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DSU Medical Corp. v. JMS Co., Ltd., 471 F.3d 1293 (2006)

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471 F.3d 1293
United States Court of Appeals,
Federal Circuit.

DSU MEDICAL CORPORATION and MEDISYSTEMS **CORPORATION**, Plaintiffs-Appellants,
v.
JMS CO., LTD. and JMS NORTH AMERICA **CORPORATION**, Defendants-Cross Appellants,
and
ITL **Corporation** PTY, Ltd., Defendant-Cross Appellant.
ITL **Corporation** PTY, Ltd., Plaintiff-Cross Appellant,
v.
DSU Medical Corporation, Defendant-Appellant.

Nos. 04-1620, 05-1048, 04-1052. Dec. 13, 2006.

Synopsis

Background: Owner of patents for **medical** needle guards sued competitors for infringement. The United States District Court for the Northern District of California, D. Lowell Jensen, Senior District Judge, entered judgment on jury verdict in favor of owner against two competitors. Competitors appealed, and patent owner cross-appealed.

Holdings: The Court of Appeals, Rader, Circuit Judge, held that:
1 term “guard slidably enclosing a sliding assembly comprising a needle and a winged needle hub” required that the guard substantially contain the needle-assembly at all times;
2 word “slot” did not incorporate any thickness limitation;
3 closed-shell configuration of alleged device infringed patent;
4 the en banc Court of Appeals held that to establish inducement, owner was required to offer evidence of culpable conduct, directed to encouraging another's infringement;
5 the original Court of Appeals panel further held that jury was well within the law to conclude that competitor that manufactured alleged device did not induce importer-competitor to infringe by purposefully and culpably encouraging importer's infringement;
6 exclusion of expert testimony on lost profits damages was not an abuse of trial court's discretion;
7 substantial evidence supported jury award for lost profits due to lost sales to the infringing guard;
8 substantial evidence supported jury verdict that certain claims of patent were invalid as obvious; and
9 trial court's response to a jury question was not abuse of discretion.

Affirmed.

Michel, Chief Judge, and Mayer, Circuit Judge, filed a concurring opinion with regard to en banc review.

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Attorneys and Law Firms

***1297** William J. O'Brien, Alschuler Grossman Stein & Kahan LLP, of Santa Monica, California, argued for plaintiffs-appellants. Of counsel on the brief was Alan H. Blankenheimer, Heller Ehrman White & McAuliffe LLP, of San Diego, California.
Richard H. Zaitlen, Pillsbury Winthrop Shaw Pittman LLP, of Los Angeles, California, argued for defendants-cross appellants JMS Co., Ltd., et al. With him on the brief were Julian D. Forman; and Kevin T. Kramer, of Washington, DC. Of counsel were Ross R. Barton, of McLean, Virginia; and Blair M. Jacobs, Sutherland, Asbill & Brennan LLP, of Washington, DC.
Marc N. Bernstein, The Bernstein Law Group, of San Francisco, California, argued for defendant-cross appellant, ITL **Corporation** PTY, Ltd. With him on the brief were Ronald P. Flynn and Sarah Botz.

Before RADER, SCHALL, and LINN, Circuit Judges.

Opinion

Opinion for the court filed by Circuit Judge RADER.

Concurring opinion filed by Chief Judge MICHEL, and Circuit Judge MAYER on en banc Section III B.

RADER, Circuit Judge.

DSU Medical Corporation (**DSU**) and Medisystems **Corporation** (MDS) (collectively **DSU**) sued JMS Company, Limited (JMS) and JMS North America (collectively JMS) and ITL **Corporation** Pty, Limited (ITL) for patent infringement, inducement to infringe, and contributory infringement of United States Patent Nos. 5,112,311 ('311) and 5,266,072 ('072). After a six-week jury trial produced a unanimous verdict, the United States District Court for the Northern District of California entered a final judgment finding claims 46-47, and 50-52 of the '311 patent invalid as obvious. The trial court also entered a final judgment, pursuant to the unanimous verdict, of infringement against JMS and JMS North American on claims 49, 53, and 54 of the '311 patent, and of non-infringement for ITL. ***DSU** Med. **Corp**. v. JMS Co., JMS N. Am. **Corp**., & ITL **Corp**. PTY,* Nos. C-00-1826-DLJ, C-99-2690-DLJ, slip op. at 3-4 (N.D.Cal. May 7, 2004) (*Judgment*). The jury awarded total damages of $5,055,211 for infringement against JMS and JMS North America, and the trial court entered a final judgment holding both jointly and severally liable for the award. Finding no reversible error, this court affirms.

I.

The '311 and '072 patents claim a guarded, winged-needle assembly. The invention reduces the risk of accidental needle-stick injuries. Needle puncture wounds can transmit blood-borne diseases such as Hepatitis B and AIDS. The '311 and '072 patented inventions effectively guard standard winged-needle-sets to prevent needle-stick injuries.

The '311 patent claims a “slotted, locking guard for shielding a needle, and a winged needle assembly including a needle, a winged needle hub, and a slotted, locking guard.” '311, col.1, l. 8-11. This invention includes both “[a] slotted guard for locking a needle in a shielded position as the needle is removed from the patient”, and “a guarded winged needle assembly ... slidably mounted within the guard.” *Id.*, abstract. Figures 5-6 illustrate one embodiment of the patented invention:

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Figure 5 is a side view of a needle, winged needle hub (3), and slotted needle guard (1). '311 patent, col. 3, ll. 4-6. In this depiction, the needle (5) remains retracted within the needle guard (1). *Id.* Figure 6 shows the same needle from above. '311 patent, col. 3, ll. 7-10.

