapered and partially threaded. The photographs below show the prior-art Synthes condylar buttress plate and the conical, partially threaded holes of Haas:

Synthes Plate



Haas's conical, partially threaded holes

The essence of the analysis that led the Board to overturn the examiner's decision can be summarized as follows: The prior art references did not teach or suggest the exclusive use of conical, partially threaded holes in a condylar buttress plate because it was not believed that those holes could be used with non-locking screws to provide compression. While the '744 specification stated that the partially threaded holes of the '686 patent could be used with non-locking screws to obtain compression, the Board did not treat that admission as fatal to Syn-

thes's case because the holes in the plates of the '686 patent were not fully conical from the top surface to the bottom surface of the plate, as required by claim 1. And although the holes in the Haas plate were both threaded and fully conical, the Board determined that one of ordinary skill would not have used a standard screw in the kind of hole disclosed in Haas because there was no evidence that conical, partially threaded holes were known to be suitable for use with both non-locking and locking screws, and because using a conventional bone screw in a conical tapered hole with a small chamfer, as in Haas, would result in the screw head sitting unacceptably high above the bone plate.

A

There are several problems with the Board's analysis.

First, to the extent that the Board based its ruling on its conclusion that it would not have been obvious to use a standard compression screw in a threaded hole to obtain compression, the Board overlooked the fact that claim 1 of the '744 patent did not require that the head screws provide compression. If a physician regarded it as preferable to have stabilization rather than compression in the head portion of a bone plate, an obvious solution would have been to use more threaded holes and locking screws in that part of the plate. Contrary to Synthes's suggestion that compression is invariably needed in the head portion of condylar buttress plates, the '744 specification indicates that locking screws are sometimes used in all of the threaded holes of the head portion of the bone plate. '744 patent, col. 6, ll. 47–50 ("generally, threaded holes 56b, 56c [the screw holes in the head portion] are arranged so that the inserted locking screws converge toward each other"). As an alternative to using all locking screws in the head holes, the specification provides that non-locking screws can be substituted for locking screws in any of those holes "if a surgeon elects." *Id.* Accordingly, the

embodiment in which locking screws are used in all of the head screw holes would not provide compression in the head portion of the plate, but would still be within the scope of claim 1.

Second, the Board's conclusion that using a standard compression screw in a conical, partially threaded hole would cause the screw to protrude above the line of the plate is the result of not reading the prior art for all that it teaches. The plate hole illustrated in Haas contains a chamfer, and it is undisputed that a chamfer can be used to countersink a screw head so that it does not sit above the top surface of the plate.[4] The Board's observation that the chamfer in Haas is narrow ignores the point that the disclosure of a chamfer is not limited to the precise size of the chamfer depicted in the illustration of the Haas device. Chamfers are conventional features in the art and can be sized to accommodate screw heads of varying heights. Nothing about the Haas reference limits the size of the chamfer or in any way suggests that it could not be made larger than it appears to be in the drawings contained in the Haas reference. In any event, even the illustrations in the Haas reference make clear that the chamfer in Haas is large enough to allow the screw to be countersunk so that it does not protrude above the level of the plate. That portion of the Board's analysis therefore does not provide a basis for disregarding the chamfer disclosed in Haas.[5]

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[4] Synthes argues that Smith & Nephew waived this argument by not presenting it in its appeal briefs to the Board. However, because the Board considered and rejected the argument as properly raised, we may review that determination.

[5] Figures 9 and 22 of the '744 patent demonstrate that, even in the claimed invention, the screw may protrude above the surface of the plate. Synthes does not

Even if countersinking were not an option, a person of ordinary skill would not have had to use a screw with a "rounded-bottom head" that would stick out from the plate. Instead, a conically shaped screw could sit in the Haas holes without any risk of protrusion. The '744 specification states, as a general proposition, that "any surgical screw that has a non-threaded head . . . of an appropriate size and geometry for select plate holes of the bone plate can be used" in the claimed bone plate. '744 patent, col. 4, ll. 20–22. The patent thus suggests the choice of any appropriate screw design rather than limiting the choice to a screw that would sit too high in a conical hole.

