EXHIBIT 7

Not Reported in F.Supp.2d, 2006 WL 1646113 (N.D.Cal.)
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United States District Court,
N.D. California.
FRESENIUS MEDICAL CARE HOLDINGS, INC., a New York corporation; and Fresenius USA, Inc., a Massachusetts corporation, Plaintiffs and Counterdefendants,
v.
BAXTER INTERNATIONAL, INC., a Delaware corporation; and Baxter Healthcare Corporation, a Delaware corporation, Defendants and Counterclaimants.
No. C 03-01431 SBA(EDL).

June 12, 2006.

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ORDER DENYING BAXTER'S MOTION *IN LIMINE* NO. 4 PRECLUDING EVIDENCE AND ARGUMENT REGARDING PATENT DEATHS AND PRODUCT RECALLS

SAUNDRA BROWN ARMSTRONG, District Judge.

***1** This matter comes before the Court on Baxter's Motion *in Limine* No. 4 to preclude evidence and argument regarding patient deaths and product recalls. Having considered the submissions and arguments of the parties, and the applicable facts and law, the Court hereby DENIES Baxter's Motion.

The "patient death and product recall" evidence Baxter seeks to preclude includes numerous recalls of both hemodialysis machines, including System 1000, and disposables and other components, including dialyzers and bloodlines. [FN1] This evidence is relevant to both the calculation of a reasonable royalty and the validity of the patents-in-suit, especially in view of Baxter's heavy reliance on Fresenius's commercial success in the market.

FN1. While Baxter phrased the evidence at issue as evidence regarding "patient deaths and product recalls," the patient death evidence is tangential to the recall evidence.

With respect to evidence of machine recalls, Baxter offers no argument as to why this evidence should be precluded. Fresenius contends that this evidence is highly relevant to the calculation of a reasonable royalty under the *Georgia Pacific* framework. The Court agrees.

First, commercial success of the product allegedly made under the patented technology is one of the important factors to be considered in determining a reasonable royalty. *Georgia-Pacific Corp. v. U.S. Plywood Co.*, 318 F.Supp. 1116, 1120 (D.C.N.Y.1970) ("8. The established profitability of the product made under the patent; its commercial success; and its current popularity."). In this case, Baxter argues that Fresenius's commercial success with its hemodialysis products was due to the incorporation of a touch screen in the 2008K machines and therefore would lead to a higher royalty rate in the hypothetical negotiation. Fresenius counters that evidence of Baxter's repeated recalls demonstrates otherwise. Fresenius argues that the multiple recalls have severely affected Baxter's reputation in the marketplace and has contributed significantly to Fresenius's commercial success with its hemodialysis products, including the 2008K machines. Evidence of machine recalls tends to show that Fresenius's success in selling its 2008K machines was due to factors such as perceived differential in hemodialysis product quality between Baxter and Fresenius, rather than the patented technology.

Second, a key part of the reasonable royalty determination under *Georgia Pacific* is whether the accused infringer had acceptable non-infringing alternatives available to it at the time of the hypothetical negotiation. *Id.* at 1120 ("9. The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results."). In this case, Fresenius contends that its 2008H hemodialysis machine-which did not use a touch screen-was such an alternative, and that had Althin or Baxter demanded an excessive royalty, Fresenius would have continued selling the 2008H machine. Baxter argues, however, that the 2008H machine was not an acceptable alternative because it lacked a touch screen. To rebut this argument, Fresenius contends that if Fresenius could not sell the 2008K machines, customers facing the choice between the safe, reliable 2008H machines and the less than reliable Althin/Baxter machines would have chosen the 2008H machines, notwithstanding its lack of a touch screen. To determine whether the 2008H machine is an acceptable non-infringing alternative as Fresenius claims, the jury needs to be presented with a complete and accurate view of the marketplace. Evidence of recalls of Baxter's hemodialysis products forms part of the market reality that should be considered by the jury. FN2

FN2. Relatedly, Baxter bases its over $80 million royalty damages claim on the theory that if Fresenius could not add a touch screen to its machines, it would suffer severe market contraction and lost sales; and to avoid this loss of sales, Fresenius would have paid a very high royalty. Baxter's theory assumes that without a touch screen product, Fresenius would lose sales to Althin/Baxter's products with a touch screen. Fresenius argues, however, even without a touch screen product, it would not have suffered any meaningful market contraction because customers would have preferred the proven reliability of Fresenius's machines-even without a touch screen-to the Althin/Baxter products. Again, to resolve the dispute, the jury needs to be presented with a full and accurate view of the marketplace.

