

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JANE L. TOFANELLI, individually,)
and in her capacity as)
EXECUTRIX OF THE ESTATE OF)
JOSEPH D. TOFANELLI)
Plaintiffs,)
)
v.) CIVIL ACTION NO.
) 07-11840-DPW
)
BIOGEN IDEC, INC., ELAN)
CORPORATION, PLC AND ELAN)
PHARMACEUTICALS, INC.,)
Defendants.)

MEMORANDUM AND ORDER
August 5, 2008

The Plaintiff Jane L. Tofanelli filed this wrongful death action against Biogen Idec, Inc. ("Biogen"), Elan Corporation, PLC, and Elan Pharmaceuticals, Inc. ("Elan Pharmaceuticals") (collectively the "Defendants") alleging that the Defendants failed to provide adequate warnings of the risks associated with the prescription drug Tysabri. The drug was approved by the Food and Drug Administration under an accelerated approval process. It was administered to Joseph D. Tofanelli, the husband of the Plaintiff. Mr. Tofanelli thereafter died due to an uncontrolled opportunistic herpes simplex virus infection.

The Plaintiff originally filed this case in Massachusetts state court, and the Defendants removed to federal court. The Plaintiff argues that federal court lacks subject matter jurisdiction and has moved for remand to the state court. The Defendants, for their part, oppose the motion to remand and have moved to transfer the case to the Southern District of Iowa where

the drug was administered to Mr. Tofanelli. I will grant the motion to remand the case and, consequently, do not address the Defendants' motion to transfer since remand makes that motion moot.

I. BACKGROUND

Jane L. Tofanelli filed this case on her own behalf and as executrix of her husband's estate, alleging that her husband died due to the negligence, gross negligence, and wanton and malicious conduct of the Defendants. The Complaint specifically alleges at paragraph 33 that the Defendants "were aware of but failed to adequately warn regarding the immunosuppressant dangers and risks of Tysabri."

According to the complaint, the Defendants began marketing Tysabri, a prescription drug used for the treatment of remitting and relapsing multiple sclerosis ("MS"), in the United States on November 24, 2004. Mr. Tofanelli had been diagnosed with MS for 23 years, and based on available information regarding Tysabri, his physicians prescribed the drug to him as a treatment for his MS. On February 17, 2005, Mr. Tofanelli received his prescribed infusion of Tysabri.

Shortly after Mr. Tofanelli's infusion, the Defendants disclosed additional information regarding the side effects caused by the drug. One day after Mr. Tofanelli's infusion, the Defendants notified the United States Department of Health and

Human Services, Food and Drug Administration ("FDA") that a patient participating in a Tysabri clinical trial had died from progressive multifocal leukoencephalopathy ("PML"), "an opportunistic viral infection of the brain that usually leads to death or severe disability." Eleven days after Mr. Tofanelli's infusion, Tysabri was pulled from the market by the Defendants.

On May 25, 2005, the Plaintiff discovered Mr. Tofanelli in a collapsed state. Mr. Tofanelli was hospitalized, and when his condition did not improve, an MRI was conducted, which showed "significant right-sided temporal horn changes consistent with herpes encephalitis." The Plaintiff alleges "Mr. Tofanelli died from the effects of this opportunistic infection on June 6, 2005."

The Complaint alleges that, at the time Tysabri was initially marketed by the Defendants, data obtained during pre-marketing clinical trials indicated that "the use of Tysabri was associated with the development of atypical or opportunistic infections." Notwithstanding this information, the labeling for Tysabri contained no warning about these effects.

In June of 2006, the Defendants obtained FDA approval to reintroduce Tysabri to the United States marketplace. In conjunction with the drug reintroduction, the Defendants also provided revised labeling for Tysabri that was approved by the FDA. The labeling included new warnings about the risk of

atypical and opportunistic infections and specifically stated:

- "Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability."
- "Progressive multifocal leukoencephalopathy, an opportunistic infection caused by the JC virus that typically occurs in patients that are immunocompromised, has occurred in 3 patients who received Tysabri in clinical trials."
- "Immunosuppression - The immune system effects of Tysabri may increase the risk for infections."
- "In post-marketing experience, one patient who received Tysabri developed herpes encephalitis and died."

After the Plaintiff filed her Complaint in Middlesex Superior Court raising state law product liability claims, the Defendants removed this case to federal court on the basis of federal question jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1441.

