UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: VIOXX	:	**MDL NO. 1657**
PRODUCTS LIABILITY LITIGATION	:	**SECTION: L**
	:	
	:	**JUDGE FALLON**
	:	**MAG. JUDGE KNOWLES**

THIS DOCUMENT RELATES TO
Calandra, et al. v. Merck & Co., Inc., 05-2914
De Toledo, et al. v. Merck & Co., Inc., 05-5083

ORDER & REASONS

Pending before the Court is the Defendant's Motion to Dismiss the Foreign Class Actions, or, in the Alternative, Strike the Foreign Class Allegations (Rec. Doc. 2641), the Plaintiff's Motion for Leave to File 1st Amended French Class Action Complaint (Rec. Doc. 4949), and the Plaintiff's Motion for Leave to File 1st Amended Italian Class Action Complaint (Rec. Doc. 4950). For the following reasons, the Defendant's Motion to Dismiss is GRANTED and the Plaintiffs' Motions for Leave to Amend are DENIED.

I. Background

Vioxx (known generically as rofecoxib) belongs to a general class of pain relievers known as non-steroidal anti-inflammatory drugs ("NSAIDs"). This class of drugs contains well-known medications sold either over the counter–such as Advil (ibuprofen) and Aleve (naproxen)–or by prescription–such as Daypro (oxaprozin) and Voltaren (diclofenac). NSAIDs

work by inhibiting cyclooxygenase ("COX"), an enzyme that stimulates synthesis of prostaglandins, which are chemicals produced in the body that promote certain effects.

Traditional NSAIDs have been a longstanding treatment option for patients needing relief from chronic or acute inflammation and pain associated with osteoarthritis, rheumatoid arthritis, and other musculoskeletal conditions. This relief, however, comes with significant adverse side effects. Specifically, traditional NSAIDs greatly increase the risk of gastrointestinal perforations, ulcers, and bleeds ("PUBs"). This risk is increased when high doses are ingested, which is often necessary to remedy chronic or acute inflammation and pain. Scientists estimated that traditional NSAID-induced PUBs caused a significant number of deaths and hospitalizations each year.

In the early 1990s, scientists discovered that the COX enzyme had two forms–COX-1 and COX-2–each of which appeared to have several distinct functions. Scientists believed that COX-1 affected the synthesis or production of prostaglandins responsible for protection of the stomach lining, whereas COX-2 mediated the synthesis or production of prostaglandins responsible for pain and inflammation. This belief led scientists to hypothesize that "selective" NSAIDs designed to inhibit COX-2, but not COX-1, could offer the same pain relief as traditional NSAIDs with the reduced risk of fatal or debilitating PUBs. In addition, scientists believed that such drugs might be able to prove beneficial for the prevention or treatment of other conditions, such as Alzheimer's disease and certain cancers, where evidence suggested that inflammation may play a causative role.

In light of these scientific developments, Merck & Co., Inc. ("Merck") and several other pharmaceutical companies began the development of such drugs, which became known as "COX-2 inhibitors" or "coxibs." Vioxx is a COX-2 inhibitor.

On May 20, 1999, the Food and Drug Administration ("FDA") approved Vioxx for sale

in the United States. From its initial approval, Vioxx gained widespread acceptance among physicians treating patients with arthritis and other conditions causing chronic or acute pain. Subsequently, Vioxx was introduced into markets around the world, including France in April of 2000, and Italy in the summer of 2000.

Before and after its initial approval, Vioxx was subjected to a number of studies and tests, including, but not limited to, VIGOR, APPROVe, ViP, VICTOR, ADVANTAGE, the Alzheimer's studies, Professor Kronmal's reanalysis of Merck's clinical data, the Solomon study, the Juni study, the Ray study, the Graham study, the Kimmel study, the Levesque study, the Mamdani study, the Ingenix study, the Johnsen study, the Nussmeier study, and the Fitzgerald hypothesis. In addition, a large amount of scientific literature was written on the effects of Vioxx and other COX-2 inhibitors.

On September 30, 2004, Merck withdrew Vioxx from all markets worldwide, when interim unblinded data from a long-term, blinded, randomized placebo-controlled clinical trial, known as APPROVe, seeking to assess whether Vioxx could help prevent the recurrence of precancerous colon polyps, indicated that the use of Vioxx increased the risk of cardiovascular thrombotic events such as myocardial infarctions and ischemic strokes.