Mr. David Utterberg, a co-inventor of the '311 patent, owns **DSU** and MDS. **DSU** owns the '311 patent; MDS has an exclusive license to make and sell the '311 invention for large-bore needles, including Arterial-Venous Fistula (AVF) sets used for dialysis and aphaeresis. MDS markets AVF needles under the brand names "MasterGuard" and "PointGuard."

The alleged infringing device, made by ITL (an Australian company) sells under the name Platypus ™ Needle Guard (Platypus). ITL manufactures the Platypus in Malaysia and Singapore. The Platypus needle guard is a "stand-alone" product: a small configured piece of plastic. This plastic guard structure is not attached to any other device. In other words, the Platypus does not include a needle, but only a sheathing structure. Some claims of the '311 patent recite both a slotted guard and a guarded winged needle assembly. Before use, the Platypus resembles an open clamshell (open-shell configuration). During use, the halves of the clam shell close to form the needle guard (closed-shell configuration). The following illustration shows the Platypus in open-and closed-shell configuration:

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Transcript of Record at 18685, 18629, ***DSU Medical Corp**. v. JMS Co., JMS North America **Corp**., & ITL **Corp**. PTY*, Nos. 04-1620, 05-1048, 05-1052 (Fed.Cir. Sept. 21, 2004) (*Transcript*). The Platypus has an upper and a lower "jaw." When closed, the upper jaw extends around and overlaps the inner, lower jaw. During use, a **medical** technician closes the Platypus and locks it around tubing connected to the winged needle assembly. When the technician removes the needle from a patient, the worker slides the guard down the tube until the needle assembly's wings meet and pry the jaws apart. The wings and their attached needle assembly slide into and through the guard, forcing the jaws ever wider as the wings make their way into a notched opening at the guard's back. Ultimately the wings slide into the rear opening. At that point, the jaws close around the used needle.

JMS is a large Japanese **medical** supply business that competes with MDS in the United States market. Beginning in June 1999, JMS purchased Platypus needle guards from ITL, entering into an agreement to distribute the Platypus worldwide (the Supply Agreement). Under the Supply Agreement, JMS bought open-shell configuration Platypus guard units from ITL in Singapore and Malaysia. JMS generally closed the Platypus guards around needle sets before distributing them to customers.

DSU alleges that the Platypus infringes the '311 patent. **DSU** also alleges that JMS and ITL contributed to and induced each other's infringement. JMS sought to sell ITL's infringing Platypus until it could produce its substitute non-infringing product, the WingEater. ITL offered to supply its infringing Platypus. **DSU** additionally seeks damages from JMS because it "stole" MDS's ability to renew a MasterGuard exclusive license with a former customer, Fresenius USA Manufacturing, Inc. (Fresenius).

II.

1 **2** On February 5, 2001, the trial court entered a claim construction order. ***DSU** Med. **Corp**. v. JMS Co., JMS N. Am. **Corp**., & ITL **Corp**. PTY*, Nos. C-00-1826-DLJ, C-99-2690-DLJ (N.D.Cal. Feb. 5, 2001) (*Claim Construction Order*). This court reviews claim construction without deference. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "[T]he claims of a patent define the invention to which the ***1300** patentee is entitled the right to exclude." *Phillips v. AWH **Corp**.*, 415 F.3d 1303, 1312 (Fed.Cir.2005) (citing *Vitronics **Corp**. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996) ("We look to the words of the claims themselves ... to define the

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scope of the patented invention”)). This court recently enunciated predominant claim construction principles in *Phillips.* 415 F.3d at 1312-24.

3 The trial court construed “slidably enclosing” in claim 1 of the '311 patent:

> 1. A guard *slidably enclosing* a sliding assembly comprising a needle and a winged needle hub ....

'311 patent, col. 15, ll. 46-47 (emphasis added). The trial court concluded that this term in claim 1 “requires that the guard substantially contain the needle-assembly at all times.” *Claim Construction Order,* slip op. at 9. Because the Platypus is a “stand-alone guard” without a needle, the trial court granted summary judgment of non-infringement to the defendants on multiple claims.[1] *Id.,* slip op. at 15-19.

The language and context of the claims support the trial court's construction of “*slidably enclosing* a sliding assembly.” Again, the trial court read the claim to require that the guard substantially contain the needle-assembly at all times. *Claim Construction Order,* slip op. at 9. In the first place, claim 1 expressly recites the presence of a needle as part of the sliding assembly. Thus, the claimed “assembly” would not be complete without a needle. The claim also uses the term “enclosing.” In the context of an invention “for locking a needle in a shielded position as the needle is removed from a patient,” that language suggests constant shielding or covering of the sharp. '311 patent, col. 2, ll. 8-9. The specification reinforces that suggestion:

> [T]he guard is folded about its hinge position and locked ... into a generally cylindrical, folded configuration. Alternatively, the guard may be molded ... to enclose a sliding hub/needle assembly that has been positioned between the two pieces.

'311 patent, col. 2, ll. 53-58. By emphasizing that the guard is locked in a protective configuration, or molded to enclose the needle assembly, the specification conveys the concept of a permanent cover for the needle. Indeed, the figures in the specification show a completely enclosed, and thus guarded, needle. Figures 15-19 also show the needle hub as permanently housed in the guard. '311 patent, figures 15-19. The trial court also methodically considered and rejected each of **DSU's** arguments that the term means only generally surrounding the needle and hub. *Claim Construction Order,* slip. op. 8-15. This court concurs in the district court's analysis.

4 The court also construed “slot,” as used in claims 1, 46, and 52. *Claim Construction Order,* slip op. at 19-24. The relevant portion of claim 46 is:

> 46. A guard for slidably enclosing a sliding assembly ... said guard comprising ...
>
> a hollow member proportioned for receiving said needle and winged needle hub, said hollow member defining at least one longitudinal *slot* proportioned to receive a wing of said needle hub projecting outwardly through the *slot* when the needle hub resides within the hollow member in sliding relation thereto, and means, associated with the hollow member, for engaging said wing ***1301*** projecting through said *slot* when the needle and hub are in a slidingly retracted position in which the needle is enclosed by the hollow member for locking said needle hub and needle in said retracted position.

'311 patent, col. 20, ll. 20-39 (emphases added). Claim 52 is:

> 52. The guard of claim 46 in which said *slot* extends in a longitudinal direction through one end of said hollow member, to provide sliding access to said wing.

'311 patent, col. 20, ll. 63-65 (emphasis added). The trial court held that the term did not require “a defined width.” *Claim Construction Order,* slip op. at 19. Later the district court, at the request of defendants, clarified that “ ‘[s]lot’ shall mean ‘an opening in the guard capable of receiving a wing that projects through the opening and having both an upper edge and a lower edge that are defined by the sidewall of the guard.’ ” ***DSU*** *Med.* ***Corp****. v. JMS Co., JMS N. Am.* ***Corp****., & ITL* ***Corp****. PTY,* Nos. C-00-1826-DLJ, C-99-2690-DLJ (N.D.Cal. Apr. 30, 2001) (*Construction Clarification Order I*). In claim 46, because “proportioned to receive” modifies “slot,” the trial court explained that “slot” “shall mean ‘sized relative to the wing so that

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the wing extends through the slot when the hub is within the hollow member and so said slot can accommodate the wing's movement as it translates the length of the slot.' " *Id.; see also* ***DSU*** *Med.* ***Corp****. v. JMS Co., JMS N. Am.* ***Corp****., & ITL* ***Corp****. PTY*, Nos. C-00-1826-DLJ, C-99-2690-DLJ, slip op. at 29 (N.D. Cal. Jan 16, 2002) (*Construction Clarification II & SJ Order*).

The trial court identified the crux of the dispute over "slot" as "whether ... the slots for the wings should have defined widths closely approximating the wings' thickness." *Construction Clarification Order I*, slip op. at 19. If "slot" limits the size of the opening to accommodate the "minor" thickness of the '311 patent's wings, the Platypus would not infringe because its jaws accommodate any thickness. *Claim Construction Order*, slip op. at 19. On the other hand, if "slot" contains no thickness limitation, the Platypus would infringe because it opens to receive a wing of any size. *Id.*, at 19.

The claim language recites only "slot." Thus, the claim itself does not incorporate any thickness limitation. Moreover, the specification provided no size limitation on the opening. In a tribute to its complete analysis, the trial court went beyond those primary sources to also consult the prosecution history. *Phillips*, 415 F.3d at 1317 (a court "should also consider the patent's prosecution history, if it is in evidence"). The record before the Patent Office shows that the patentees amended the claims of Application Serial Number 252,564, which is the application from which the '311 patent (and '072 patent) derived, to avoid U.S. Patent No. 4,840,619 (Hughes Patent).

In amending the claims to avoid the Hughes Patent, however, the applicant did not limit the size of the slot, as argued by JMS and ITL. The amendments concerned only the orientation of the needle wings that moved back and forth through the slot. To distinguish the Hughes Patent, the patentee did not have to, and did not actually, limit the width of the slot. Thus, the trial court correctly construed "slot" as not requiring a defined width, as long as it was capable of receiving a wing. *Construction Clarification Order I*, slip op. at 14.

Under this claim construction, the trial court found that "as a matter of law, every reasonable jury would find that there is a slot in the [Platypus] closed-shell configuration." *Construction Clarification II & SJ Order*, slip op. at 29. Therefore, the trial court held that when sold in the United ****1302*** States in its "closed-shell" configuration, the Platypus literally infringed claims 46-47, 49, and 52-53 of '311 patent, when closed over the tubing of a needle-set. *Id.*

5 Viewing the evidence in the light most favorable to the nonmoving party, this court holds that the trial court correctly concluded that the closed-shell configuration of the Platypus does have a slot. As applied to the Platypus, its slot is an opening in a needle guard capable of receiving a wing that projects through the opening. Further, the slot has both an upper edge and a lower edge defined by the sidewall of the guard. The Platypus's slot is also sized relative to the wing and can accommodate the needle wing as it moves through the length of the slot. Furthermore, the Platypus contains the other limitations of claims 46-47, 49, and 52-53 of the '311 patent. Therefore, in its closed-shell configuration, the Platypus does infringe claims 46-47, 49, and 52-53 of the '311 patent. This court affirms the trial court's summary judgment ruling.

III.

6 The jury found that JMS North America and JMS directly and contributorily infringed, and that JMS additionally induced JMS North America to infringe. *Transcript*, at 453. However, the jury returned a verdict of non-infringement in favor of ITL. *Id.*, at 453-54. The jury entered a verdict finding that ITL did not engage in contributory infringement or inducement to infringe. *Id.*, at 453. The trial court denied **DSU's** motion for new trial on the jury's verdict that ITL did not contributorily infringe or induce infringement. This court reviews a denial of a motion for a new trial after a jury trial for an abuse of discretion. *Chiron* ***Corp****. v. Genentech, Inc.*, 363 F.3d 1247, 1258 (Fed.Cir.2004) (citing *De Saracho v. Custom Food Mach., Inc.*, 206 F.3d 874, 880 (9th Cir.2000)).