II. ANALYSIS

A. Standard of Review

In this context, "the propriety of the removal . . . turns on whether the case falls within the original 'federal question' jurisdiction of the federal courts." *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 808 (1986). The Defendants, as the party seeking removal, bear the burden of showing that removal is proper. *BIW Deceived v. Local S6, Indus. Union of Marine and Shipbuilding Workers of Am., IAMAW*, 132 F.3d 824, 831 (1st Cir. 1997).

The statutory grant of removal provides that "any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States." 28 U.S.C. § 1441(a). The statutory grant of federal jurisdiction provides that a federal district court has original subject matter jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331; see also U.S. Const. art. III, § 2. If the federal court lacks subject matter jurisdiction to hear the case, however, then the case must be remanded, see 28 U.S.C. § 1447(c).

Although a case "arising" under federal law will generally have a federal cause of action, federal question jurisdiction also encompasses actions "where the vindication of a right under state law necessarily turn[s] on some construction of federal law." *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 8-9 (1983). Based on the "well-pleaded complaint" rule, the federal right must, however, be an essential element raised in the complaint rather than a defense relied upon by the defendant. *Id.* at 9-11. A federal preemption defense, in particular, will not confer federal jurisdiction except where an "area of state law has been completely preempted." *Caterpillar, Inc. v. Cecil Williams*, 482 U.S. 386, 393 (1987). *Cf. AFSCME Council 93 v. Gordon*, 505 F. Supp. 2d 183 (D. Mass. 2007)

(removal not available in labor dispute in which application of federal statutes was embedded); *Wiener v. Wampanoag Aquinnah Shellfish Hatchery Corp.*, 223 F. Supp. 2d 346 (D. Mass. 2002) (removal not available in land use dispute involving federally recognized Native American tribe).

In a recent treatment of this type of jurisdictional issue, the Supreme Court has advised that federal question jurisdiction turns on whether "a state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005), *rehearing denied*, 545 U.S. 1158 (2005).

B. Motion to Remand

The Defendants have the burden of showing that the Plaintiff's claims "arise" under federal law. On its face, the Complaint only purports to raise product liability claims based on state law, but the Defendants argue that these claims actually and legibly raise substantial federal issues embedded in the state claim. Specifically, the Defendants assert that the "plaintiff seeks to litigate [the] FDA's consideration of the pre-marketing clinical trial data for Tysabri." The Defendants claim that this litigation challenges the FDA's regulatory authority to approve the initial and accelerated marketing of certain prescription drugs.

The Defendants' arguments attempt to frame the federal question as an issue raised by the claims in the Complaint rather than a preemption defense to be raised by the Defendants. Styling the question in that fashion is a prudent strategic course because "[a] defense such as federal preemption . . . is not a basis for removal, even if the defense is anticipated in the complaint, and even if it is the only true issue in the case." *Commonwealth v. Fremont Inv. & Loan*, Civil Action No. 07-11965-GAO, 2007 WL 4571162, at *2 (D. Mass. Dec. 26, 2007). In order for the Defendants to prevail, they must show that the Plaintiffs' claims either: 1) are completely pre-empted by federal law or 2) fall within the "federal ingredient" doctrine. *Id.* I address each of these possibilities in turn.

1. Complete Preemption

The Defendants do not undertake to argue that federal law completely preempts state law in the area of drug regulation, thus I only address this issue briefly to provide context. If federal law completely preempts state law in a particular area, then a "complaint that comes within the scope of the federal cause of action necessarily 'arises under' federal law." *Franchise Tax Bd.*, 463 U.S. at 23-24. But the Supreme Court has only recognized three federal statutory schemes as supporting complete preemption, those for: (i) labor contracts under § 301 of the Labor-Management Relations Act, 29 U.S.C. § 185; (ii) ERISA benefits under § 502(a) of the Employee Retirement Income

Security Act, 29 U.S.C. § 1132(a), and (iii) usury claims against federally chartered banks under §§ 85 and 86 of the National Bank Act, 12 U.S.C. §§ 85-86. *U.S. Airways Master Executive, Council v. Amer. West Master Executive Council*, 525 F. Supp. 2d 127, 133-34 (D.D.C. 2007); see *Fayard v. Northeast Vehicle Servs., LLC*, ___F.3d ___, 2008 WL 2719889, at *5 (1st Cir. July 14, 2008).

Labeling under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* has not to date been determined to provide grounds for complete preemption. There is no current basis to find what has conventionally been termed complete preemption here and consequently complete preemption is not available to justify removal.

