

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

Applera Corporation and :
Roche Molecular Systems, Inc., :
plaintiffs, :
v. : 3:98cv1201 (JBA)
MJ Research Inc. and Michael :
and John Finney, defendants. :

**Ruling on Plaintiffs' Motion in Limine to Exclude Evidence or
Argument by Defendants Regarding Customer Class
Exemptions [Doc. #762-4]**

Plaintiffs move pursuant to Fed. R. Evid. 402 and 403 to preclude defendants from presenting evidence or arguing at trial that certain classes of MJ's thermal cyclers customers and certain uses of MJ's thermal cyclers by MJ's customers are exempt from liability for direct infringement of the patents-in-suit, and that, as a result of these exemptions, defendants also are exempt from liability for inducing these customers to infringe the patents-in-suit, including the PCR process patents. As set forth below, plaintiffs' motion [Doc. #762-4] is GRANTED.

I. Background

By supplemental responses to interrogatories dated September 25, 2003, defendant MJ asserts that it cannot induce direct infringement of the patents-in-suit by certain of its end user customers because those customers cannot as a matter of law directly infringe the patents-in-suit as a result of either their

status or the uses to which they put MJ's thermal cyclers. See Cote Decl. [Doc. #784] Ex. 20 (MJ's Supplemental Responses) at 3-4, ¶ 1.g.-i.; see also Cote Decl. [Doc. #787] Ex. 42 (Defs.' Proposed Jury Instructions) ¶¶ III. Inst. 4, III. Inst. 5. Defendants include among the classes of customers exempt from direct infringement non-commercial or basic researchers operating under the "experimental use exception"; state governments, agencies and institutions; U.S. government contractors and grantees; foreign customers who have performed PCR on MJ thermal cyclers outside the United States; customers who have used their MJ thermal cyclers for purposes other than PCR, for example, cycle sequencing; and customers who perform PCR on MJ thermal cyclers in Roche's fields. See id.

II. Discussion

A. Non-Commercial or Basic Researchers

Plaintiffs contend that defendants' proposed jury instruction regarding experimental use, which asks the Court to charge the jury that any non-commercial or basic researchers performing PCR on MJ thermal cyclers are not directly infringing the patents-in-suit, is wrong and in conflict with binding precedent. Plaintiffs rely on the Federal Circuit's decision in Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002).

Defendants respond that a number of MJ's largest customers

use MJ thermal cyclers for non-commercial research purposes, most notably, U.S. laboratories and universities performing research related to the U.S. Human Genome Project. Because, according to defendants, that project seeks to research human DNA and make the information publicly available free of charge, defendants argue that these customers are not seeking to obtain a profit or commercial gain from their research but are acting for the advancement of science, and therefore, under the common law experimental use exception, cannot be liable for direct infringement. Defendants thus confirm that they "intend to argue that, because the non-commercial Human Genome Project researchers cannot be liable for direct infringement of plaintiffs' patents, MJ cannot be liable for inducing their infringement." Defs.' Opp'n [Doc. # 845] at 4. Defendants argue that Madey does not preclude automatically institutional, educational and academic customers from benefit of the experimental use exception but merely raises factual determinations for the jury.

The Federal Circuit repeatedly cautions that the judicially created experimental use defense under which defendants here attempt to take refuge continues to exist only in "very limited" and "very narrow" form, and is "strictly limited." Madey, 307 F.3d at 1359, 1360, 1361, 1362. The defendant in a patent infringement case bears the burden of establishing the availability of the defense. See id. at 1361. To do so, the

defendant must show that the use of the patented invention was "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." Id. at 1362 (quoting Embrex, Inc. v. Service Engineering Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000)). Incorrect formulations of the defense include those inoculating uses that are 'solely for research, academic, or experimental purposes' or 'made for experimental, non-profit purposes only.' See id. at 1361. Use that is in any way commercial or has the slightest commercial implication is not immunized by the defense. See id. at 1362. In addition, the defense does not immunize

any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.

In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.

Id. (emphasis added).

Defendants' representation that MJ's customers' non-commercial and not-for-profit research use of MJ's thermal

cyclers, including research for the U.S. Human Genome Project, will form the basis for the experimental use defense at trial raises great concern under Madey of confusing the jury with legally irrelevant evidence and argument. The proper focus is not on whether uses are non-commercial or not-for-profit but rather whether they are in keeping with defendants' customers' legitimate business objectives, including educating project participants, and increasing the university's or laboratory's status or ability to lure research grants, students, or researchers; but not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.