A.

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On appeal, **DSU** argues that ITL committed contributory infringement. According to **DSU**, the Platypus, which ITL sold to JMS, had no substantial noninfringing use. Therefore, **DSU** argues, ITL committed contributory infringement as a matter of law. ITL responds that it made and sold "most Platypus guards" outside of the United States. ITL also contends that the record contains no evidence that the Platypus was used in an infringing manner in the United States.

The Platypus sets that came into the United States fall within three categories:

> (1) JMS imported into the United States approximately 30 million Platypus guards that, prior to importation into the United States, it had already assembled into the closed-shell configuration, combined with needle sets. These units accounted for the vast majority of Platypus sales in the United States.
>
> (2) Fresenius purchased approximately 3.5 million Platypus guards, in the open-shell configuration without needle sets. ITL billed JMS for the shipments and shipped them to Fresenius in the United States at JMS's request. Fresenius ultimately decided that guards without needle sets did not meet FDA regulations, and it returned about 3 million.
>
> (3) ITL sent approximately 15,000 Platypus in the open-shell configuration to JMS in San Francisco. **DSU** introduced no evidence that those units were ever put into the closed-shell configuration in the United States.

Additionally, the record contained evidence that when instructed to do so by JMS, ITL would ship Platypus guard units F.O.B. into the United States. The record also shows, however, that ITL only sold the Platypus in its open-shell configuration.

7 **8** **9** Therefore, this court must determine whether the jury's verdict is against ***1303** the clear weight of the evidence. Under § 271(c):

> [w]hoever offers to sell or sells *within the United States* ... a component of a patented machine, manufacture, combination or composition ... constituting a material part of the invention, *knowing* the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce *suitable for substantial noninfringing use*, shall be liable as a contributory infringer.

35 U.S.C. § 271(c) (2000) (emphases added). In discussing 35 U.S.C. § 271(c), the Supreme Court stated:

> One who makes and sells articles which are only adapted to be used in a patented combination will be presumed to intend the natural consequences of his acts; he will be presumed to intend that they shall be used in the combination of the patent.

Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd., 545 U.S. 913, 125 S.Ct. 2764, 2777, 162 L.Ed.2d 781 (2005). In addition, the patentee always has the burden to show direct infringement for each instance of indirect infringement. *Dynacore Holdings **Corp**. v. U.S. Philips **Corp**.*, 363 F.3d 1263, 1272 (Fed.Cir.2004); *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed.Cir.1993) ("Liability for either active inducement of infringement or contributory infringement is dependent upon the existence of direct infringement."). Thus, to prevail on contributory infringement, **DSU** must have shown that ITL made and sold the Platypus, that the Platypus has no substantial non-infringing uses in its closed-shell configuration, that ITL engaged in conduct (made sales) within the United States that contributed to another's direct infringement, and that JMS engaged in an act of direct infringement on those sales that ITL made in the United States.

The trial court properly applied these legal principles. The trial court determined that the record showed that ITL supplied the Platypus, that the Platypus had no substantial non-infringing uses in its closed-shell configuration, and that ITL intended to make the Platypus that resulted in the potential for contributory infringement as a product designed for use in the patented combination. ***DSU** Med. **Corp**. v. JMS Co., JMS N. Am. **Corp**., & ITL **Corp**. PTY,* Nos. C-00-1826-DLJ, C-99-2690-DLJ, slip op. at 1-3 (N.D.Cal. Sept. 20, 2004) (*Post Trial Motions' Order*). In fact, even beyond the minimal intent requirement for contributory infringement, ITL acted with the knowledge of the '311 patent and knowledge that the component was especially

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made or adapted for use in an infringing manner. *Id.*, slip op. at 22-24. However, the district court denied the motion for a new trial because the record does not show that "the alleged contributory act ha[d] a direct nexus to a specific act of direct infringement." *Id.*, slip op. at 25. In denying the new trial, the court stated:

> And while it is true that Plaintiffs introduced evidence that "ITL sold and shipped millions of 'stand alone' guards directly to United States customers, including JMS [North America] and end-users like Fresenius," *there was no direct evidence* at trial establishing that these guards were actually closed and used as an act of direct infringement in the United States.

Id., slip op. at 26.

Upon review of the record, this court perceives, as well, an absence of evidence of direct infringement to which ITL contributed *in* the United States. Under the terms of the '311 patent, the Platypus only infringes in the closed-shell configuration. When open, the Platypus, for instance, lacks a "slot" as well as other claimed features. ITL only contributed to placing the Platypus into the closed-shell configuration ***1304** in Malaysia (category 1, above); not in the United States. Section 271(c) has a territorial limitation requiring contributory acts to occur in the United States. Furthermore, this court cannot reverse a jury verdict of non-infringement on mere inferences that the Platypus guard units sold in the United States (i.e., the open-shell configuration in categories 2 and 3, above) were put into the infringing closed-shell configuration. The record does not show that the Platypus guards ITL shipped into the United States in the open-shell configuration were ever put into an infringing configuration, i.e., closed-shell. On categories 2 and 3, above, the record contains no evidence of direct infringement, i.e., that the open-shell Platypus guards imported by ITL were sold or used in their closed-shell configuration. As a result, the trial court did not abuse its discretion in denying **DSU's** motion for new trial on ITL's contributory infringement.

On the issue of induced infringement, **DSU** argues that ITL induced infringement by inducing JMS to sell the closed-shell configuration in the United States. The district court denied **DSU's** motion for a new trial on the ground that, although JMS directly infringed, ITL did not intend JMS to infringe.

B.

RESOLUTION OF CONFLICTING PRECEDENT

Section III. B., only, is considered en banc.

Opinion for the court filed by Circuit Judge RADER, with NEWMAN, LOURIE, SCHALL, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, Circuit Judges, join. Concurring opinion filed by MICHEL, Chief Judge, and MAYER, Circuit Judge.

10 **11** This court addresses Part III. B., of this opinion en banc. This section addresses, in the context of induced infringement, "the required intent ... to induce the specific acts of [infringement] or additionally to cause an infringement." *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon **Corp**.*, 420 F.3d 1369, 1378 n. 4 (Fed.Cir.2005) (citing *MercExchange, L.L.C. v. eBay, Inc.*, 401 F.3d 1323, 1332 (Fed.Cir.2005)). This section clarifies that intent requirement by holding en banc that, as was stated in *Manville Sales **Corp**. v. Paramount Systems, Inc.*, 917 F.2d 544, 554 (Fed.Cir.1990), "[t]he plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." The requirement that the alleged infringer knew or should have known his actions would induce actual infringement necessarily includes the requirement that he or she knew of the patent. *See Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1364 n. 4 (Fed.Cir.2006) (citing *Manville* and explaining that the inducing infringement standard was satisfied "because it is undisputed that [the alleged infringer] had notice of the patent").

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12 **13** **DSU** claims the district court improperly instructed the jury on the state of mind necessary to prove inducement to infringe under 35 U.S.C. § 271(b). This court reviews the legal sufficiency of jury instructions on an issue of patent law without deference to the district court. *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed.Cir.2000). "This Court reviews jury instructions in their entirety and 'only orders a new trial when errors in the instructions as a whole clearly mislead the jury.' " *Chiron*, 363 F.3d at 1258 (quoting *Delta-X **Corp**. v. Baker Hughes Prod. Tools, Inc.*, 984 F.2d 410, 415 (Fed.Cir.1993)).

***1305** **14** **15** Under section 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). To establish liability under section 271(b), a patent holder must prove that once the defendants knew of the patent, they "actively and *knowingly* aid[ed] and abett[ed] another's direct infringement." *Water Technologies **Corp**. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed.Cir.1988) (emphasis in original). However, "knowledge of the acts alleged to constitute infringement" is not enough. *Warner-Lambert Co. v. Apotex **Corp**.*, 316 F.3d 1348, 1363 (Fed.Cir.2003) (citation omitted). The "mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *Id.* at 1364 (citing *Manville*, 917 F.2d at 554).

16 **DSU** asked the court to instruct the jury, purportedly in accordance with *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464 (Fed.Cir.1990), that to induce infringement, the inducer need only intend to cause the *acts* of the third party that constitute direct infringement. The trial court gave the following instruction to the jury:

> In order to induce infringement, there must first be an act of direct infringement and proof that the defendant knowingly induced infringement with the intent to encourage the infringement. The defendant must have intended to cause the acts that constitute the direct infringement and must have known or should have known than[sic] its action would cause the direct infringement. Unlike direct infringement, which must take place within the United States, induced infringement does not require any activity by the indirect infringer in this country, as long as the direct infringement occurs here.

Transcript, at 432. Thus, the court charged the jury in accordance with *Manville.* The statute does not define whether the purported infringer must intend to induce the infringement or whether the purported infringer must merely intend to engage in the acts that induce the infringement regardless of whether it knows it is causing another to infringe. **DSU** complains that the instruction is incorrect because it requires that the inducer possess specific intent to encourage another's infringement, and not merely that the inducer had knowledge of the acts alleged to constitute infringement.[2]

17 In *Grokster*, which was a copyright case, the Supreme Court cited with approval this court's decision in *Water Technologies* when it discussed inducement of infringement, stating:

> The rule on inducement of infringement as developed in the early cases is no different today. Evidence of "active steps ... taken to encourage direct infringement," such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe, and a showing that infringement was encouraged overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use.

Grokster, 125 S.Ct. at 2779 (citation and footnote omitted). As a result, if an entity offers a product with the object of promoting ***1306** its use to infringe, as shown by clear expression or other affirmative steps taken to foster infringement, it is then liable for the resulting acts of infringement by third parties. *Id.* at 2780. "The inducement rule ... premises liability on purposeful, culpable expression and conduct ...." *Id.*

18 *Grokster*, thus, validates this court's articulation of the state of mind requirement for inducement. *See Manville*, 917 F.2d at 544. In *Manville*, this court held that the "alleged infringer must be shown ... to have *knowingly* induced infringement," 917 F.2d at 553, not merely knowingly induced the *acts* that constitute direct infringement. This court explained its "knowing" requirement:

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> It must be established that the defendant possessed specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute inducement. The plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts *and* that he knew or should have known his actions would induce actual infringements.

Id. at 553. In *Water Technologies*, also cited with approval by the Supreme Court, 125 S.Ct. at 2779, this court clarified: "While proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice." 850 F.2d at 668.[3] Although this court stated "that proof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement," *Hewlett-Packard*, 909 F.2d at 1469, *Grokster* has clarified that the intent requirement for inducement requires more than just intent to cause the acts that produce direct infringement. Beyond that threshold knowledge, the inducer must have an affirmative intent to cause direct infringement. In the words of a recent decision, inducement requires " 'that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement.' " *MEMC Elec.*, 420 F.3d at 1378 (Fed.Cir.2005) (quoting *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed.Cir.2002)). Accordingly, inducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities. *Grokster*, 125 S.Ct. at 2780; *Manville*, 917 F.2d at 553. Accordingly, the district court correctly instructed the jury in this case.

C.