Thousands of lawsuits followed in both state and federal court. On February 16, 2005, as a result of the sheer mass of these lawsuits and the potential for many more, the Judicial Panel on Multidistrict Litigation ("JPML") ordered that the Vioxx litigation be centralized, designated as an MDL, and assigned to this Court. There are approximately 5,700 cases currently pending in this MDL, including eleven lawsuits filed on behalf of purported classes of foreign citizens from England, Australia, Italy, France, South Africa, Canada, Germany, Israel, New Zealand, the Netherlands, and Poland who were prescribed, purchased, used, and/or ingested Vioxx. In

addition, there are two lawsuits that are even more far-reaching, one filed on behalf of a purported class of all citizens of Europe who used Vioxx, and the other on behalf of a purported class of every Vioxx user in the world.

II. Present Motions

On January 13, 2006, Merck moved to dismiss all of the foreign class action complaints under the doctrine of *forum non conveniens*, or alternatively, to strike the class allegations. The parties subsequently agreed that, at this time, the Court should address the motion only as it applies to the Italian and French class action complaints. Both the Italian and French complaints were originally filed in the United States District Court for the Northern District of Illinois and have been transferred to this Court pursuant to the JPML's order.

First, Merck argues that the Italian and French complaints bear no relationship to the United States and thus should be dismissed so that the claims can be more conveniently litigated in Italy and France. Merck argues that the following facts demonstrate that this litigation belongs in Italy and France: (1) Vioxx was subjected to extensive regulation by the governments of Italy and France prior to its introduction into these markets; (2) regulators in Italy and France ultimately approved the sale of Vioxx and required that certain warnings and packaging information be included; (3) the Plaintiffs were prescribed Vioxx in Italy and France by doctors practicing in those countries; (4) the Plaintiffs purchased and ingested Vioxx in Italy and France; and (5) the Plaintiffs allegedly sustained injuries and received treatment in Italy and France.

The Plaintiffs argue that this litigation belongs in the United States because Merck designed, tested, and manufactured Vioxx at its Global Headquarters in Whitehouse Station, New Jersey. The Plaintiffs also argue that Merck directed the worldwide distribution of Vioxx from New Jersey. Merck disputes these allegations, and asserts that the Vioxx sold in Italy and

France was manufactured in a multi-stage process that took place in a variety of countries. Moreover, Merck argues that decisions about the sale and marketing of Vioxx in Italy and France took place both in New Jersey and locally in Italy and France by its subsidiaries.

Alternatively, Merck argues that these lawsuits should not proceed as class actions. The Court has not yet addressed the certification question for any class in this MDL. However, Merck argues that the class allegations in the Italian and French complaints should be stricken because a class judgment in the United States would not be given preclusive effect in Italy and France. As will become clear, the Court need not delve into the Italian and French law of *res judicata* at this time.

Second, more than four months after Merck moved to dismiss these cases, the Plaintiffs in both actions filed Motions for Leave to File Amended Complaints. The Plaintiffs seek to include an additional allegation in their complaints that "each and every decision related with the development, design, manufacture, testing, marketing, and commercialization of the drug Vioxx were made by Defendant in the state of New Jersey." Merck argues that the Plaintiffs' motions to amend are futile attempts to delay the inevitable dismissal of these actions.

III. Law and Analysis

To secure a *forum non conveniens* dismissal, Merck "must demonstrate (1) the existence of an available and adequate alternative forum and (2) that the balance of relevant private and public interest factors favor[s] dismissal." *Vasquez v. Bridgestone/Firestone, Inc.*, 325 F.3d 665, 671 (5th Cir. 2003); *see also Piper Aircraft Co. v. Reyno*, 454 U.S. 235 (1981); *Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 506-09 (1947).

(A) Alternative Forums

A defendant seeking dismissal on the basis of *forum non conveniens* must demonstrate

that an alternative forum exists which is both available and adequate. *McLennan v. Am. Eurocopter Corp., Inc.*, 245 F.3d 403, 424 (5th Cir. 2001). In this case, Merck argues that the courts of Italy and France are available and adequate alternative forums in which the Plaintiffs' claims should be litigated.

"A foreign forum is available when the entire case and all parties can come within the jurisdiction of that forum." *Alpine View Co. Ltd. v. Atlas Copco AB*, 205 F.3d 208, 221 (5th Cir. 2000) (quoting *In re Air Crash Disaster Near New Orleans, La.*, 821 F.2d 1147, 1165 (5th Cir. 1987)). The availability of an alternative forum is often secured by conditioning a *forum non conveniens* dismissal on the defendant's waiver of various jurisdictional obstacles in the alternative forum. Merck argues that its subsidiaries operating in Italy and France are amenable to service of process in those countries. In addition, Merck has agreed to submit to jurisdiction in civil actions filed in Italy and France. Therefore, Italy and France are available alternative forums.

"A foreign forum is adequate when the parties will not be deprived of all remedies or treated unfairly, even though they may not enjoy the same benefits as they might receive in an American court." *Alpine View*, 205 F.3d at 221. The Plaintiffs argue that Italy and France are inadequate alternative forums because these countries lack class action devices, employ fee-shifting, and prohibit lawyers from working on a contingency-fee basis. Even if these allegations were completely accurate, they would not render the alternative forums inadequate.

An alternative forum is inadequate only if it deprives the plaintiff of *all remedies* or treats the plaintiff unfairly. *See Vasquez*, 325 F.3d at 671 (emphasis added). Neither the Italian nor French courts would completely deprive the Plaintiffs of all remedies. It is undisputed that the purported class members could maintain individual actions in Italy and France. Moreover, both

countries have effective collective action mechanisms that allow groups of plaintiffs who allege similar injuries to file suit together.[1] While these mechanisms may not be as developed as the Rule 23 class action in America, they are far from inadequate. Regardless, "[t]he lack of a class action device is not a basis for concluding that a foreign forum is inadequate for *forum non conveniens* purposes." *Pavlov v. Bank of New York Co., Inc.*, 135 F. Supp. 2d 426, 434 (S.D.N.Y. 2001). Similarly, the existence of fee-shifting and prohibitions on contingency-fee arrangements do not render an alternative forum inadequate. *See Coakes v. Arabian Am. Oil Co.*, 831 F.2d 572, 576 (5th Cir. 1987).

United States courts have repeatedly found that Italy and France provide wholly adequate alternative forums. *See, e.g., Piper Aircraft Co.*, 454 U.S. at 252 n.18 (France); *Gschwind v. Cessna Aircraft Co.*, 161 F.3d 602, 606-07 (10th Cir. 1998) (France); *Magnin v. Teledyne Cont'l Motors*, 91 F.3d 1424, 1429-31 (11th Cir. 1996) (France); *Hyatt Int'l Corp. v. Coco*, 302 F.3d 707, 718 (7th Cir. 2002) (Italy); *King v. Cessna Aircraft Co.*, 405 F. Supp. 2d 1374, 1377-78 (S.D. Fla. 2005) (Italy). This Court agrees and finds that Italy and France are available, adequate alternative forums.

(B) Public & Private Interest Factors

The second step of the *forum non conveniens* framework requires the Court to "consider whether 'certain private and public interest factors weigh in favor of dismissal.'" *Karim v. Finch Shipping Co.*, 265 F.3d 258, 268-69 (5th Cir. 2001) (quoting *McLennan*, 245 F.3d at 424). The

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[1] Several articles have been written about these various mechanisms. *See* Richard H. Dreyfuss, *Class Action Judgment Enforcement in Italy: Procedural "Due Process" Requirements*, 10 Tul. J. Int'l & Comp. L. 5, 10-11 (2002); Louis Boré, *L'Action en Représentation Conjointe: Class Action Française ou Action Mort-Née?*, Recueil Dalloz-Sirey 267 (Oct. 12, 1995); William B. Fisch, *European Analogues to the Class Action: Group Action in France and Germany*, 27 Am. J. Comp. L. 51 (1979).

private interest factors include:

> [T]he relative ease of access to sources of proof; availability of compulsory process for attendance of unwilling, and the cost of obtaining attendance of willing, witnesses; . . . and all other practical problems that make trial of a case easy, expeditious and inexpensive.

Piper Aircraft Co., 454 U.S. at 241 n.6. The United States Supreme Court discussed the public interest factors in *Gulf Oil Corp. v. Gilbert*:

> Administrative difficulties follow for courts when litigation is piled up in congested centers instead of being handled at its origin. Jury duty is a burden that ought not to be imposed upon the people of a community which has no relation to the litigation. In cases which touch the affairs of many persons, there is reason for holding the trial in their view and reach rather than in remote parts of the country [or world] where they can learn of it by report only. There is a local interest in having localized controversies decided at home.

330 U.S. 501, 508-09 (1947). In balancing the private and public interests, no one factor is given conclusive weight, but the "central focus" of the *forum non conveniens* inquiry is on convenience. *See Dickson Marine Inc. v. Panalpina, Inc.*, 179 F.3d 331, 342 (5th Cir. 1999).