Moreover, plaintiffs here point to deposition testimony suggesting that at least part of the customer base envisioned by defendants as falling within the experimental use exception are commercial research outfits or molecular biology researchers involved in organizations whose primary business objective is research. See Cote Decl. [Doc. #784] Ex. 18 (Titus Depo.) at 556, 564; Cote Decl. [Doc. #787] Ex. 43 (Nussbaum Depo.) at 319-322. Defendants, by contrast, have not directed the Court to any evidence to be offered to properly support the experimental use defense, only arguments that are legally incorrect.

Accordingly, to avoid the potential of great jury confusion, for example, evidence or argument suggesting that a research university or laboratory employing MJ thermal cyclers for the

genome project cannot directly infringe the patents-in-suit because the usage is non-commercial or not-for-profit, plaintiffs' motion is GRANTED on the experimental use exception without prejudice for defendants to proffer to the Court the evidence they believe is legally relevant to the applicability of the experimental use defense with respect to any particular customer under Madey standards.

B. State Customers

Defendants' proposed jury instruction regarding state governments, agencies, and instrumentalities, to which plaintiffs take exception, reads,

There are classes of end-users who, as a matter of law, cannot infringe a patent.

...

- (2) State governments and their agencies and instrumentalities, including State colleges and universities, all of whom, are, like the U.S. Government, incapable of infringing a patent pursuant to sovereign immunity principles....

Cote Decl. [Doc. #787] Ex. 42 (Defs.' Proposed Jury Instructions) III. Inst. 4. Plaintiffs argue that, although the Eleventh Amendment to the U.S. Constitution prohibits a patentee from suing a state or instrumentality thereof in federal court for money damages for patent infringement, it does not preclude suit in federal court against the state officer who performed the infringing acts for injunctive relief under the Ex Parte Young

doctrine. Plaintiffs further reason that merely because states are immune from a particular type of remedy for their direct infringement of a patent it does not follow that their Eleventh Amendment immunity from money damages should be extended to their suppliers to exempt them from liability for inducing infringement. Plaintiffs find support in Syrrx v. Oculus Pharms., Inc., 2002 WL 1840917 (D. Del. Aug. 9, 2002) and Hercules, Inc. v. Minnesota State Highway Dept., 337 F.Supp. 795 (D. Minn. 1972).

Defendants argue that, under Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank, 527 U.S. 627 (1999), State governmental entities and their instrumentalities are immune from liability for direct infringement under the Eleventh Amendment, and therefore, there can be no inducement of infringement where the direct infringer is alleged to be a State governmental entity.

The Court agrees with plaintiffs. Florida Prepaid holds that, although a state or instrumentality thereof can infringe a patent, see e.g. Florida Prepaid, 527 U.S. at 643 ("...a State's infringement of a patent, though interfering with a patent owner's right to exclude others, does not by itself violate the Constitution."), Congress did not validly abrogate the states' sovereign immunity under the Eleventh Amendment when amending the Patent Act to permit suits for money damages in federal court

based on such infringement, see id. 647-48. This does not leave the patentee without remedy with respect to a state's or its instrumentalities' infringement of a patent. It seems clear that a patentee may still restrain a state's patent infringement by suing the responsible state officer for injunctive relief in federal court pursuant to the Ex Parte Young doctrine, see Seminole Tribe of Florida v. Florida, 517 U.S. 44, 72 n.16 (1996); see also Genentech, Inc. v. Regents of Univ. of Cal., 143 F.3d 1446, 1454 (Fed. Cir. 1998) vacated on other grounds by 527 U.S. 1031, and, depending on the state, pursue damage remedies for infringement in state court, see Florida Prepaid, 527 U.S. at 642-45 and n.9.

The premise for defendants' jury instruction, that a state entity is incapable of infringing a patent, thus fails. Infringement and liability therefor are two separate and distinct concepts, as is recognized elsewhere in patent law, for example, where a patent is held both to be infringed and invalid. Further, the availability of remedies against a state entity's direct infringement demonstrates that its immunity from damages in federal court suits stems not from a policy that encourages state infringement but rather from the unique considerations surrounding a state's sovereign immunity under the Eleventh Amendment. This policy provides no reason to extend the protection of sovereign immunity to a private party that induces

a state's direct infringement, but rather to treat such inducement in accordance with 35 U.S.C. § 271(b) by holding the inducer liable as an infringer to the extent it induces direct infringement of a patent notwithstanding that the direct infringer possesses a unique status precluding pecuniary liability for its direct infringement in federal court. Plaintiffs' motion is GRANTED on this point.