19 The district court denied **DSU's** motion for a new trial on the issue of inducement to infringe. This court reviews a denial of a motion for a new trial after a jury trial for abuse of discretion, affirming on any basis that supports the verdict. *Chiron*, 363 F.3d at 1258. In denying the motion for new trial, the trial court stated:

> Fundamental principles of law hold that it is up to the jury to make determinations of witness credibility, to decide the existence of any factual inferences, and to determine the weight to be attributed to any direct or indirect evidence. Although Plaintiffs introduced circumstantial evidence which permitted inferences of ITL's intentions, it is up to the Jury to decide whether or not to draw any inference and to consider the weight of any such evidence. Assessing ***1307** competing evidence is what the law asks juries to do, and the Court declines to take over this fundamental role of the Jury.

Post Trial Motions Order, slip op. at 15. The jury heard evidence about the commercial transactions between ITL and JMS, including JMS's intention to sell ITL's Platypus to Fresenius until JMS could get its own WingEater approved by the Food and Drug Administration (FDA) and ready for market. The jury also heard evidence that Mr. Utterberg's lawyer informed ITL in January 1997 that the Platypus infringed the '311 patent. Additionally, the jury learned that ITL contacted an Australian attorney, who concluded that its Platypus would not infringe. JMS and ITL then also obtained letters from U.S. patent counsel advising that the Platypus did not infringe. Mr. William Mobbs, one of the owners of ITL who had participated in the design of the Platypus, testified that ITL had no intent to infringe the '311 patent. *Post Trial Motions Order*, slip op. at 15.

20 Thus, on this record, the jury was well within the law to conclude that ITL did not induce JMS to infringe by purposefully and culpably encouraging JMS's infringement. To the contrary, the record contains evidence that ITL did not believe its Platypus infringed. Therefore, it had no intent to infringe. Accordingly, the record supports the jury's verdict based on the evidence showing a lack of the necessary specific intent. The trial court certainly did not abuse its discretion.

IV.

Based on a finding that MDS became the exclusive licensee of the '311 patent on July 17, 2001, the jury awarded MDS lost profit damages in the amount of $4,400,000. *Transcript*, at 455. It also awarded **DSU** a reasonably royalty for sales of the Platypus, at a rate of 5¢ per unit, totaling $655,211. *Id.* at 456.

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21 **DSU** appeals the trial court's denial of its motion for a new trial on price erosion damages and for three additional months of lost profits damages. *Post Trial Motions Order*, slip op. at 67. This court reviews a district court's denial of a motion for a new trial on the amount of damages for an abuse of discretion. *Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1394 (Fed.Cir.2003); *Unisplay, S.A. v. Am. Elec. Sign Co.*, 69 F.3d 512, 517 (Fed.Cir.1995).

A.

22 **DSU** complains that it was entitled to a new trial because the jury did not award its requested price erosion damages. On these points, the verdict form does not segregate the damages award into categories beyond lost profits and reasonable royalties. However, the jury had before it evidence of price erosion. Accordingly, this court has no basis to speculate that the jury did not award price erosion damages as part of its lost profits or reasonable royalty analysis. *Crystal Semiconductor* ***Corp****. v. TriTech Microelecs. Int'l, Inc.*, 246 F.3d 1336, 1360 (Fed.Cir.2001). The trial court properly denied **DSU's** motion for new trial on price erosion damages.

23 **DSU** also complains that it deserves a new trial because the jury should have decided that MDS was an exclusive licensee on April 5, 2001. The jury entered a verdict that the date on which MDS became an exclusive licensee of **DSU**, and thus, the date on which it would be entitled to collect infringement damages, was July 17, 2001. The trial court allowed the jury to make this determination, instructing it that MDS became an exclusive licensee of the '311 patent sometime ***1308** between April 5, 2001 and July 17, 2001. Substantial evidence supports the jury's decision to reject any contract between MDS and **DSU** earlier than July 17, 2001. The jury was free to determine, for instance, that Mr. Utterberg's testimony on this point was simply not credible. Mr. Utterberg testified that he "shook hands with himself" on an earlier date-as president and sole owner of both contracting parties. *Post Trial Motions Order*, slip op. at 56-57. At other times, however, he also contradicted himself and undermined the suggestion that a contract was entered into earlier than July 17, 2001. *Id.* at 57. Thus, the trial court did not abuse its discretion in denying a new trial on the date of the contract.

B.

24 The trial court excluded testimony from **DSU's** expert witness, Dr. Stephen A. Degnan, on "the hypothetical existence or hypothetical terms of a contract between [MDS] and Fresenius ... [and] as to any calculation or measure of patent infringement damages based upon any sale of the WingEater needle guard." ***DSU*** *Med.* ***Corp****. v. JMS Co.*, 296 F.Supp.2d 1140, 1159 (N.D.Cal.2003) (*In Limine Order*). According to **DSU**, JMS's infringement interfered with MDS's "decade-long" contractual relationship with Fresenius. Specifically, MDS contended that JMS used sales of the infringing Platypus guard to "steal" the contract with Fresenius, with the intent to later replace the infringing Platypus with its non-infringing WingEater. Thus, MDS sought lost profit damages, not only for the award it received from lost sales to the infringing Platypus, but also for sales it lost to the non-infringing WingEater. The trial court disallowed Dr. Degnan's testimony on this subject because "sales of acceptable noninfringing substitute products [could not] be the basis of legally compensable patent damages," and the WingEater was an acceptable noninfringing substitute for the patented products. *Id.*

25 Although reviewing a district court's "*Daubert* " ruling to exclude testimony for an abuse of discretion, this court reviews eligibility for lost profits damages without deference. *Micro Chem.*, 317 F.3d at 1391 (decision to admit expert testimony reviewed under regional circuit law); *Genentech, Inc. v. Amgen, Inc.*, 289 F.3d 761, 768 (Fed.Cir.2002) (Ninth Circuit reviews evidentiary rulings for abuse of discretion); *Rite-Hite* ***Corp****. v. Kelley Co.*, 56 F.3d 1538, 1544 (Fed.Cir.1995) (whether the lost profits are legally compensable is a question of law this court reviews de novo).

