VIOXX LITIGATION: CAVE IN, WINDFALL OR ANOTHER DAY AT THE BOUDIN FACTORY

I. INTRODUCTION

The manufacture, marketing and sale of Vioxx, a non-steroidal, anti-inflammatory drug by Merck & Company, Inc. ("Merck") from May, 1999 through September, 2004 resulted in a veritable explosion of litigation, not only in the United States, but also around the world.[1] It gave rise in the United States to numerous individual lawsuits for personal injury; federal regulatory action; economic damage suits by federal and state governments; class actions for stockholder securities fraud; class actions for consumer economic damages; state consolidated actions for personal injury; and, a multi-district litigation case that expanded the boundaries of procedural law and drew both criticism and praise. While this paper will address each of the various areas of the litigation, the main focus will be on the multi-district litigation case due to its unique and creative approach to resolving the largest part of the dispute. The question is whether, at the end of the day, the result was a cave in by any party, a windfall for any party or just another day at the boudin factory.[2]

II. HISTORY OF THE DRUG

During the 1990's, Merck researched, designed, manufactured and distributed Vioxx to relieve pain resulting from osteoarthritis, rheumatoid arthritis, menstrual pain and migraine headaches.[3] Vioxx is described as a non-steroidal, anti-inflammatory drug (NSAID)

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1 See, e.g., *Mignacca, et al v. Merck Frost Canada, Ltd., et* al, No. 04-CV-045435 CP, Ontario Superior Court of Justice; and A. Klein and Campbell, a Reversal of Fortune in Australia For the Defense, Defense Research Institute, pg. 62, March, 2012.

2 The MDL litigation took place in New Orleans, Louisiana, where boudin is the Cajun sausage of choice. Like other sausages, one might hesitate to eat it if one saw it being made.

3 *In Re: Vioxx Products Liability Litigation*, 760 F.Supp. 2d 640, 642 (E.D. La. 10-19-10); MDL No. 1657.

used to treat the above described conditions, but with the added benefit of reduced gastrointestinal complications that commonly occur with other NSAID's.[4]

In November, 1998, Merck requested approval of Vioxx from the Food and Drug Administration (the "FDA") after having conducted preliminary testing.[5] In January, 1999, Merck began a new clinical study called the Vioxx Gastrointestinal Outcomes Research ("VIGOR") designed to determine whether Vioxx was safer for gastrointestinal issues than Naproxen.[6] On May 20, 1999, the FDA approved Vioxx for sale in the United States. [7] Merck then instituted a very aggressive advertising campaign, spending over $500 million on consumer and physician advertisements.[8]

The VIGOR study did show that Vioxx patients had fewer ulcers than Naproxen patients, but it also turned up indications that Vioxx patients had a risk of serious heart problems and death twice as great as the Naproxen patients.[9] As a result, the FDA sought a change in the labeling for Vioxx, addressing the increased risk.[10] After much negotiation, the label change was

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4 Mancinelli, Placing Blame for the Vioxx Debacle, May 2006, available at https:\\dash.harvard.edu\bitstream\handle\1\9453694\Mancinelli06.html (hereinafter "Mancinelli").

5 Prakesh & Valentine, Timeline: The Rise and Fall of Vioxx, 11/10/07, available at http://www.npr.org\templates\story\story.php?storyId=5470430&utm (hereinafter "Prakesh & Valentine").

6 *Id*.

7 *In Re: Vioxx Products Liability Litigation,* supra, at 642.

8 C. Solomon & S. Summers, *Vioxx: Birth and Death of a Super Aspirin,* Mealey's Litigation Report: Authorized Drugs, November 2004, pgs. 1-6.

9 Prakesh & Valentine, supra; see, also, *Mancinelli*, supra.

10 *Mancinelli*, supra.

effected on March 20, 2002.[11] A number of issues regarding the VIGOR study and the FDA regulator process remained.[12]

Other studies were conducted after VIGOR, but Vioxx remained on the market until September 20, 2004, when the results of Adenomolous Polyp Prevention on Vioxx (APPROVe) study were revealed. This study also showed an increased risk of cardiovascular thrombotic events, such as heart attacks and ischemic strokes.[13] As a result of these findings, Merck withdraw Vioxx from the market on September 20, 2004.[14]

Between the introduction of Vioxx on May 20, 1999 and the withdrawal on September 20, 2004, it is estimated that 105 million prescriptions were written in the United States.[15] Vioxx was Merck's third leading drug with $2.5 billion in annual sales.[16] After the withdrawal, thousands of individual suits and numerous class actions were filed in both state and federal courts in the United States, not to mention suits outside of the country.[17] Additionally, an SEC investigation, a Department of Justice investigation and a Congressional iInvestigation ensued as well, with a resulting $950 million paid in fines in settlement, along with the guilty plea to a misdemeanor offense.[18]

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11 *Id.*

12 *Id.*; Mancinelli provides great detail regarding the regulatory issues beyond the scope of this paper.