C. Federal Government Contractors and Grantees

Defendants propose to charge the jury:

There are classes of end-users who, as a matter of law, cannot infringe a patent.

...

- (1) The United States government and its agencies and instrumentalities, and contractors and grantees who perform research "by" or "for" the United States, all of whom cannot infringe a patent as a matter of law pursuant to sovereign immunity principles....

Cote Decl. [Doc. #787] Ex. 42. Plaintiffs object to this instruction as appearing "to assume that all activities by U.S. government contractors or grantees constitute use 'for' the United States and that all government contracts and grants provide the 'authorization and consent' of the United States, which are necessary predicates for exemption of third parties from liability for patent infringement under 28 U.S.C. § 1498(a)," Pls.' Mem. [Doc. #772-4] at 10, and argue that it is an assumption directly contrary to Madey v. Duke University, 307

F.3d 1351 (Fed. Cir. 2002). Plaintiffs point out that 28 U.S.C. § 1498(a) creates an affirmative defense for a private party on which it bears the burden of proof at trial, see Toxgon Corp. v. BNFL, Inc., 312 F.3d 1379, 1381-83 (Fed. Cir. 2002), and that, to establish it, defendants "must establish either (1) express consent to the infringement in the government grant, or (2) implied consent, which may be found only where (i) the government expressly contracted for work to meet certain specifications; (ii) the specifications cannot be met without infringing on a patent; and (iii) the government had some knowledge of the infringement," Pls.' Mem. [Doc. #772-4] at 12, citing Larson v. United States, 26 Cl. Ct. 365, 369-70 (Cl. Ct. 1992).

Defendants accept plaintiffs' formulations of the applicable doctrine under 28 U.S.C. § 1498(a), see Defs.' Opp'n [Doc. #845] at 7, but simultaneously state that certain of their customers, Federally Funded Research and Development Centers ("FFRDCs"), perform research that is by definition "for" the United States within the meaning of 28 U.S.C. § 1498(a). Citing various federal regulations, defendants argue that they "need not show that the Government 'authorized' or 'consented' to the use of the thermal cyclers because this 'authorization or consent' is expressly required to be a part of the contract," Defs.' Opp'n [Doc. #845] at 8, presumably meaning the contract between the customer FFRDCs and the Government. Defendants, however, do not

proffer to the Court the specific contracts entered into by the FFRDC customers and the Government.

Defendants contend that MJ's grantee customers "who conducted research that is funded by the U.S. Government would also be absolved of any liability for direct infringement," Defs.' Opp'n [Doc. #845] at 8, notwithstanding the Federal Circuit's contrary conclusion in 2002 in Madey, electing instead to rely on John J. McMullen Assocs., Inc. v. State Bd. Of Higher Educ., 268 F.Supp. 735, 739-40 (D. Ore. 1967) and Bereslavsky v. Esso Standard Oil Co., 175 F.2d 148, 150 (4th Cir. 1949). In the alternative, defendants argue that whether MJ's contractor or grantee customers qualify as performing work for and with the authorization or consent of the United States presents issues of fact for trial.

Madey, 307 F.3d 1351 and Toxgon, 312 F.3d 1379 demonstrate the total absence of merit in defendants' arguments. The determination of whether 28 U.S.C. § 1498(a) provides an effective affirmative defense requires analysis of the particular statements or aspects of the particular governmental grant or contract purportedly providing the Government's authorization or consent to be sued, see e.g. Madey, 307 F.3d at 1354, 1359-60, which requirement applies with equal force to FFRDCs since, in the subsection immediately following the regulation cited by defendants, the regulations explicitly provide that a consent to

infringement clause is optional for certain types of contracts, see 48 C.F.R. 27.201-2(a). A jury instruction that mere use of patents under the authority of a government research grant satisfies the use for and authorization of requirements of 28 U.S.C. § 1498(a) would certainly be legal error. See id. at 1359-1360. The Madey court stated,

... by failing to explain or demonstrate precisely how the ONR grant authorizes the government's consent to suit or authorizes Duke to use or manufacture the patented articles for the government, the district court has provided no findings or analysis upon which we can base our review of the issue appealed.... Although a research grant may not meet the requirements of §1498(a), from the limited record presented by the parties, it cannot be determined whether the ONR grant may authorize the necessary predicates for § 1498(a).