***2** Third, evidence of product recalls is relevant to the terms of the hypothetical license. *Id.* at 1120 ("7. The duration of the patent and the term of the license."). License agreements have historically included provisions for adjusting royalty rates. Quality control problems of a competitor-licensor is likely to lead the licensee to re-negotiate for a

lower royalty rate over the term of the hypothetical license.

Fourth, evidence of product recalls is also relevant to the determination of the commercial relationship between Fresenius and Althin, Baxter's predecessor, or Baxter, which is another factor to be considered in calculating a reasonable royalty. *Id.* at 1120 ("5. The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter."). The quality problems Baxter faced were largely inherited from its predecessor Althin. Evidence of recalls tends to show that customers view Fresenius's machines as superior than Althin's or Baxter's machines. In such a case, the degree to which Althin's or Baxter's and Fresenius' machines (and disposables) compete is reduced, which in turn would tend to reduce the royalty rate in the hypothetical negotiation.

Moreover, Baxter has relied heavily on Fresenius's commercial success as "secondary considerations" evidence in countering Fresenius's invalidity contention based on obviousness. "For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re GPAC, Inc.*, 57 F.3d 1573, 1580 (Fed.Cir.1995). Evidence of recalls is relevant to a determination of whether there is the requisite nexus between Fresenius's commercial success and the patented technology. In the hemodialysis market, sales for products are primarily driven by factors such as vendors' reputations for quality, service, machine reliability. [Kelleher Decl. (Dkt. No. 447), Ex. 1, at ¶¶ 19, 137-138, 141-142 & n. 84.] Evidence of product recalls tends to show that Fresenius's commercial success in the market was due to its reputation in product quality and reliability, rather than the patented technology, which in turn will support a finding that there is a lack of the requisite nexus between Baxter's alleged secondary considerations evidence and the merits of the claimed invention.

With respect to the evidence of recalls of dialyzers and bloodlines, Baxter argues that such evidence should be excluded because these products are "not even at issue." However, it is Baxter, not Fresenius, who has chosen to make these products an issue. Baxter's damages claim is based in part on Fresenius's sales of unpatented "disposables, spare parts, and service," including dialyzers, under the theory that Fresenius was able to sell these products as "convoyed" products along with the accused machines. Fresenius contends that customers purchased its dialyzers because of their superior quality, not because the customers may also have purchased a 2008K machine at some point in time. Evidence of recalls of Althin/Baxter's disposables and other hemodialysis components tends to show that customers were seeking out Fresenius's products based on the fact that they were superior to the competition, not because Fresenius introduced a machine with a touch screen, and thus is relevant to the calculation of damages.

***3** "All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority." Fed.R.Evid. 402. Baxter invokes Federal Rule of Evidence 403 as a reason to exclude this evidence, claiming that the evidence will be prejudicial to Baxter and confusing to the jury. The Court, however, finds that Federal Rule of Evidence 403 does not warrant the preclusion of the evidence.

With respect to the evidence of machine recalls, Baxter does not, and cannot make any argument as to why the relevant evidence should nonetheless be excluded. Baxter bases its prejudice claim largely on the allegedly "inflammatory" patient death evidence. This argument does not apply to evidence of machine recalls because none of the machine recalls involved patient deaths.

With respect to the evidence of recalls of dialyzers and bloodlines, the probative value of the evidence substantially outweighs any marginal prejudice to

Baxter or supposed danger of jury confusion.

Baxter's reliance on products liability cases is misplaced. In the cases relied on by Baxter, before reaching the conclusion that the probative value of the recall evidence was substantially outweighed by the Rule 403 dangers, the courts first found that the recalls arising out of unrelated defects had no relevance to the products liability claims at issue. *Olson v. Ford Motor Company*, 410 F.Supp.2d 869, 873-74 (D.N.D.2006); *Verzwyvelt v. St. Paul Fire & Marine Insurance Company*, 175 F.Supp.2d 881, 888 (W.D.La.2001). To the contrary, in the present case, as discussed above, evidence of repeated recalls of Baxter's products are highly relevant to both the validity of the patents-in-suit and the computation of a reasonable royalty should Fresenius be found to have infringed any valid and enforceable claim of the patents-in-suit.

