

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ARTHREX INC., a Delaware Corporation,)
)
 Plaintiff,)
)
 v.)
)
 dj ORTHOPEDICS LLC, a Delaware)
 Corporation,)
)
 Defendant.)

C.A. No. 02-67 GMS

MEMORANDUM AND ORDER

I. INTRODUCTION

On January 28, 2002, the plaintiff, Arthrex, Inc., filed suit alleging that the defendant, dj Orthopedics (“DJO”), infringed United States Patent No. 5,919,196 (the ‘196 patent). On February 13, 2002, the plaintiff filed a motion for a preliminary injunction to prevent the defendant from engaging in any further infringing activity during the pendency of the case. The plaintiff asserts, *inter alia*, that it has a high likelihood of success of the merits of its infringement claim. The plaintiff then argues that since the patent is both valid and infringed, there is a presumption of irreparable harm. The defendant responds by asserting that the ‘196 patent is not valid because it was anticipated by prior art, thereby making success on the merits and irreparable harm more difficult to prove.

Upon reviewing the submissions of the parties and the applicable law, the court is persuaded that the requirements of success on the merits and irreparable harm have not been met in this case. The court will, therefore, deny the plaintiff’s motion for a preliminary injunction. The court will now explain its reasoning.

II. FACTUAL SUMMARY

Arthrex is Delaware corporation engaged in the development and manufacture of products and techniques used during surgery. Arthrex owns the '196 patent, which claims a surgical method for transplanting cartilage to treat bone defects in the knee. The method taught in the patent is known as the OATS system.¹ With the OATS system, Arthrex developed a method for repairing cartilage defects in the knee by harvesting a graft of bone and cartilage from one section of the knee (“the donor site”) and placing it into the a damaged area (“the recipient site”). The OATS system employs a “punching” device - similar to a syringe in form - that allows the user to extract a bone section and reinsert it into the recipient site. Specifically, claim 17 of the '196 patent teaches:

A method of transplanting osteochondral cores in a joint having articular cartilage and subchondral bone, using a tube having a distal end and pin, the method comprising the steps of: inserting the pin into the tube; introducing an osteochondral bone core into the tube; removing the tube from the selected site with the bone core remaining within the tube; positioning the distal end of the tube at an opening of a bone socket; and urging the pin distally so as to advance the bone core into the bone socket.

'196 Patent, cl.17.

DJO competes with Arthrex in the surgical industry. DJO’s technology, referred to as the “ProCart System,” is similar in principle to the OATS system. According to the literature, DJO’s process comprises “plugs [being] harvested from low-load bearing areas (trochlea or intercondylar notch) and implanted into damaged condylar areas.” (D.I. 5 at 7 (quoting DJO’s ProCart Surgical Technique Manual at p. 1). Although Arthrex has sold numerous OATS units amounting to nearly three million dollars in sales, DJO, a smaller company, has earned only \$8,500 from ProCart sales.

¹ OATS is an acronym for Osteochondral Autograft Transfer System.

The Arthrex and DJO processes share several similarities, only a few of which will be discussed here. For instance, where the '196 patent teaches that the "tube harvester is driven into the subchondral bone . . . to a depth of approximately 15 mm," the DJO Manual states that the DonorTrepine, or plunger, should be "impacted to a depth of between 15-20 mm." (Id.) Both processes require mallets to push the harvester into the bone. (Id.) Both also require that the handle of the harvester be turned approximately ninety degrees to remove the bone graft from the harvester. (Id.) The employed devices are also visually similar.

Given the many similarities between the processes, DJO does not defend this motion by arguing non-infringement. Rather, DJO asserts that the '196 patent was anticipated by prior art. First, DJO alleges that an earlier article by Dr. Yoshitaka Matsusue, "Arthroscopic Multiple Osteochondral Transplantation to the Chondral Defect in Knee Associated with Anterior Cruciate Ligament Disruption," anticipates claim 17. The Matsusue article does discuss using a "cylindrical bone pegger" to take a "osteochondral autogenic bone graft." (D.I. 18, Exh. 1 at 2.) The article also speaks of using a "pusher" to move the bone pegger into the bone. (Id.) Second, DJO asserts that the method of the '196 patent was disclosed in U.S. Patent No. 5,152,763, issued to Johnson (the '763 patent). The '763 patent also employs a plunger-like device to harvest bone grafts. Specifically, the patent claims a "solid inner cylindrical plunger having a pushing end and a grasping end . . ." '763 patent, 1:39-40. Further, the patent states that "the bone grafter with the retracted plunger is pushed into the donor cancellous bone to the desired depth." *Id.* at 2:48-51. The device depicted in the Johnson patent is also visually similar to the DJO and Arthrex devices. Arthrex does not dispute the relevance of this prior art - it argues that the art is distinguishable and that both the article and the patent were before the examiner during the prosecution of the '196 patent.