2. Federal Ingredient

The Defendants do mount full argument that the state law product liability claims in this litigation fall within the "federal ingredient" doctrine, because the claims challenge the FDA's decision to grant Tysabri accelerated marketing approval. "Federal ingredient" jurisdiction arises when a "plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." *Franchise Tax Bd.*, 463 U.S. at 27-28. Nevertheless, the federal forum is generally unavailable if granting jurisdiction would disturb the balance established between the federal and state judiciaries. See *Grable*, 545 U.S. at 314. The precise scope of the "federal

ingredient" doctrine is unclear,¹ and the First Circuit, even before *Grable* was handed down, observed that federal jurisdiction pursuant to this doctrine "should be applied with caution". *Almond v. Capital Props., Inc.*, 212 F.3d 20, 23 (1st Cir. 2000).

The Defendants assert that there is a substantial federal interest in protecting the congressionally mandated "central role of [the] FDA in approving drugs." Under the FDCA, "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug." 21 U.S.C. § 355(a). In addition, the FDA may approve a drug pursuant to a "fast track" process if the drug is "intended for the treatment of a serious or life-threatening condition and it demonstrates the potential to address unmet medical needs for such a condition." 21 U.S.C. § 356(a)(1). The FDA conducts a risk-benefit analysis, and the Defendants argue that state law failure to warn claims based on pre-marketing information used in the FDA's analysis threaten the

¹ Different approaches to the scope of the doctrine can be observed in two recent cases involving state law malpractice claims arising from alleged mishandling of federal question litigation. Compare *Singh v. Duane Morris LLP*, ___ F.3d ___, 2008 WL 2908912, at *2-3 (5th Cir. July 30, 2008) (holding that a malpractice claim based on legal representation in a federal trademark case does not raise a substantial federal interest) with *Air Measurement Techs., Inc. v. Akin Gump Strauss Hauer & Feld, L.L.P.*, 504 F.3d 1262 (Fed. Cir. 2007) (holding that a federal court has subject matter jurisdiction over a malpractice claim stemming from representation in a federal patent lawsuit).

agency's ability to fulfill its congressionally mandated role of approving drugs.

The Defendants undertake to fashion a line between the allegations in the Complaint, which they argue are preempted by the FDA's role in evaluating drugs for initial and accelerated approval, and a preemption defense. A practical and commonsense reading of their contentions leads me to the conclusion that this is simply a preemption defense hopefully recast in different words. But even assuming the defendants have not drawn a line invisible to the human eye, they must still show that the federal interest embedded in this state law products liability case is within the elusive "federal ingredient" doctrine limned in *Grable*.

The Defendants rely on the FDA 2006 Final Rules issued on January 24, 2006 to support their assertion that state law tort claims that infringe upon the FDA's drug approval authority raise the substantial federal issue of preemption. In its Final Rules, the FDA states:

State law actions also threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public - the central role of FDA - sometimes on behalf of a single individual or group of individuals.

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006). This statement is part of a discussion that is said to "represent[] the government's long standing views on preemption, with a particular emphasis on how that doctrine applies to [s]tate laws that would require labeling that conflicts with or is contrary to FDA-approved labeling." *Id.* at 3934. In an amicus brief recently filed by the Solicitor General, the government, while conceding that the Supreme Court "need not rely on deference to conclude that . . . claims challenging FDA's weighing of health risks and benefits are preempted," Brief of United States as Amicus Curiae Supporting Petition at 26, *Wyeth v. Levine*, No. 06-1249 (U.S. June 2, 2008), offers "a more generally applicable rule of decision" based upon the FDA's 2006 preemption rule. *Id.* at 27. In summary, this rule of decision would provide that state product liability claims regarding drugs are preempted when "they challenge labeling that FDA approved after being informed of the relevant risk." *Id.* at 7.

This proposed rule of decision is plainly at odds with Massachusetts law, under which compliance with FDA labeling regulations does not necessarily protect the manufacturer from state law failure to warn claims. See *MacDonald v. Ortho Pharm. Corp.*, 394 Mass. 131, 139 (1985); *Brochu v. Ortho Pharm. Corp.*,

642 F.2d 652, 658 (1st Cir. 1981).²

Courts elsewhere that have considered the issue of whether the FDA's drug approval authority preempts state law failure to warn claims have reached differing conclusions. The Supreme Court has granted certiorari in *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006), *cert. granted*, __ U.S. __, 128 S. Ct. 1118 (2008), to address the question.³ Although preemption is an interesting and hotly contested issue, it is nonetheless one I do not resolve because limits on the availability of removal present an antecedent hurdle to the exercise of this Court's jurisdiction to address the issue on the merits at all.⁴

² I note that these cases were decided prior to the FDA 2006 Final Rules and recent developments in the law of preemption in the context of the FDA regulatory regime. *Cf. Riegel v. Medtronic, Inc.*, __ U.S. __, 128 S.Ct. 199 (2008).