Moreover, the likelihood of unfair prejudice and jury confusion existed in *Olson* and *Verzwyvelt* is absent in this case. In products liability cases, because of the likelihood for spillover between recalls and inference of fault, there is a real danger that unfair prejudice and jury confusion will arise if the plaintiff is permitted to parade before the jury evidence of a product recall of a different product. *See Verzwyvelt*, 175 F.Supp.2d at 888-89. However, in this patent case, such danger does not exist. Even if there is any likelihood for spillover between recalls and inference of fault, Baxter's liability is not at issue and thus will not be prejudiced. In addition, prejudice is unlikely to arise in this case because both Baxter and Fresenius are commercial entities. *Posttape Associates v. Eastman Kodak Co.*, 537 F.2d 751, 758 (3d Cir.1976) ("It is doubtful that there would be any prejudice because the parties were both commercial entities[.]").

As noted by the court in *United States v. Bainbridge Management, L.P.*, Case Nos. 01 CR 469-1, 01 CR 469-6, 2002 WL 31006135, at *1 (N.D.Ill. Sept.5, 2002), a case relied on by Baxter, evidence is excluded on a motion in limine "only if the evidence is clearly inadmissible for any purpose." FN3 "In weighing the probative value of evidence against the dangers and considerations enumerated in Rule 403, the general rule is that the balance should be struck in favor of admission." *United States v. Dennis*, 625 F.2d 782, 797 (8th Cir.1980); *see also United States v. Dodds*, 347 F.3d 893, 897 (11th Cir.2003) (noting that Rule 403 is "an extraordinary remedy which the district court should invoke sparingly, and [t]he balance ... should be struck in favor of admissibility"). Even in the context of products liability actions, where recall evidence is relevant to a central issue in a case, admission is warranted. *See, e.g., Snodgrass v. Ford Motor Co.*, Case No. Civ 96-1814(JBS), 2002 WL 485688, at *3-*6 (D.N.J. March 28, 2002) (denying motion to preclude evidence of safety recall even though it was conceded that the evidence was prejudicial to Ford because the evidence was relevant to issues central to the case).

> FN3. *Bainbridge* is also distinguishable from the present case in that the evidence excluded in *Bainbridge* had no probative value. In *Bainbridge*, the defendants were indicted with mail and wire fraud, health care fraud, and racketeering charges. The crux of the indictment involved a kickback and bribery scheme. Physicians allegedly used unnecessary medical procedures to generate fees and obtain funds from Medicare, Medicaid, and private insurers. In excluding the evidence of the death of two patients, allegedly the results of two such unnecessary procedures, the court found that the evidence was not probative of either the necessity of the medical procedures performed or the elements of wire and mail fraud, racketeering, or health care fraud. *Bainbridge*, 2002 WL 31006135, at *2.

***4** In this case, evidence relating to the quality and reliability of Baxter's hemodialysis products is highly relevant to both the calculation of a reasonable royalty and Baxter's contention of secondary

considerations. The prejudice to Baxter, if any, would be nominal, and in any event would not be "unfair." *See Snodgrass,* 2002 WL 485688, at *5 (noting that exclusion under Rule 403 requires that the prejudice be *unfair).* Introduction of the recall evidence "does not portend a foregone conclusion in [Fresenius's] favor, nor does it suggest decision in [Fresenius's] favor due to an emotionally-charged issue, such as gender-based derogatory comments in a sex discrimination case." *Id.* Moreover, jury confusion is unlikely given that Baxter is not being sued for products liability of products unrelated to the recalls here. Any residual confusion can be cured by clear limiting instructions of the purposes for which the evidence may be considered. *See id.* at *6. Therefore, Rule 403 does not warrant preclusion of the relevant recall evidence in this case.

For the foregoing reasons, the Court hereby DENIES Baxter's Motion *in Limine* No. 4.

IT IS SO ORDERED.

N.D.Cal.,2006.
Fresenius Medical Care Holdings, Inc., v. Baxter Intern., Inc.
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