As noted above, the trial court reasoned that MDS "cannot be awarded lost profit damages based upon any sale by the defendant of the noninfringing WingEater needle guard." *In Limine Order*, 296 F.Supp.2d at 1156. It also reasoned that Dr. Degnan's

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proffered methodology, "requiring inter alia hypothesized terms in hypothesized contracts, is not grounded on established legal principle and is far too remote factually to be within the line drawn for legally compensable patent injuries." *Id.* Specifically, the trial court faulted Dr. Degnan's "accelerated market entry" notion that MDS would have captured the market in advance of the introduction of the WingEater, but for the infringing sales of the Platypus. *Id.* at 1151.

MDS, however, also argues that the foreseeability principle in *Rite-Hite* supports its case for lost profits on the WingEater. While it may be possible for an infringement to have a foreseeable, and therefore compensable, effect on future contracts, the trial court was correct to perceive that it could not occur when the future contract was itself for a non-infringing substitute. In *Grain Processing* ***Corp***. ****1309*** *v. American Maize-Prods. Co.*, 185 F.3d 1341 (Fed.Cir.1999), this court observed that "[m]arket sales of an acceptable noninfringing substitute often suffice alone to defeat a case for lost profits." *Id.* at 1352. Indeed in *Grain Processing*, as in this case, the noninfringing substitute that defeated the claim for lost profits was not yet offered for sale in the marketplace. *Id.* at 1354-55. Here, Dr. Degnan admitted that the WingEater was available in October 2001, and the FDA approved the WingEater for sale on June 20, 2001. Thus, Dr. Degnan's failure to consider the effect of the availability of the WingEater supports the trial court's exclusion of the hypothetical contract theory.

26 **27** In addition, *Grain Processing* stands for another proposition as well: "To prevent the hypothetical from lapsing into pure speculation, this court requires sound economic proof of the nature of the market and likely outcomes with infringement out of the picture." 185 F.3d at 1350. Indeed, the concept of sound economic proof requires some grounding in "sound economic and factual predicates." *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1311 (Fed.Cir.2002). The trial court perceived that Dr. Degnan did not ground his "accelerated market entry" theory in sound economic principle. The trial court perceived that Dr. Degnan relied too heavily on hypothesized contracts in hypothesized markets that lacked sound economic grounding. While damages analysis invariably involves hypothetical reconstruction of a "but for" marketplace, that reconstruction must include some footing in economic principle, which the trial court found lacking. Thus, this court detects no abuse of discretion in the trial court's exclusion of Dr. Degnan's testimony on lost profits damages.

V.

28 The trial court denied JMS's and ITL's motions for Judgment as a Matter of Law (JMOL) contesting the $4.4 million award for lack of support with substantial evidence. *Post Trial Motions Order*, slip op. at 55. This court reviews a trial court's JMOL rulings after a jury verdict by reapplying the district court's own standard. *Applied Med. Res.* ***Corp***. *v. United States Surgical* ***Corp***., 147 F.3d 1374, 1376 (Fed.Cir.1998). To prevail on appeal, JMS and ITL must show that substantial evidence does not support the jury's factual findings or that the trial court erred in applying the law on JMOL motions. *Perkin-Elmer* ***Corp***. *v. Computervision* ***Corp***., 732 F.2d 888, 893 (Fed.Cir.1984).

29 **30** This court sustains a jury's award of damages "unless the amount is grossly excessive or monstrous, clearly not supported by the evidence, or based only on speculation or guesswork." *Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc.*, 249 F.3d 1341, 1355 (Fed.Cir.2001). The jury was accorded discretion to resolve conflicts in the evidence of damages. *Brooktree* ***Corp***. *v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1580 (Fed.Cir.1992). Moreover, this court will resolve "any doubts about the amount ... against the infringer." *Kalman v. Berlyn* ***Corp***., 914 F.2d 1473, 1482 (Fed.Cir.1990) (quoting *Ryco, Inc. v. Ag-Bag* ***Corp***., 857 F.2d 1418, 1428 (Fed.Cir.1988)).

31 In an attempt to question the jury's lost profits verdict, JMS attempts to suggest that the market included numerous other noninfringing alternatives to the Platypus. Nevertheless, the jury awarded MDS lost profits beginning April 17, 2001. JMS acknowledged that it could not bring a guarded needle to the market by that date. JMS acknowledged that, as a result of its inability to bring its own guarded needle to market by that date, MDS could ****1310*** tie-up customers with multi-year MasterGuard contracts. Thus, even though the FDA approved the WingEater for sale in June 2001, it could not have replaced any sales of the patented invention, according to JMS's own admission, until its first commercial sale in October 2001. Furthermore,

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DSU provided evidence that no other non-infringing alternatives were acceptable during the necessary time periods. Though Nipro Medical Corporation distributed a guarded needle set called the "SafeTouch," it had design flaws that led to two FDA-published recalls, and prior to recall, it had limited geographical distribution and unsatisfactory manufacturing capacity. Though Diasol Inc. distributed, in the United States, a guarded needle set called the "Shelly," an independent rating agency (Emergency Care Research Insitute)[4] called Diasol's "Shelly" "unacceptable." *In Limine Order*, slip op. at 16. The record also shows that the "Shelly" sold only in very small quantities, and was not available to distributors like Fresenius.