Third, the Board's reliance on the fact that the partially threaded holes in the '686 patent are only partly conical (and partly cylindrical) does not undermine the '744 patent's admission that partially threaded holes, regardless of their shape, could provide compression. Neither the Board nor Synthes has argued that there is anything about the Haas fully conical shape that would suggest that a standard, non-locking screw could not have been used in such a hole to achieve compression. As already noted, the '744 specification indicates that "any surgical screw that has a non-threaded head . . . of an appropriate size and geometry" can be used to practice the invention. '744 patent, col. 4, ll. 20–22. The patent confirms what common sense suggests: a person of skill could adjust a plate hole's geometry—whether conical, cylindrical, or otherwise—to fit any standard screw without sacrificing compression. In fact, in the portion of its opinion upholding some of the examiner's rejections, the Board specifically found that although the prior art plates—Synthes, Koval, K982222, and Haas—all used a

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indicate what constitutes an "unacceptably high" screw position, or why countersinking could not have been used to limit or avoid the protrusion problem.

"different type of threaded holes for receiving corresponding locking screws, use of any of those threaded holes [including the fully conical holes of Haas] would have been obvious to one of ordinary skill."

The discussion of the '686 patent in the '744 specification does not focus on the fact that the holes of the '686 patent are only partially conical. Instead, the discussion indicates that because the holes of the '686 patent are partially threaded, either locking or non-locking screws can be used. Curiously, the '744 specification goes on to state that "[b]ecause the plate holes are only partially threaded, the locking screws used may not be able to maintain the fixed angular relationship between the screws and plate under physiological loads." '744 patent, col. 2, ll. 18-21. Yet the disputed claims of the '744 patent recite that the holes in the head portion of the plate have "at least a portion that has a thread to engage a thread on a head of a bone anchor." Thus, the '686 patent cannot be distinguished on the ground that its holes are only partially threaded, since the claims of the '744 patent themselves recite holes that may be only partially threaded.

To the extent that the '744 specification distinguished the '686 patent on the ground that the threads in the holes of the '686 patent do not entirely surround the locking screw (a point made by one of Synthes's experts), the difference between a thread that surrounds the screw and one that only partially surrounds the screw is one of degree only and is not a distinction on which validity turns. Not surprisingly, the Board did not rely on that distinction in its decision.

The '744 specification's description of the '686 patent therefore discloses that the prior art used non-locking screws in threaded holes. Because that prior art reference demonstrated that non-locking screws could achieve compression in either type of hole, the motivation to combine the Haas holes with the condylar plates was

clear: The use of threads in all of the holes would offer the advantage of added flexibility for the surgeon, who could choose to use locking or non-locking screws in any of the holes in the head portion of the plate.

Fourth, the Board refused to consider two prior art references, the DRP and the LRP, which, like the '686 patent, disclosed the use of non-locking screws in threaded holes. The Board discounted those references on the ground that the examiner had not relied on them as a basis for his rejections. The examiner, however, incorporated Smith & Nephew's arguments by reference, including its discussion of those two references. The references were clearly probative as to whether it was known at the time of the invention that non-locking screws could be used in threaded holes. As such, they supported Smith & Nephew's rebuttal of Synthes's argument that the combination of the prior art condylar buttress plates with Haas would have rendered the prior art plates inoperable, on the theory that compression could not be obtained without at least some unthreaded holes in the head portion of the plate.

Synthes marketed the LRP and the DRP in the 1990s. The LRP was intended to deal with mandible fractures. In its brief to the Board, Synthes admitted that the plate holes in the LRP were designed so that the holes could "either be used to form a locking construct or a non-locking construct." That was because the holes had a lower threaded portion for providing a locking function with locking screws and an unthreaded upper portion "for providing a seating surface for use with the unthreaded head of a standard [compression] screw."

The DRP was intended to deal with wrist fractures. That plate featured holes in the "distal arm" portion of the plate that were all partially threaded and were specifically designed for use with either locking screws or non-locking, compression screws. Although Synthes notes

that neither the LRP nor the DRP are used with weight-bearing bones and therefore use holes with only "minimal threading," that does not meaningfully distinguish them from the claimed invention, which also requires only partially threaded holes.

Finally, as already noted, the '686 patent disclosed the use of partially threaded holes to accommodate either locking or non-locking screws. Synthes acknowledged as much in the specification of the '744 patent. That intrinsic evidence from the '744 specification was plainly relevant and admissible to rebut Synthes's argument that such a structure would not have been obvious because it would not have worked.