13 760 F.Supp. 2d 640, 642.

14 *Id.*, at 642.

15 *Id.*, at 642.

16 Pearson and Voreacos, Merck to Pay $830 Million to Settle Vioxx Securities Claims (01/15/16), available at www.bloomberg.com\news\articles.

17 760 F.Supp. 2d 640, 642.

18 *Mancinelli*; see, also, Arnold, Merck Wraps Up Vioxx Litigation With Feds, states: $1b in fines, new CIA, available at http://www.mmm-online.com\Merck-Wraps-Up-Vioxx-Litigation-With-Feds-States

III. HISTORY OF THE LITIGATION

A. Non-Personal Injury Claims

Numerous claims were filed against Merck for economic damages resulting from the marketing and sale of Vioxx, in addition to the personal injury claims and the regulatory actions by the federal government. Claims were brought by individual suits, multiple plaintiff suits and class actions. Claims were asserted by state governments, the federal government, shareholders and consumers. This was a very mature mass tort.

One type of suit was those brought by various states' attorneys general for damages to the state based upon increased payments for Vioxx by the states' respective health and Medicare programs due to alleged false and misleading information published by Merck in the marketing of Vioxx.[19] Twenty-nine states and the District of Columbia entered into a settlement for a total of $58 million in damages, plus various remedial provisions involving "a broad swath of pharmaceutical company activities."[20]

Another type of economic damage suit was a securities class action for damages to stockholders of Merck based on the alleged misrepresentations made by Merck related to Vioxx which negatively impacted the price of Merck stock.[21] The class consisted of "all persons and entities, who from May 21, 1999 to September 29, 2004, inclusive, purchased or otherwise acquired Merck Common Stock or Merck Call Options, or sold Merck Put Options."[22] This was

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19 See, e.g., comments by Texas Attorney General Greg Abbott in Pringle, The Merck Vioxx Litigation, available at http://www.counterpunch.org\2006\09\20\the-merck-vioxx-litigation

20 Merck Settles Vioxx Litigation With State Attorneys General - An Analysis, 05/29/08, available at www.ehcca.com/presentations/pharmaaudio20081217\friede_whitepaper.pdf

21 *In Re: Merck & Company, Inc., Securities Derivative & ERISA Litigation*, MDL No. 1658 (SRC), C.A. Nos. 05-1151 and 05-2367 (SRC) (CLW) (N.J. 2013).

22 *Id.*, at Doc. 986 (06/28/16).

a settlement class action under Federal Rules of Civil Procedure 23(a) and (b)(3), which provided for $830 million to be used for the benefit of the class members in accordance with a plan of allocation, and $232 million to be used to pay fees and expenses.[23]

Still another type of economic damage suit was a consumer class action that was certified out of the federal multi-district litigation ("MDL") in the Eastern District of Louisiana which also ultimately settled the vast majority of the Vioxx personal injury claims.[24] This class action was for individual consumers who purchased Vioxx for themselves, and excluded any personal injury claims.[25] The settlement was for $23 million "from which class members may seek recovery for their out-of-pocket costs for purchasing Vioxx and up to $75.00 in connection with post-withdrawal medical consultation related to Vioxx use or a one-time payment of $50.00 with proof of a Vioxx prescription."[26] These amounts were subject to a prorated reduction if total claims and expenses exceeded the $23 million cap.[27]

As large as these settlements were together, they came nowhere close to $4.85 billion settlement amount of the personal injury claims resolved through the MDL process. Furthermore, the MDL process had a much more challenging and complex path to resolution, as will be discussed hereinbelow.

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23 *Id.*, Stipulation and Agreement of Settlement (February 8, 2016).

24 *In Re: Vioxx Products Liability Litigation*, Docket No. 2:05-MD-01657-EEF-DEK (E.D. La.).

25 *Id.*, Final Order and Judgment Certifying the Class for Purposes of Settlement, Approving of Class Action Settlement & Dismissing the Actions with Prejudice, Docket No. 64784 (01/03/14).