DJO also asserts that Arthrex engaged in inequitable conduct before the Patent and Trademark Office (“The PTO”). Specifically, it alleges that Arthrex failed to bring a German patent to the attention of the PTO, or that if it did, it did not provide an English translation as required. Arthrex asserts that it did make reference to the prior art in one of its submissions to the PTO.

DJO also asserts that Arthrex is precluded from asserting a claim of irreparable harm because it has licensed the ‘196 patent to the Mitek Corporation. Arthrex does not dispute that the license exists, but claims that the license covered claims 13 and 15 of the ‘196 patent which are not at issue in this litigation. Finally, DJO argues that Arthrex was aware of the alleged infringing activity for months before it filed the present motion. DJO thus contends that Arthrex’s motion should fail.

III. STANDARD OF REVIEW

A movant is entitled to a preliminary injunction where it can demonstrate that: (1) it has a reasonable likelihood of success on the merits; (2) it will suffer irreparable harm if the injunction is not granted; (3) the balance of hardships is in its favor; and (4) the injunction is in the public interest. *See Reebok Intern. Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994). No one of these four factors alone is dispositive. *See Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988). Nevertheless, the court cannot issue a preliminary injunction unless the movant establishes both of the first two factors. *See Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001)(citations omitted).

IV. DISCUSSION

A. Likelihood of Success on the Merits

Success on the merits is established where the movant demonstrates that the patent is both valid and infringed. *See Reebok*, 32 F.3d at 1555. DJO does not argue that its activities do not infringe the '196 patent, but rather argues that the patent is invalid due to Arthrex's inequitable conduct before the PTO or the patent's obviousness in light of prior art. Although Arthrex appears to assert that DJO's claims of invalidity will ultimately fail, the Federal Circuit has stated, "In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself." *See Amazon.com*, 239 F.3d at 1359. Indeed, facts relevant to a finding of invalidity that might not prevent the award of summary judgment might prevent the issuance of a preliminary injunction. *See id.*

Without expressing an opinion on the invalidity claim, the court finds that DJO has presented enough facts to raise a substantial question as to the validity of the '196 patent. A substantial question is raised when the patentee cannot prove the defense lacks substantial merit. *See id.* at 1350-51. Arthrex does not dispute that each item is prior art. Although Arthrex argues that the technology discussed in the prior art (the Matsusue article, the '763 patent) is distinguishable from the '196 patent, there are enough similarities to raise at least a question of validity at this point. All of the disclosed devices appear similar. Each employs a syringe-like apparatus to remove the graft. Additionally, the processes disclosed in the prior art and the '196 patent are similar. All appear to contemplate the use of a harvesting device that is tapped into the knee to a similar depth. The

similarity of the devices and processes involved causes the court to find that DJO has raised a substantial question as to whether the '196 patent was anticipated by prior art.

Arthrex argues that DJO must prove that each claim is invalid. DJO, however, has also asserted claims of invalidity based upon inequitable conduct. This claim, if proven, would invalidate the entire patent. *See e.g., Winbond Electronics Corp. v. International Trade Com'n*, 262 F.3d 1363, 1372 (Fed. Cir. 2001) (noting that patent obtained through inequitable conduct may not be enforced). “A court may hold a patent unenforceable for inequitable conduct when an applicant submits material false information, or fails to submit material information, with an intent to deceive the PTO.” *See id.* DJO asserts that the German patent was not fully disclosed and that Arthrex’s statement that the German patent “corresponded” with the English patent it did disclose was inaccurate. Arthrex does not dispute that the German patent was material, or that it never provided a complete English translation. More important, although Arthrex responds to the claim that it properly mentioned the patent, it does not fully respond to the allegations regarding the differences between the English and German patents. In particular, it does not address the limitations regarding pins and awls. Given this factual background and the Federal Circuit’s recent expression that an attempt to selectively present a foreign reference may result in a finding of inequitable conduct, *see Semiconductor Energy Lab. v. Samsung Elec. Co.*, 204 F.3d 1368, 1377 (Fed. Cir. 2000), the court concludes that the question of inequitable conduct, while not resolved, is fairly before the court.