We recognize, of course, that the "substantial evidence" standard of review requires a deferential approach to the Board's findings. *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). In this case, however, the facts are largely undisputed, and the Board's decision regarding the obviousness of including only threaded holes in the head portion of the condylar plate was mainly the result of the analytical errors discussed above, not the Board's resolution of factual questions.[6] Accordingly, we conclude

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[6] To the extent that Synthes sought to create a factual dispute through the declaration of Dr. Turen that "one of ordinary skill in the art would not have thought it to have been obvious to replace all of the unthreaded holes in the head portion of the plates disclosed in the primary references," that statement is contrary to the statement in the patent that the prior art taught partially threaded holes that "allow either non-locking or locking screws to be used," '744 patent, col. 3, ll. 17–18, as well as the LRP and DRP references. Expert opinions that are contrary to admissions in the specification do not create a factual issue. *See Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1361–62 (Fed. Cir. 2007).

that the Board erred in ruling that removing the non-threaded holes from the head portion of the prior art plates would not have been expected to allow the plates to impart compression between the head portion and the bone.

B

Given the compelling evidence that it would have been obvious to modify any one of the three primary references to have only threaded holes in the head portion, the sole remaining feature that distinguishes the plate system of claim 1 from the prior art condylar plate systems using partially threaded holes is the fully conical shape of the holes in the plate recited in claim 1. And that feature is found in the secondary reference, Haas. Accordingly, the critical remaining question is: Would it have been obvious to a person of ordinary skill in the art to combine the partially threaded holes of the Synthes device, the Koval article, or the K982222 submission with the partially threaded, conical holes of Haas?

The evidence before the Board does not indicate that the choice of a fully conical hole, as opposed to a partially conical hole, would produce a surprising result or involve anything more than a choice among designs already found in the prior art. Synthes has not suggested that using a fully conical hole, as opposed to a hole that is partially conical and partially cylindrical, confers some significant advantage, nor is there anything in the '744 specification to suggest any such advantage.[7] Moreover, the prior art made clear that after substituting conical, partially threaded holes for the unthreaded holes in the head portion, the device still "would have worked for its intended purpose," even assuming Synthes's contention that

[7] Synthes has not relied on any objective indicia of non-obviousness, such as commercial success, to buttress its case.

achieving compression was the primary intended function of the claimed plate. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009). This case is therefore one that falls within the Supreme Court's characterization of obviousness as entailing an improvement that is no "more than the predictable use of prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

Both in its brief and at oral argument, Synthes argued that achieving compression with non-locking screws in conically tapered, partially threaded holes was unknown in the prior art and, in fact, would have been inoperable. This naturally raises the question of how Synthes managed to make such a combination work. Obtaining compression in threaded holes, according to Synthes, became possible only through the use of a "specialized" or "specially-designed" screw devised for that purpose. But the patent does not claim or otherwise disclose any such "specially designed" screw. Upon being pressed at oral argument to identify the "specially designed screw" to which Synthes alluded in its brief, counsel for Synthes pointed to Figure 1 of the patent. That figure, however, is not identified in the patent as a "specialized" or "specially designed" screw. To the contrary, the specification refers to Figure 1 as merely "an example of a non-locking screw" and states that "any surgical screw that has a non-threaded head . . . of an appropriate size and geometry for select plate holes of the bone plate can be used." '744 patent, col. 4, ll. 18–22.

The problem with Synthes's argument is that it is contending that a standard non-locking screw would be inoperative to obtain compression in a threaded hole, while at the same time claiming that it managed to achieve exactly that objective, all through the *deus ex machina* of a "specialized screw." But an unclaimed and undisclosed feature such as the "specialized screw" cannot

be the basis for finding Synthes's patent to be non-obvious over the prior art. *See E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988), quoting *McCarty v. Lehigh Valley R. Co.*, 160 U.S. 110, 116 (1895) ("[N]o principle of law . . . would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty . . . .").[8]

The patentability of the invention at issue in this case turns on the structure of the holes, not the special nature of the non-locking screw that is to be used with those holes. The conical, partially threaded holes themselves were well known in the art, as was the advantage of adding more of them to the head of a condylar bone plate in place of unthreaded holes. Both the screws and the holes perform their conventional, expected function in securing the plate. Because we hold that the examiner correctly ruled that disputed claims would have been obvious, we reverse the decision of the Board.

REVERSED

[8] Counsel for the Acting Director specifically disclaimed reliance on any "specialized screw" supposedly disclosed in the patent.