26 *Id.*

27 *Id.*

B. Personal Injury Claims

1. Multi-District Litigation

As mentioned above, after Merck withdraw Vioxx from the market, thousands of individual lawsuits and a number of class actions were filed in state and federal courts all over the United States related to Vioxx usage, alleging product liability, tort, fraud and warranty causes of action.[28] On October 30, 2002, California was the first state to institute a consolidated state court proceeding[29], followed by New Jersey on May 20, 2003[30], and Texas on September 6, 2005.[31] Then, on February 16, 2005, the Federal Judicial Panel on Multi-District Litigation conferred MDL status on all Vioxx lawsuits filed in federal courts throughout the United States, and transferred those cases to Judge Eldon E. Fallon of the Eastern District of Louisiana to coordinate discovery and consolidate pre-trial matters pursuant to 28 U.S.C. §1407.[32]

The MDL only initially dealt with federal cases, but there were over 50,000 claims outstanding in state courts, particularly California, New Jersey and Texas.[33] At the request of Merck's counsel, Judge Fallon early on reached out to Judge Carol E. Higbee of the Superior Court of New Jersey, Justice Victoria Chaney of the Superior Court of Los Angeles, California, and Judge Randy Wilson of the 157th District Court of Harris County, Texas, to

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28 *In Re: Vioxx Products Liability Litigation*, MDL 1657, Docket No. 63195 (08/09/11).

29 Coordination proceeding, Special Title (Rule 3.550(c)), Vioxx Cases, Case JCCP No. 4247, Dept. 24, Los Angeles County Superior Court, California.

30 *In Re: Vioxx Litigation,* Case No. 619, Superior Court, Law Division, Atlantic County, New Jersey.

31 *In Re: Texas State Vioxx Litigation*, Master Docket No. 2005-59499, 157th District Court, Harris County, Texas.

32 *In Re: Vioxx Liability Litigation*, MDL 1657, Docket No. 63195 at pg. 2.

33 *Id.,* at pg. 3.

coordinate their judicial efforts.[34] Judge Fallon then moved quickly to set the first MDL status conference on March 18, 2005 to set forth the process for moving forward.[35]

Given the complexity, breadth and expense of this case, the court appointed a steering committee of counsel to represent the various parties.[36] However, the court went further to advise any attorneys who were not on the steering committee or any subcommittee appointed thereby, that such attorneys, if they chose to do so, could participate in common benefit work on behalf of all parties by joining a subcommittee.[37] The steering committee was particularly encouraged to establish such subcommittees and include non-steering committee members in the subcommittees.[38] The state court judges also established similar practices.[39]

The parties then began to conduct significant discovery efforts, including document production and review of over 9 million documents and the taking of thousands of depositions, with the unsurprising result that at least 1,000 discovery motions were argued to the court.[40] Once sufficient discovery was completed, the court and counsel selected six federal

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34 *Id.*, at pg. 3; telephone interview with Judge Fallon on November 29, 2016; telephone interview with Phillip A. Wittmann, counsel for Merck, on November 29, 2016 (the author's senior partner - in the interest of full disclosure)

35 *Id.,* at pg. 3.

36 *Id.*, at pg. 3.

37 *Id.*, at pg. 3.

38 *Id.*, at pg. 3.

39 *Id*, at pg. 3.

40 *Id.*, at pg. 4.

cases for bellwether trials from the federal court cases.[41] An additional 13 trials were conducted before juries in state courts during the same time period.[42]

These test cases or "bellwether trials" were utilized in the Vioxx MDL to provide information from real life jury trials to help effect a settlement.[43] Judge Fallon puts it best:

> A typical bellwether case often begins as no more than an individual lawsuit that proceeds through pre-trial discovery and on to trial in the usual binary fashion: one plaintiff versus one defendant. Such a case may take on "bellwether" qualities, however, when it is selected for trial because it involves facts, claims, or defenses that are similar to the facts, claims, and defenses presented in a wider group of related cases. The primary argument presented here in support of the informational approach is that the results of bellwether trials need not be binding upon consolidated parties with related claims or defenses in order to be beneficial to the MDL process. Instead, by injecting juries and fact finding into multi-district litigation, bellwether trials assist in the maturation of disputes by providing an opportunity for coordinating counsel to organize the products of pre-trial, discovery, evaluate the strengths and weaknesses of their arguments and evidence, and understand the risks and costs associated with the litigation. At a minimum, the bellwether process should lead to the creation of "trial packages" that can be utilized by local counsel upon the dissolution of MDL's, a valuable by-product in its own right that supplies at least a partial justification for the traditional delay associated with MDL practice. Perhaps more importantly, the knowledge and experience gained during the bellwether process can precipitate global settlement negotiations and ensure that such negotiations do not occur in a vacuum, but rather in light of real-world evaluations of the litigation by multiple juries.[44]

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41 *Id.*, at pg. 4.

42 *Id.*, at pg. 4.