Thus, substantial evidence supports the jury award for lost profits due to lost sales to the infringing Platypus guard. Further, this court does not perceive that the jury award is grossly excessive or monstrous, or based only on speculation or guesswork.

VI.

DSU also appeals the denial of all of its motions for new trial on various of the trial court's evidentiary rulings. *Post Trial Motions' Order*, slip op. at 3-4. DSU based its motions on a variety of alleged errors in admitting or excluding evidence. For instance, DSU faults the district court for admitting the testimony of Mr. Timothy Erskine on the question of obviousness of the '311 patent, for admitting evidence about the prosecution history of the related '072 patent, and for excluding evidence of ITL's patent infringement insurance from the consideration of willfulness. The Ninth Circuit reviews "decisions regarding admission of evidence for abuse of discretion," *Rogers v. Raymark Indus., Inc.*, 922 F.2d 1426, 1429 (9th Cir.1991) (citing *Daily Herald Co. v. Munro*, 838 F.2d 380, 388 (9th Cir.1988)). This court detects no abuse of discretion in any of these rulings.

32 DSU also asserts that the jury's verdict, finding claims 46-47 and 50-52 obvious, is against the great weight of the evidence. However, the lengthy trial record showed that the prior art contained all elements of claims 46-47, 50-52 of the '311 patent. This record includes: the testimony of Mr. Erskine; United States Patent No. 4,935,012 (Magre patent) and United States Patent No. 3,572,334, which disclose every element of '311 patent's claims 46, and 50-51; the Magre patent and United States Patent No. 3,463,152, which disclose every element of '311 patent's claims 46-47 and 50; the Magre patent and United States Patent No. 4,170,933, which disclose every element of claim 46; and the Magre patent and the Hughes patent, which disclose every element of claims 46-47 and 52. The record also showed evidence of adequate motivation to combine these references to reach a decision of obviousness. In addition, the jury heard adequate evidence on the objective indicia of non-obviousness. As a result, substantial evidence supports the obviousness verdict. The trial ***1311** court properly denied a new trial on this basis as well.

33 DSU also appeals the trial court's response to a question from the jury during jury deliberations. During deliberations, the jury requested a clarification on the hindsight jury instruction. *Transcript*, at 14984-85, 15019, 15036. The trial court responded by referring the jury back to the jury instructions on invalidity. *Id.* at 14985, 15019. Both parties had earlier accepted those instructions. Thus, the trial court did not abuse its "wide discretion" in responding to a jury question. *Arizona v. Johnson*, 351 F.3d 988, 994 (9th Cir.2003).

VII.

In conclusion, this court affirms the trial court's grant of summary judgment of non-infringement on the combination claims (combination of guard and needle assembly) and on the open-shell configuration of the stand-alone claims. This court affirms the trial court's evidentiary rulings. This court also affirms the trial court's denial of all of the post-trial motions, affirming entry of the final judgment in its entirety.

COSTS

Each party shall bear its own costs.

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AFFIRMED

MICHEL, Chief Judge, and MAYER, Circuit Judge, concurring.

Although we agree with the court's analysis in Section III.B, we do not consider it necessary to address this issue en banc. **DSU** misreads *Hewlett-Packard* as if we had said "proof of actual intent to cause the acts which constitute the infringement is a necessary *and sufficient* prerequisite to finding active inducement," but we did not. There is no actual conflict between *Hewlett-Packard* and *Manville* and, thus, no need for intervention by the full court. Such rare intervention should be reserved for real conflicts as well as cases of exceptional importance. *See* Fed. R.App. P. 35(a). In our opinion, the panel was free to conclude that the district court correctly rejected **DSU's** proffered jury instruction because, misunderstanding *Hewlett-Packard*, **DSU** did not correctly state the law.

Moreover, we write to make clear that we do not set forth a new standard here as to what satisfies the "knowledge of the patent" requirement in cases brought under 35 U.S.C. § 271(b). *See, e.g.*, *Insituform Techs., Inc. v. Cat Contr. Inc.*, 161 F.3d 688, 695 (Fed.Cir.1998) (analyzing section 271(b) liability under both actual and constructive knowledge standards). There is no dispute that ITL **Corporation** Pty, Ltd., had actual knowledge of United States Patent No. 5,112,311. Accordingly, the "knowledge of the patent" issue is not before us.

Parallel Citations

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Footnotes

1 The trial court granted a summary judgment of non-infringement on claims 1, 4-9, 12, 19, 20, 22-23 of the '311 patent, and on claims 1, 6, and 7 of the '072 patent.

2 In *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1469 (Fed.Cir.1990), this court stated that "[p]roof of actual intent to cause the acts which constitute infringement is a necessary prerequisite to finding active infringement." **DSU** reads this statement as standing for the proposition that proof of intent to cause infringing acts is all that is required in order to establish inducement of infringement.

3 *See also nCube **Corp**. v. Seachange Int'l, Inc.*, 436 F.3d 1317, 1325 (Fed.Cir.2006) (This court noted that "at least ... the alleged inducer had [to have] knowledge of the infringing acts," which included evidence of SeaChange's intent that its customers use the ITV systems it sold with Scientific-Atlanta equipment to perform the patented method.)

4 Emergency Care Research Institute is a non-profit health services research agency that has been providing information and technical assistance to the healthcare community to support safe and cost-effective patient care for over 30 years. It has been called the "Consumer Reports for **medical** devices" and the "preeminent source for healthcare risk management information and advice."

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