³ In *Levine v. Wyeth*, the Supreme Court of Vermont found no federal preemption because it did not find a conflict between state laws and FDA regulations. 944 A.2d at 193-94. The Vermont court viewed the FDA regulations as providing a floor on labeling requirements, which allowed drug manufacturers "to add or strengthen a warning 'to increase the safe use of the drug product' without prior FDA approval." *Id.* at 193 (citing 21 C.F.R. ¶ 314.70(c)(6)(iii)(C)). By contrast, the Third Circuit, after reviewing the FDCA, the FDA's regulations, and the FDA's actions taken pursuant to its statutory authority, recently held certain failure-to-warn claims preempted. *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 276 (3d. Cir. 2008).

⁴ Although the parties both point to case law supporting their respective arguments regarding whether the state claims have been preempted by FDA regulations, they have not asked me to resolve the issue, nor should I, since:

[a]s a matter of common practice, a district court confronted with a question of subject matter

The Defendants are essentially proposing that I exercise federal jurisdiction given the unsettled nature of the law in this area. I decline their offer. Nothing in this dispute requires "resort to the experience, solicitude and hope of uniformity that a federal forum offers." *Grable*, 545 U.S. at 312. A federal interest in ensuring uniformity in the interpretation of a federal statute "is considerably mitigated by the fact that, even if there is no original district court jurisdiction for these kinds of actions, [the Supreme Court] retains power to review the decision of a federal issue in a state cause of action." *Merrell Dow*, 478 U.S. at 816; *Franchise Tax Bd.*, 463 U.S. at 12 n. 12 ("If the state courts reject a claim of federal preemption, that decision may ultimately be reviewed on appeal by this Court."). State courts are equally capable of determining federal preemption issues and to the extent the Supreme Court wishes to review their decisions, it can grant certiorari. In fact, this approach is reflected in the travel of *Levine v. Wyeth*, the drug labeling preemption case decided by the state Supreme Court of Vermont. A writ of certiorari was granted, and the case is now awaiting oral

jurisdiction reviews a plaintiff's complaint not to judge the merits, but to determine whether the court has the authority to proceed. When conducting this inquiry, the court only asks whether the complaint, on its face, asserts a colorable federal claim.

BIW Deceived, 132 F.3d at 832.

argument before the Supreme Court.

In the conventional allocation of legal responsibilities between state and federal courts, "[t]he States traditionally have had great latitude under their police powers to legislate as 'to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) (quoting *Slaughter-House Cases*, 16 Wall. 36, 62 (1873)). Through their police powers, states have traditionally provided private remedies to protect citizens from harms such as a manufacturer's inadequate product warnings. These rights have created a large pool of product liability cases. The Defendants suggest the stream of cases that would be diverted from state to federal courts is narrowed by focusing only on those drug cases where the plaintiff challenges a warning based on pre-marketing information. This would similarly be true if the Supreme Court adopted the Solicitor General's proposed rule that claims challenging labeling the FDA has approved after being informed of the relevant risk are preempted. Nevertheless, as the Supreme Court observed in *Grable* "[a] general rule of exercising federal jurisdiction over state claims resting on federal mislabeling . . . would . . . herald[] a potentially enormous shift of traditionally state cases into federal courts." *Grable*, 545 U.S. at 319.

In any event, the rule of decision now being contended for by the government in *Levine*, is not consistent with the current state of Massachusetts products liability law as recognized for the past quarter century by the First Circuit, see *Brochu v. Ortho Pharm. Corp.*, 642 F.2d at 658. The prospect it raises for the defensive assertion of something less than complete preemption as a grounds for removal does not find favor in current case law, see *Caterpillar, Inc. v. Cecil Williams*, 482 U.S. at 393.

The issues in this case are matters to be addressed in the first instance by the state courts. Perhaps those courts, with the benefit of a decision by the Supreme Court in *Levine*, will find it necessary to recognize federal preemption of some sort as applicable to this case. But the present posture of case law does not justify removal from state court to this court.

III. CONCLUSION

I find that the Defendants have not met their burden of showing that removal is proper. Accordingly, I GRANT the Plaintiff's motion to remand the case.

/s/ Douglas P. Woodlock
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE