UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
NORTHERN DIVISION
AT COVINGTON

CIVIL ACTION NO. 14-96-DLB-JGW

PATRICIA FENN **PLAINTIFF**

vs. **MEMORANDUM OPINION AND ORDER**

PHILIPS ELECTRONICS
NORTH AMERICA CORPORATION, et al. **DEFENDANTS**

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Defendants Philips Respironics, Inc. and Philips Electronics North America Corporation (hereinafter "the Philips Defendants") move to dismiss this action for lack of subject-matter jurisdiction, arguing that Plaintiff Patricia Fenn's (hereinafter "Fenn") state tort claims do not present a federal question simply because they incorporate alleged violations of the Food, Drug, and Cosmetic Act ("FDCA"), as modified by the Medical Device Amendments of 1976 ("MDA"). The Philips Defendants also contend that dismissal is appropriate because Fenn did not properly serve them or file suit within the applicable statute of limitations. Defendants Rotech Healthcare and Rothert's Hospital Equipment, Inc. (hereinafter "the Rotech Defendants") also filed a Joint Motion, adopting and incorporating by reference all arguments raised by the Philips Defendants (Doc. # 15).

I. Factual and Procedural Background

Patricia Fenn is a 71 year old woman who suffers from asthma, chronic obstructive pulmonary disease ("COPD"), diabetes mellitus, morbid obesity and sleep apnea. (Doc.

1, p. 5, ¶ 12). These medical conditions made it difficult for Fenn to breathe while asleep, so she began using a Continuous Positive Airway Pressure ("CPAP") device at night. (*Id.* at p.3, ¶ 1). Fenn's CPAP machine, the REMStar Auto with A-Flex Sleep Therapy System, was manufactured by the Philips Defendants. (*Id.*). The Rotech Defendants, who provide home healthcare equipment and services, distributed the device to Fenn. (*Id.*).

On May 10, 2013, Fenn fell asleep while using the CPAP device, only to awake later that night with a bad taste in her mouth. (*Id.* at p. 7, ¶ 19). The machine was emitting a bad odor, like something burning, and the mask was covered with a brownish coating. (*Id.*). Although Fenn had been feeling fine earlier that evening, she began experiencing headache, nausea, abdominal pain and vomiting shortly after removing the mask. (*Id.*). When her symptoms worsened, Fenn called 911 and EMS transported her to the emergency room at St. Elizabeth Hospital. (*Id.*).

After arriving at St. Elizabeth, Fenn continued to report difficulty breathing, throbbing headache with an 8/10 pain level and blurry vision in her left eye. (*Id.* at p. 7-8, ¶ 19-20). Fenn also told hospital staff that the CPAP machine had an "explosive event where the mask actually slammed her in the face." (*Id.* at p. 8, ¶ 20). It is unclear how long Fenn stayed at the hospital, what kind of treatment she received or whether chronic injuries resulted. (*Id.*). The Complaint offers only a general statement that Fenn's damages for physical pain and suffering, emotional distress, loss of earning capacity, loss of enjoyment of life, incurred medical and hospital expenses and loss of earning capacity "have occurred in the past and will continue into the future." (*Id.* at p. 16, ¶ 53).

According to the Complaint, the Rotech Defendants took custody of Fenn's CPAP machine after the incident. (*Id.* at p. 3, ¶ 1). The Rotech Defendants then sent the FDA

a “grievously inaccurate” Medwatch Form FDC 3500A, which failed to described Fenn’s injuries or identify corrective measures taken. (*Id.* at p. 8, ¶ 21). Fenn alleges that the device is still in the custody of the Rotech Defendants. (*Id.* at p. 3, ¶ 1).

Fenn filed this civil action on May 9, 2014. (Doc. # 1). That same day, her attorney sent blank summonses to both the Philips Defendants and the Rotech Defendants.[1] The Philips Defendants responded by filing their Joint Motion to Dismiss for Lack of Jurisdiction (Doc. # 9), which the Rotech Defendants adopted (Doc. # 15). About one month later, the Clerk of Court issued a Notice of Deficiency as to these summonses and directed Fenn to file the summonses stating the method of service. Fenn did as required and the Clerk of Court issued the summonses, which were returned executed on June 25, 2014 (Doc. # 17). Defendants then renewed their Joint Motion (Doc. # 19).

II. Analysis

1. Standard of Review

“Motions to dismiss for lack of subject matter jurisdiction fall into two general categories: facial attacks and factual attacks.” *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir. 1994). While factual attacks focus on the factual existence of subject matter jurisdiction, facial attacks challenge the sufficiency of the pleadings. *Id.* Facial attacks are evaluated under the same standard applicable to Rule 12(b)(6) motions. *Id.* Accordingly, courts must “accept all material allegations as true and construe them in the light most favorable to the nonmoving party.” *Id.*

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1) The blank summonses were deficient because they were not issued by the Clerk of Court. Although Fenn’s attorney filled out the necessary information, he did not present the completed documents to the Clerk of Court for signature and sealing. *See* Fed. R. Civ. P. 4(b); LR 4.3.

Although Defendants have not specified whether their Motion qualifies as a factual attack or a facial attack, it reads as a facial attack. Instead of disputing any of the facts alleged in the Complaint, Defendants focus on why federal question jurisdiction should not lie. Accordingly, the Court will evaluate Defendants' Motion under the Rule 12(b)(6) standard.

2. Clarification of the Complaint

Before delving into its substantive analysis, the Court must address a few ambiguities in Plaintiff's Complaint. Patricia Fenn brings a total of ten state law claims against the Philips Defendants and the Rotech Defendants: (1) negligence; (2) negligence *per se*; (3) breach of express warranty; (4) breach of warranty as to merchantability; (5) breach of implied warranty; (6) strict liability for failure to warn; (7) strict liability for design defect; (8) strict liability for manufacturing defect; (9) strict liability for failure to adequately test; and (10) punitive damages. (Doc. # 1, p. 14-24, ¶ 47-112). According to the Complaint, the Court has federal question jurisdiction over some of these claims because they include alleged violations of the Food, Drug, and Cosmetic Act ("FDCA") and Medical Device Amendments ("MDA"), thereby raising issues of "federal statutory and regulatory interpretation." (*Id.* at p. 6, ¶ 14). Other claims are supposedly subject to supplemental jurisdiction because they "are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy." (*Id.* at p. 6-7, ¶ 16).

It would certainly be helpful to know which claims are subject to the federal question jurisdiction analysis, and which are merely before the Court on supplemental jurisdiction, but the Complaint makes no such distinctions. The individual counts also provide dubious guidance. Although the Complaint includes an introductory section about the mechanics

of the FDCA and MDA, only one of the counts specifically cites to FDCA and MDA requirements. (*Id.* at p. 16, ¶ 55). But because the Complaint also generally alleges that some of the state law claims impose requirements that are parallel to those imposed by the FDCA and MDA, the Court hesitates to limit its federal question analysis to just one claim. Thus, out of an abundance of caution, the Court will analyze the Complaint as if all claims were predicated on federal question jurisdiction, as any supplemental jurisdiction arguments are likely to rise and fall with that determination.

3. The Food, Drug, and Cosmetic Act and Medical Device Amendments

The FDCA "specifically empowers the Food and Drug Administration ("FDA") to regulate production and labeling practices of medical product manufacturers and distributors." *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 674 (W.D. Ky. 2013); 21 U.S.C. § 301 *et seq*; *see also Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134 (2000) (finding that one of the FDCA's "core objectives is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use"). However, "Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA." *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n. 4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions.").

For many years, "the introduction of new medical devices was left largely for the States to supervise as they saw fit." *Reigel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). However, the Medical Device Amendments of 1976 "imposed a regime of detailed federal oversight," in which the level of administrative control varies according to the complexity

of the device and the risk of usage. *Id.* at 316; 21 U.S.C. § 360c *et seq*; *see also Sadler*, 929 F. Supp. 2d at 674. The MDA also "swept back some state obligations" with the following express preemption clause:

> Except as provided in subsection (b)[2] of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a); *Sadler*, 929 F. Supp. 2d at 674. This clause does not prevent states "from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (internal quotations omitted).

4. Federal Question Jurisdiction

a. Evolution of 'Arising Under' Jurisdiction

District courts "have original jurisdiction of all civil actions *arising under* the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331 (emphasis added). A claim is said to 'arise under' federal law if a federal question is "presented on the face of the plaintiff's properly pleaded complaint." *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987); *Merrell Dow Pharm., Inc. v. Thompson*, 478 U.S. 804, 808 (1986). "It is not enough that the plaintiff alleges some anticipated defense to his cause of action, and asserts that

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2) Subsection (b) "permits the FDA to exempt some state and local requirements from preemption." *Reigel*, 552 U.S. at 316.

the defense is invalidated by some provision of the Constitution of the United States." *Louisville & Nashville R.R. Co. v. Mottley*, 211 U.S. 149, 152 (1908).

In the vast majority of federal question cases, this "well-pleaded complaint rule" is easily satisfied because federal law actually creates the cause of action. *Merrell Dow*, 478 U.S. at 808-809. However, a case may also 'arise under' federal law "'where the vindication of a right under state law necessarily turn[s] on some construction of federal law.'" *Id.* (quoting *Franchise Tax Board v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 9 (1983)). Stated another way, it must "'appear[ ] that some substantial, disputed question of federal law is a necessary element of one of the well-pleaded state claims.'" *Id.* (quoting *Franchise Tax Bd.*, 463 U.S. at 13). The "mere presence of a federal issue in a state cause of action does not automatically confer federal question jurisdiction." *Id.*

If the state claim incorporates a federal standard for which there is no private right of action, the inquiry becomes more difficult. In *Merrell Dow v. Thompson*, the Supreme Court of the United States considered whether a state negligence action, based in part on a pharmaceutical company's alleged violations of the FDCA, gave rise to federal question jurisdiction. 478 U.S. at 804. The Court answered this question in the negative, reasoning that "the congressional determination that there should be no federal remedy for the violation of this federal statute is tantamount to a congressional conclusion that the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently 'substantial to confer federal question jurisdiction.'" *Id.* at 814.

Over the next twenty years, a circuit split developed as to whether *Merrell Dow* "always requires a federal cause of action as a condition for exercising federal-question jurisdiction," prompting the Court to revisit its federal question analysis. *Grable & Sons*

Metal Prod., Inc. v. Darue Eng'g & Mfg. 545 U.S. 308, 311-12 (2005). In *Grable*, the Court considered "whether want of a federal cause of action to try claims of title to land obtained at a federal tax sale precludes removal to federal court of a state action with nondiverse parties raising a disputed issue of federal title law." *Id.* at 310. This time, the Court found that the case warranted federal jurisdiction because "Grable has premised its superior title claim on a failure by the IRS to give it adequate notice, as defined by federal law." *Id.* at 314-15. The notice question was not only a necessary element of Grable's state quiet title action, but also a substantial and disputed federal issue, as the parties disagreed on the meaning of 'notice' for purposes of federal tax law. *Id.* The Court further reasoned that it was possible to entertain the case "without disturbing any congressionally approved balance of federal and state judicial responsibilities" because so few state quiet title actions involve contested issues of federal law. *Id.* at 315.

The Court then turned its attention to *Merrell Dow*, clarifying that the case "should be read in its entirety as treating the absence of a federal private right of action as evidence relevant to, but not dispositive of the 'sensitive judgments about congressional intent' that § 1331 requires." *Id.* at 318. The absence of a private right of action became important in *Merrell Dow* "when the Court treated the combination of no federal cause of action and no preemption of state remedies for misbranding as an important clue to Congress's conception of the scope of jurisdiction to be exercised under § 1331." *Id.* Under the circumstances presented in *Merrell Dow*, the exercise of jurisdiction would have effectively opened the floodgates, "[f]or if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action." *Id.* By contrast, "jurisdiction over actions like Grable's would not

materially affect, or threaten to affect, the normal currents of litigation." *Id.* at 319.

b. Examination of the Federal Issue

Like *Merrell Dow* and *Grable*, the instant case also involves state law claims that allegedly turn on interpretations of federal law. Accordingly, the Court will focus on "whether the federal issue is: (1) necessarily raised; (2) actually disputed; (3) substantial; and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn v. Minton*, 133 S.Ct. 1059, 1065 (2013).

In analyzing the first factor, the Court looks to *Mauk v. Medtronic, Inc.*, in which the Western District of Kentucky considered whether state law claims referencing the MDA necessarily raised a federal issue. *See* No. 3:13-CV-01066-CRS-JDM, 2014 WL 4203134 at *7 (W.D. Ky. Aug. 22, 2014). The court answered this question in the affirmative. *Id.* Not only would the plaintiffs have to avoid preemption by alleging a violation of state law that paralleled a violation of federal law, thereby proving a violation of federal law, but the preemption analysis would likely require the court to interpret the MDA. *Id.*; *see also* 21 U.S.C. § 360k(a)(1) (preempting any state requirements that are different from, or in addition to, any requirements imposed by the MDA).

Fenn's state law claims similarly reference the FDCA and MDA, so she too must demonstrate that the alleged violations of state law parallel violations of federal law in order to escape preemption. Because Fenn must essentially prove a violation of federal law, and because this analysis will require the Court to interpret the MDA, a federal issue is necessarily raised in this case.

As for the second factor, Fenn broadly states that the Court will have to determine whether Defendants' conduct conformed to FDCA and MDA requirements, and if they did

not, in what manner Defendants violated the FDCA and MDA. Although Fenn fails to identify a more precise legal or factual dispute, the Complaint's in-depth treatment of the FDCA's § 510k marketing requirements leads the Court to believe that compliance with § 510k may be the central issue in this case. Thus, the Court will infer at this juncture that there is an actually disputed federal issue. *See Mauk*, 2014 WL 4203134 at *7 (finding that "the federal issue is disputed, as the central issue to be resolved is whether Medtronic promoted off-label uses of Infuse, and whether this promotion was the source of Plaintiffs' injuries").

The Supreme Court of the United States has recently clarified the third factor. In *Gunn v. Minton*, the Court held that the 'substantiality' requirement is not met simply because the resolution of that federal issue is "vitally important to the particular parties in that case." 133 S.Ct. at 1068. There must be "something more, demonstrating that the question is significant to the federal system as a whole." *Id.* The possibility that a state court might incorrectly resolve the issue is insufficient. *Id.* at 1066.

Nothing in the record suggests that the federal questions involved in this case are significant to the federal system as a whole. The few other courts that have addressed this issue in the context of the FDCA and MDA reached a similar conclusion. *See Mauk*, 2014 WL 4203134 at *8 and *Goade v. Medtronic, Inc.*, No. 13-5123-CV-SW-ODS, 2013 WL 6237853 at *5-6 (W.D. Mo. Dec. 3, 2013) (noting that federal issues have been found substantial when they directly affect the government's operations, as in *Grable*). While these cases may have involved slightly different aspects of the FDCA, the Court is not aware of any nuances in this case that would dictate a different result.

Thus, the Court arrives at the final, and arguably most important, factor–whether the federal issue is capable of resolution in federal court without disrupting the federal-state balance approved by Congress. Although case law is clear that the lack of a private right of action for FDCA and MDA violations does not control the federal question jurisdiction analysis, it is a relevant factor for the Court's consideration. *Grable*, 545 U.S. at 318. Moreover, the lack of a private right of action, when combined with no preemption of state remedies, is "an important clue to Congress's conception of the scope of jurisdiction to be exercised under § 1331." *Id.* After all, "if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. *Id.*

These conditions, which ultimately led the *Merrell Dow* Court to find that federal question jurisdiction was lacking, are also present in this case. Fenn's state law claims include alleged violations of the FDCA/MDA, for which there is no private right of action. While the preemption issue has not been extensively briefed, Fenn has repeatedly stated that her state law claims parallel the federal requirements, and there is case law to suggest that at least some of her claims would not be preempted. *See Waltenburg v. St. Judge Med., Inc.*, No. 3:13-CV-011-06-TBR, 2014 WL 3586471 (W.D. Ky. July 21, 2014) (holding that negligence, strict liability manufacturing defect and negligent failure to warn claims under Kentucky law are not preempted by the MDA's express preemption provision); *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670 (W.D. Ky. Mar. 8, 2013) (concluding that negligence and strict liability for failure to test claims were not expressly preempted). If this Court were to exercise federal jurisdiction over this case, its decision might "attract [ ] a horde of original filings and removal cases raising other state claims with embedded federal

issues," which would certainly disrupt the federal-state balance approved by Congress. *Grable*, 545 U.S. at 318.

Thus, the Court concludes that federal question jurisdiction is not present in this case. Although there seems to be a necessarily raised and disputed federal issue, it simply does not have the broader implications for the federal system to qualify as 'substantial,' nor is it capable of resolution without disrupting the federal-state balance. Having found that federal question jurisdiction is lacking, the Court need not address the parties' arguments with respect to improper service and the statute of limitations.

5. Supplemental Jurisdiction

Since the Court has determined that federal question jurisdiction does not exist, supplemental jurisdiction will not lie either. While there are situations in which it is proper to resolve the supplemental jurisdiction claims after disposition of the original jurisdiction claims, this is certainly not one of those instances. *See Landefeld v. Marion Gen. Hosp., Inc.*, 994 F.2d 1178, 1182 (6th Cir. 1993) (finding no error in the district court's decision to dismiss the plaintiff's pendent state breach of contract and tort claims following dismissal of his federal handicap discrimination claim); *Aschinger v. Columbus Showcase Co.*, 934 F.2d 1402, 1412 (6th Cir. 1991) (stating that district courts should balance the interests of judicial economy and the avoidance of multiplicity of litigation against the possibility of needlessly deciding state law issues). Thus, this action must be dismissed in full. Fenn is free to re-file her action in the appropriate state court within ninety (90) days of the entry of this Order. *See* Ky. Rev. Stat. Ann. § 413.270 (stating that "[t]he time between the commencement of the first and last action shall not be counted in applying any statute of limitation").

III. Conclusion

Accordingly, for the reasons stated herein,

IT IS ORDERED as follows:

(1) Defendants' Joint Motion to Dismiss (Docs. # 9 and 15) be, and is hereby, **granted in full**;

(2) Plaintiff's Complaint is hereby **dismissed with prejudice**; and

(3) This matter is hereby **stricken** from the Court's active docket.

This 13th day of February, 2015.

Signed By:
David L. Bunning
United States District Judge

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