Although a plaintiff's choice of forum is usually accorded deference, when the plaintiffs are foreign citizens, as is the case here, the assumption that their choice of forum is convenient is "much less reasonable." *Piper Aircraft Co.*, 454 U.S. at 256; *see also In re Union Carbide Corp. Gas Plant Disaster at Bhopal, India*, 634 F. Supp. 842, 845 (S.D.N.Y. 1986) ("The foreign plaintiffs' choice of the United States forum deserves less deference than would be accorded a United States citizen's choice."). Indeed, when foreign citizens choose a United States forum, "a plausible likelihood exists that the selection was made for forum-shopping reasons, such as the perception that United States courts award higher damages than are common in other countries." *Iragorri v. United Techs. Corp.*, 274 F.3d 65, 71 (2d Cir. 2001).

A careful consideration of the private and public interest factors suggests that foreign

forums would be much more convenient for this litigation.

First, as Merck argues, the majority of the events relevant to this litigation occurred abroad: (1) the Plaintiffs are Italian and French residents who were prescribed Vioxx in Italy and France; (2) by Italian and French doctors; (3) both of whom read and/or relied on warnings and labels in Italian and French; (4) the Plaintiffs purchased and ingested Vioxx, and allegedly suffered injuries as a result, in Italy and France; and (5) the Plaintiffs subsequently received medical treatment in Italy and France. Moreover, information relating to the Plaintiffs' individual medical histories, which is highly relevant in determining whether or not Vioxx caused the Plaintiffs' alleged injuries, and information relating to what the Plaintiffs' and their doctors knew or should have known about Vioxx, which is relevant in determining whether or not Merck failed to warn, is also located abroad. *See Vazquez*, 325 F.3d at 672-73 (finding that the district court correctly determined that trial should be held in Mexico where the product was bought in Mexico and when "all the physical evidence and medical reports" were in Mexico).

All of this directly implicates the private interest factors. American courts do not have easy access to the foreign documents and witnesses relating to these events. Nor is it likely that the compulsory process of any American court will be able to reach such documents and witnesses. In short, the American courts are likely to encounter many practical problems causing this litigation to be harder, slower, and more expensive than it would be in Italy and France.

The Plaintiffs argue that these individualized facts are ancillary, and that the central focus of this litigation is the development of Vioxx in the United States and various decisions allegedly made by Merck in New Jersey. Merck does not dispute that there are some issues relevant to this litigation that revolve around its Global Headquarters. Merck also does not dispute that documents and witnesses relating to these issues are located in the United States. However, the

plethora of localized individual issues in these two cases leads the Court to conclude that litigation of the Plaintiffs' claims in Italy and France would be much more convenient. *See Vazquez*, 325 F.3d at 673 ("Assuming *arguendo* that all information relating to the design and manufacture of the tires and vehicle is located in the United States, we still find the court's analysis [that Mexico is a more convenient forum] correct."); *Harrison v. Wyeth Labs. Div. of Am. Home Prods. Corp.*, 510 F. Supp. 1, 4 (E.D. Pa. 1980) ("Even assuming arguendo that all production and marketing decisions were made by defendant in Pennsylvania . . . , Pennsylvania's interest in the regulation of the conduct of drug manufacturers and the safety of drugs produced and distributed within its borders does not extend so far as to include such regulation of conduct on drugs produced or distributed in foreign countries.").

Second, and perhaps more important in this case, the public interest factors suggest that this litigation belongs in the Italian and French courts. The Plaintiffs are Italian and French residents whose alleged injuries have been suffered and treated in Italy and France. Thus, these are localized Italian and French controversies in which Italy and France have strong interests in deciding at home. *See Piper Aircraft Co.*, 454 U.S. at 241 n.6; *In re Rezulin Prods. Liab. Litig.*, 214 F. Supp. 2d 396, 398-99 (S.D.N.Y. 2002) (finding a strong foreign interest when a foreign citizen was treated for injuries abroad, despite the fact that the drug was prescribed, purchased, and ingested in the United States).

Moreover, the governments of Italy and France approved and regulated the sale of Vioxx in those countries. As one court has noted, "[t]he forum whose market consumes" a regulated product has a "distinctive interest in explicating the controlling standards of behavior" related to that product. *Doe v. Hyland Therapeutics Div.*, 807 F. Supp. 1117, 1129 (S.D.N.Y. 1992). Indeed, trying the Plaintiffs' claims in the United States risks disrupting the judgments of Italian

and French regulatory bodies by imposing an American jury's view of the appropriate standards of safety and labeling on companies marketing and selling drugs in Italy and France. *See Vazquez*, 325 F.3d at 674 ("If accepted, plaintiffs' argument would curtail the rights of foreign governments to regulate their internal economies and threaten to engulf American courts with foreign claims."); *Ledingham v. Parke Davis Div. of Warner-Lambert Co.*, 628 F. Supp. 1447, 1451 (E.D.N.Y. 1986) ("[W]hen a regulated industry, such as the pharmaceutical industry, is involved in an action, the country where the injury occurs has a particularly strong interest in the litigation."). An American jury would also have no good means of evaluating whether a given foreign label or marketing scheme was adequate, especially when the labeling and marketing was in a foreign language.