Id. at 1360.

Accordingly, plaintiffs' motion is GRANTED and defendants will not be permitted to advance the argument at trial (or offer evidence in support thereof) that certain of MJ's customers are exempt from liability for patent infringement under 28 U.S.C. § 1498(a) merely on the basis of their status as government contractors or grantees without clarification that MJ must also prove the infringing use was "for" the United States and with the "authorization or consent" of the United States.

D. Foreign Customers

Defendants request the following charge:

There are classes of end-users who, as a matter of law,

cannot infringe a patent.

...

- (3) MJ's foreign customers who have performed the PCR process on MJ thermal cyclers outside the United States, all of whom, cannot infringe United States patents as a matter of law....

Cote Decl. [Doc. #787] Ex. 42. Plaintiffs challenge this jury instruction to the extent it suggests that defendants cannot be held liable for inducing infringement by MJ's foreign customers of the thermal cycler patents-in-suit. Plaintiffs rely on 35 U.S.C. § 271(f)(1), which provides,

Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

Plaintiffs explain:

For example, MJ's foreign sales of MJ thermal cyclers (all of which include a metal block and Peltier device) and PCR reagents and intent to encourage its foreign customers to perform PCR on MJ thermal cyclers constitute induced infringement of claim 16 of the '493 thermal cycler patent, a combination claim for a "thermal cycling system for performing a polymerase chain reaction amplification protocol" comprising a thermal cycler with a Peltier device and metal block and a PCR reaction mixture, among other claim limitations. MJ's inducement of customers outside of the United States to perform the PCR process on such MJ thermal cyclers necessarily induces them to combine the components of the patented system of claim 16 of the '493 patent; thus MJ would be liable for infringement under § 271(f)(1) for the same reasons it is liable for inducing that infringement in the U.S. By the same reasoning, MJ would be liable for infringement of the asserted claims of the '610 and '675 patents, some of which claim apparatuses

comprising reaction tubes and thermal cyclers, among other limitations, by supply foreign customers with those separate components and encouraging their combination.

Pls.' Mem. [Doc. #772-4] at 13-14.

Defendants argue that § 271(f) was enacted in 1984 to prevent manufacturers from avoiding liability by the simple expedient of selling unassembled parts that are assembled abroad to form a patented product and not to prevent manufacturers of fully functional devices from selling those devices outside the United States "when the manufacturer has every right to sell those devices in the United States." Defs.' Opp'n [Doc. #845] at 10. Defendants conclude,

In this case, MJ is not selling component parts abroad with the intent that they be assembled into a patented product. Rather, MJ is selling a fully functioning thermal cyclers machine, which is a staple article of interstate commerce that can be sold in the United States because it has a host of non-infringing uses.

Id. at 10. In addition, with respect to the '493 patent, defendants argue that it is essentially a process patent because it requires placing a PCR reaction mixture into a thermal cyclers and that § 271(f) does not apply to process patents, citing Standard Havens v. Gencor, 953 F.2d 1360, 1374 (Fed. Cir. 1991), and arguing that, if it did, liability would require the Court to give U.S. patent law extraterritorial effect.

The Court again concurs with plaintiffs' analysis and conclusions. The examples provided by plaintiffs track the statutory language of § 271(f)(1). Defendants' distinction

between "unassembled parts" and "fully functional devices," by contrast, is not found in the statute, which focuses instead on "components of a patented invention, where such components are uncombined in whole or in part." Defendants' premise that it is permitted to sell thermal cyclers because they are staple goods appears to invoke a contributory infringement argument, which has no applicability to the concept of inducing infringement under § 271(f) (1). Defendants' contentions with respect to claim 16 of the '493 patent are readily answered by the observation that the claim is not for a process but for a thermal cycler system which includes components but not any process steps.¹

Accordingly, plaintiffs' motion is GRANTED and defendants will be precluded at trial from arguing (or offering evidence) that they are exempt from liability as a matter of law for inducing infringement by foreign customers of the thermal cycler patents (or that they are exempt from liability for direct