For all of the above reasons, the court finds that DJO has successfully raised a question as to the validity of the '196 patent.²

² The court notes that the mere fact that the prior art was before the examiner will not prevent the court from considering whether prior art renders the patent invalid. *See Celeritas Technologies, Ltd. v. Rockwell Intern. Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998).

B. Irreparable Harm

A presumption of irreparable harm will arise where the patentee has proven both infringement and invalidity. *See Amazon.com*, 239 F.3d at 1350. As previously discussed, a substantial question has been raised as to the validity of the patent. Thus, Arthrex is not entitled to the presumption.³ *Id.* Therefore, the court will examine other factors that might lead to a finding of irreparable harm.

Arthrex asserts two primary arguments in support of its position on irreparable harm. First, it argues that if an injunction is not issued, DJO will continue to gain market share, will confuse consumers, and will infringe upon Arthrex's right to exclude. The court is not persuaded by these arguments. Arthrex does not dispute that it is a large company and DJO is a much smaller company. While Arthrex does not dispute that it has sold over \$3,000,000 worth of the OATS system, it also does not dispute that DJO has sold approximately \$8,500 worth of the ProCart system. Given this large disparity in revenue, it is highly unlikely that DJO will cause substantial and irreparable harm to Arthrex's much larger market share. Moreover, even if Arthrex's revenue was not over 300 times as large as DJO's, the court finds that loss of market share alone is insufficient to support a finding of irreparable harm. *See Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991) (noting that loss of market share (or speculation that it might occur) insufficient to state irreparable harm for preliminary injunction).

More important, the court finds that Arthrex's claim that DJO's activities infringe upon its right to exclude is not entitled to great weight in the face of its licensing activities. The right secured

³ The court's finding regarding this presumption is limited to the preliminary injunction context and is further limited to the facts known at this time. The court expresses no opinion as to whether such a presumption might be warranted at a later stage in this litigation.

by the patent is the right to exclude. Engaging in licensing activity is incompatible with the right to exclude. *See T.J. Smith & Nephew v. Consolidated Med. Equip.*, 821 F.2d 646, 648 (Fed. Cir. 1987) (noting that licensing is incompatible with right to exclude). Moreover, the act of licensing suggests that any injury suffered by the patentee is compensable in money damages, obviating the claim for injunctive relief. *See High Tech Medical Instrumentation, Inc. v. New Image Industries, Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995) (noting that where patentee licenses product, the evidence suggests that any injury suffered by [patentee] [will] be compensable in damages . . .”). Arthrex argues that although it licensed the ‘196 patent, its licenses did not affect the claims at issue in this case. However, the fact is that Arthrex has demonstrated a willingness to compromise the validity of the ‘196 patent as a whole. The proposition that a patentee can license certain claims of a patent while attempting to exercise exclusivity over others runs contrary to common sense. Indeed, Arthrex cites no authority in support of its position. The court, therefore, rejects Arthrex’s argument on this point.

For all of the foregoing reasons, the court concludes that Arthrex has not shown that it will suffer irreparable harm if the injunction is denied.

V. CONCLUSION

The court finds that DJO has raised a substantial question as to the validity of the ‘196 patent. Moreover, Arthrex has failed to demonstrate that irreparable harm will result in the absence of the injunction. Thus, the first two requirements for a preliminary injunction have not been met. Therefore, the court cannot issue the preliminary injunction, and will deny the plaintiff’s motion.

NOW, THEREFORE, IT IS HEREBY ORDERED THAT:

1. The plaintiff's Motion for a Preliminary Injunction (D.I. 4) is DENIED.

Dated: April 30, 2002

Gregory M. Sleet
UNITED STATES DISTRICT JUDGE