As the *Rezulin* court noted, "the enormous volume of . . . litigation brought on behalf of United States plaintiffs . . . ensures that appropriate standards of care are applied [in the United States] and that the defendants, if they are liable, will pay quite substantial compensation and that the liability will deter them and others from inappropriate conduct in the future." *In re Rezulin*, 214 F. Supp. 2d at 399. Thus, the Italian and French interests in this litigation outweigh any interest the United States, or an individual State, may have because the "enormous volume" of Vioxx litigation brought on behalf of American plaintiffs ensures that the American interests will ultimately be protected.

This leads to another public interest factor, namely the administrative difficulties that are created when "litigation is piled up in congested centers rather than handled at its origin." *Gulf Oil Corp.*, 330 U.S. at 508-09. This Court is presently overseeing "the enormous volume" of products liability lawsuits involving Vioxx that have been filed in the federal courts. Although the multidistrict litigation system crafted by Congress in 28 U.S.C. § 1407 contemplates some

degree of congestion in transferee courts such as this one, retaining jurisdiction over the purported classes of Italian and French residents would exacerbate any administrative difficulties that this Court may already be experiencing.

The Fifth Circuit has noted that a choice-of-law analysis may also be required when considering the public interest factors. *See Quintero v. Klaveness Ship Lines*, 914 F.2d 717, 725 (5th Cir. 1990). Since the Plaintiffs' claims were originally filed in the United States District Court for the Northern District of Illinois, this Court must apply Illinois choice-of-law rules. *See Van Dusen v. Barrack*, 376 U.S. 612, 639 (1964). Illinois applies the "most significant relationship test" when determining the applicable law in tort actions. *See Ferguson v. Kasbohm*, 475 N.E.2d 984, 986-87 (Ill. App. Ct. 1985). When applying this test, courts should consider: (1) where the injury occurred, (2) where the injury-causing conduct occurred, (3) the domicile of the parties, and (4) where the relationship of the parties is centered. *See Esser v. McIntyre*, 661 N.E.2d 1138, 1141 (Ill. 1996). Applying this test, the Court finds that Italian and French law would be applicable in these cases. The Plaintiffs were injured abroad, and the injury-causing conduct occurred abroad. Moreover, although Merck is located in New Jersey, the Plaintiffs are foreign citizens. Lastly, the relationship of the parties is clearly centered in Italy and France, since this is where the Plaintiffs were prescribed, purchased, and ingested Vioxx. Thus, "the public interest factors point towards dismissal where the court would be required to untangle problems in . . . law foreign to itself." *Piper Aircraft Co.*, 454 U.S. at 251.

The Plaintiffs' requested amendments to their complaints would not affect the Court's *forum non conveniens* analysis. Therefore, the amendments are futile and the Plaintiffs' requests will be denied. *See Stripling v. Jordan Prod. Co., L.L.C.*, 234 F.3d 863, 873 (5th Cir. 2000).

IV. Conclusion

For the foregoing reasons, the Defendant's Motion to Dismiss the Foreign Class Actions is GRANTED. Accordingly, IT IS ORDERED that the Italian and French class action complaints are hereby dismissed provided that:

(i) The Defendant submit to service of process and jurisdiction in the appropriate Italian and French forums with respect to lawsuits relating to Vioxx;

(ii) The Defendant shall agree to satisfy any final judgment rendered by an Italian or French forum relating to such claims;

(iii) The Defendant will not, in raising any statute of limitations or similar defense in such forums, include the period that a suit, not barred by a statute of limitations in this country, was pending against it in a court of the United States;

(iv) The Defendant will not act to prevent the Plaintiffs from returning to this Court if the Italian or French forums decline to accept jurisdiction, provided that an action is filed in those forums within 120 days of the order of dismissal.

IT IS FURTHER ORDERED that the Plaintiff's Motion for Leave to File 1st Amended French Class Action Complaint and the Plaintiff's Motion for Leave to File 1st Amended Italian Class Action Complaint are DENIED.

New Orleans, Louisiana, this 30 day of August, 2006.

UNITED STATES DISTRICT JUDGE