¹ The Court is troubled, however, by the statement in Waymark Corp. v. Porta Systems Corp., 245 F.3d 1364, 1368 (Fed. Cir. 2001) that "[i]f 271(f)(2) required actual assembly abroad, then infringement would depend on proof of infringement in a foreign country ... rais[ing] the difficult obstacle of proving infringement in foreign countries and pose the appearance of giving extraterritorial effect to United States patent protection." The language pointed to as demonstrating that actual assembly abroad is not required under § 271(f) (2), "intending that such component will be combined," is absent from § 271(f) (1), the language of which otherwise indicates that combination abroad is required, "in such manner as to actively induce the combination of such components outside the United States in a manner that would infringe the patent if such combination occurred within the United States." Defendants have not so argued (their extraterritorial argument being cabined to the '493 patent and the nature of performing a patented process versus combining the components of a patented invention) and the record is otherwise insufficient for the Court to address this potential problem. If necessary, the matter can be taken up in post-trial briefing.

infringement of the thermal cyclers patents for foreign sales where the manufacturing, sale, or offer to sell patented thermal cyclers occurred within the United States, see 35 U.S.C. § 271(a)).

E. Customers Who Have Used MJ Thermal Cyclers for Cycle Sequencing or Other Purposes Other than PCR, and Customers Who Perform PCR on MJ Thermal Cyclers in Roche's Fields

Plaintiffs take issue with defendants' proposed instruction that it cannot be held liable for inducing infringement by customers who use MJ thermal cyclers for purposes other than for PCR, arguing that it is only correct to the extent those customers use MJ thermal cyclers exclusively for cycle sequencing or other non-PCR purposes "as MJ is liable for inducing infringement by any customer who practices PCR in Applera's fields even if MJ also causes those same customers to perform non-PCR processes in a manner that does not infringe plaintiffs' PCR patent rights." Pls.' Mem. [Doc. #772-4] at 14. Plaintiffs cite for support Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1312 (Fed. Cir. 1998) (affirming grant of summary judgment of inducement of infringement where defendant advertised and caused non-infringing as well as infringing uses).

Similarly, plaintiffs challenge defendants' proposed jury instruction that it is not liable for inducing direct

infringement by thermal cyclers customers who perform PCR within Roche's fields, arguing that it is only correct to the extent that such use is exclusively within Roche's fields, "as MJ is liable for inducing infringement by any customer who practices PCR in Applera's fields even if MJ also causes those same customers to perform PCR in a manner that does not infringe Applera's PCR patent rights." Pls.' Mem. [Doc. #772-4] at 15.

While defendants state there is no dispute on these two jury instructions, they also assert that they "intend to argue that they cannot be liable for inducing infringement by selling thermal cyclers to customers who use MJ's thermal cyclers for purposes other than PCR, or to customers who perform PCR within Roche's fields." Defs.' Opp'n [Doc. #845] at 11. Defendants take the opportunity to "note" that "it still remains plaintiffs' burden to prove direct infringement by an end user, and to do so they must show that the end user actually performed unlicensed PCR in PE/Appplera's fields as a result of MJ's inducement." Id.

As pointed out by plaintiffs, defendants' intended argument is imprecise and misleading, improperly "suggest[ing] that just because an MJ customer uses the MJ thermal cycler for purposes other than PCR or for PCR in a Roche field (e.g., human diagnostics) the customers (sic) is automatically exempt from liability for all other uses, including PCR use in Applera's fields (e.g., research)." Pls.' Reply [Doc. #825-4] at 11. A

proper argument would be that defendants cannot be liable for inducement where their end user customer does not directly infringe, for example, the PCR process patents because that customer does not use its MJ thermal cycler for PCR but uses it exclusively for other purposes, or does perform PCR on its MJ thermal cycler but does so exclusively in Roche's fields. Accordingly, plaintiffs' motion is GRANTED to preclude defendants from making their intended argument, that they are exempt from liability for inducing infringement by customers who use MJ thermal cyclers for purposes other than PCR or who perform PCR in Roche's fields. Defendants may argue that they are not liable for inducing infringement by customers who use their MJ thermal cyclers exclusively for purposes other than PCR or who perform PCR exclusively in Roche's fields.

Lastly, the Court notes that plaintiffs' statement "[d]efendants have made no showing that **any** customer's thermal cycler use is exclusively is (sic) fields outside of Applera's fields," Pls.' Reply [Doc. #825-4] at 12 (unnumbered) (emphasis in original), could be misunderstood to shift improperly the burden to defendants to prove that they did not induce infringement. To the contrary, the burden to prove defendants' liability under 35 U.S.C. § 271(b) is shouldered by plaintiff, including the required element of direct infringement of the patents-in-suit by

MJ's customers.

IT IS SO ORDERED.

/s/

Janet Bond Arterton, U.S.D.J.

Dated at New Haven, Connecticut, this 3rd day of March 2004.