43 Generally, see Fallon, et al, Bellwether Trials in Multi-District Litigation, 82 Tulane Law Review 2323 (2008).

44 *Id.*, at 2325.

Particularly, this is true in designing compensation systems in mass tort settlements by providing the "raw data" necessary to better design such a system because juries have shown the parties what facts tend to matter.[45]

Once the federal bellwether trials and state court trials were completed, Judge Fallon and the state court jurists from Texas, California and New Jersey met with the steering committees and a member of the board of directors of Merck and encouraged all parties to seek a global settlement.[46] After more than 50 meetings and several hundred telephone conferences, the parties announced on November 9, 2007 that they had reached an agreement.[47]

2. The Settlement Agreement

The settlement agreement negotiated by Merck and counsel for the plaintiffs may have been surprising to some given Merck's prior strong statements regarding its willingness to vigorously try every case rather than settle.[48] However, as Nagareda explained, the underlying facts changed the litigation landscape.

To begin with, while the scientific research had established an elevated risk of heart attacks and strokes among Vioxx users, the bellwether trials had shown how difficult it was to prove causation in the individual trial, because the plaintiffs in need of medication were

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45 *Id.*, at 2342.

46 *In Re: Vioxx Product Liability Litigation*, MDL 1657, Doc. No. 63195, pg. 5.

47 *Id.*, at pg. 5.

48 F. McClellan, The Vioxx Litigation: A Critical Look at Trial Tactics, the Torts System and the Role of Lawyers in Mass Tort Litigation, 57 DePaul Law Review 508 (2008), hereinafter "McClellan"; R. Nagareda, Embedded Aggregation in Civil Litigation, 95 Cornell Law Review 1105, 1152-1153 (2010), hereinafter "Nagareda".

already at risk and had other health issues which could lead to the same results. Only five of the 17 bellwether trials resulted in plaintiffs' verdicts.[49]

Next, the statute of limitations had effectively run on any new Vioxx cases, because the product was withdrawn in 2004, and most states had a 3-year limitation period for these type of claims.[50] So, there was very little worry over future unknown claims, and final resolution of the Vioxx claims was possible.[51]

Finally, the expenses of the litigation -- even consolidated into MDL discovery and bellwether trials -- were still extremely expensive for both the plaintiffs and Merck.[52] So, it made sense for both sides to seek a less expensive resolution.

The Settlement Agreement[53] itself was very unusual. Unlike most settlements, this agreement was not an agreement between the defendant and the plaintiffs; but rather, between the defendant and whatever plaintiffs' lawyers ultimately signed up.[54] The agreement was negotiated between Merck and a "Negotiating Plaintiffs' Counsel" group which consisted of the MDL Plaintiffs' Steering Committee and representatives of plaintiffs' counsel in the coordinated state court suits in California, New Jersey and Texas.[55]

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49 Nagareda, supra, at 1152.

50 *Id.*

51 *Id.*

52 *Id.*

53 Master Settlement Agreement available at www.officialvioxxsettlement.com\documents\Master%20Settle%20Agreement%20-%20new.pdf

54 *Id.*, at Preamble.

55 *Id.*, at Preamble.

The agreement recognized that:

1. There were approximately 26,000 active Vioxx personal injury suits in the United States, plus approximately 13,250 claimants who did not file suit, but signed tolling agreements with Merck to keep their claims viable;

2. More than 95% of the active plaintiffs were involved in either the MDL or the coordinated state cases in California, New Jersey and Texas;

3. Merck would establish a pre-funded structured private settlement program and pay an overall amount of $4.85 billion to resolve heart attack, ischemic stroke and sudden cardiac death claims related to Vioxx usage; and

4. There was no provision for any future claims.[56]

Finally, the parties agreed that there was no admission of liability or lack thereof on the part of either party as a result of this agreement.[57]

The operation of the settlement program established by the agreement can best be summarized by Judge Fallon himself:

> …The private Settlement Agreement establishes a voluntary, opt-in pre-funded program for resolving pending or tolled state and federal Vioxx claims against Merck as of the date of the settlement, involving claims of heart attack ("MI"), ischemic stroke ("IS"), and sudden cardiac death ("SCD"), for an overall amount of $4.85 billion. *Id.* § Recitals." Merck retained a walk away right to terminate the Settlement Program and Agreement if fewer than 85% of eligible participants enrolled in the Program. *See generally* art. 11. The MSA was designed to provide a fair and efficient means to compensate claimants who could present objective evidence of Vioxx usage and an associated MI, IS, or SCD injury. Claimants enrolled in the Program by signing a release, which would be delivered to Merck once the claim was paid or the claimant had elected to pursue other avenues for the amicable

56 *Id.*

57 *Id.*

resolute of their claims pursuant to the terms of the MSA. After enrolling, claimants or their primary attorneys gathered and submitted medical records to the Claims Administrator for processing and review, as set forth in the Agreement. The deadlines for submitting records were extended several times.

Each claimant's records were assessed pursuant to three "Gates": Injury, Duration, and Proximity, which required the claimant to provide evidence of a qualifying MI, IS, or SCD injury; receipt of 30 Vioxx pills within a 60 day period prior to the injury; and use of those pill at a time close to the injury. There were multiple layers of review for eligibility, including initial review by the Claims Administrator, an opportunity to submit additional records, review by a Gates Committee consisting of counsel for claimants and counsel for Merck, and a further opportunity for Merck to include the claim in the Program. If after that process a claim did not pass one of the Gates, the claimant could appeal to the Court-appointed Special Master for a final and binding review, or alternatively get off of the Settlement tracks and resume their lawsuit by filing a Future Evidence Stipulation and proceeding to trial. Claimants who qualified for the program were assigned points based on objective risk factors and the nature and extent of their injury, and were entitled to similar review of those calculations. Thus, the Settlement Program included an exit opportunity and multiple layers of review to ensure that claims received ample process.

The Settlement Agreement expressly contemplates that this Court will oversee various aspects of the administration of settlement proceedings, including appointing a Fee Allocation Committee ("FAC"), allocating a percentage of the settlement proceeds to a Common Benefit Fund, approving a cost assessment, and modifying any provisions of the Settlement Agreement that are otherwise enforceable. This is consistent with the inherent duty of an MDL transferee court. Accordingly, this Court has exercised its inherent authority over the MDL proceedings, *see* Manual for Complex Litigation (Fourth) §§ 10.224, 14.215-16, 14.231-.216 (2004), in coordination with its express authority under the terms of the Settlement Agreement to ensure that the settlement proceedings move forward in a uniform and efficient manner.

On July 17, 2008, Merck formally announced that it was satisfied that the thresholds necessary to trigger funding of the Vioxx Settlement Program would be met. *See Minute Entry, July 17, 2008*, Rec. Doc. 15362 (July 17, 2008). Merck further advised that it intended to waive its walk-away privileges and that it would commence funding the Vioxx Settlement Program by

> depositing an initial sum of $500 million into the settlement fund, clearing the way for distribution of interim payments to eligible claimants. *Id*. Eventually some 99.9% of all eligible claimants enrolled in the program.
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> The Settlement Program proceeded at a very rapid rate and Merck made additional payment in order to ensure that the claimants would receive funds in a timely fashion. Final payments to heart attack claimants were completed prior to October 14, 2009, final payments to stroke claimants were completed by June 14, 2010, and final extraordinary injury payments (i.e., payments to those who incurred or sustained extraordinary losses) were completed by June 29, 2010. Thus, in only 31 months, the parties to this MDL case were able to reach a global settlement and distribute Four Billion, Three Hundred and Fifty-three Million, One Hundred Fifty-two Thousand and Sixty-four Dollars ($4,353,152,064) to 32,886 claimants, out of a pool of 49,893 eligible and enrolled claimants. This efficiency is unprecedented in mass tort settlements of this size. It was due in large part to the ability, industry, and professionalism of the attorneys for both sides, the plan administrators, the lien administrators, the pro se curator, and the special masters.[58]

The awards ranged from $5,000 to $820,000 for strokes, and $18,000 to $1.7 million for heart attacks, including death.[59] Several interesting concepts are described in this summary.

Unlike class actions which are governed by the Federal Rules of Civil Procedure Rule 23 and the federal jurisprudence, this settlement was contractual at its base. It did not even formally involve both sets of parties to the various lawsuits. It was a contract between the plaintiffs' attorney group and the defendant, which also sought to corral and harness the power of the court to administer and enforce its provisions. This public-private hybrid role of the judge

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58 *In Re: Vioxx Products Liability Litigation*, MDL 1657, §L (E.D. La.), Order and Reasons, Doc. 63195 (08/09/11), pgs. 5-8.

59 The Vioxx Lawsuit, available at https:\\www.drugwatch.com\vioxx\lawsuit\

resulted in the court exercising authority on the cases over which it had no jurisdiction without very much in the way of statutory authority.[60]

Also, unlike class actions where members of the class are included unless they opt out, here there are no plaintiffs in the settling group at the time of the signing of the agreement; rather, they must chose to opt in.[61] As a result, additional contractual provisions are required, including the defendant's right to walk away if less than 85% registered eligible claimants opt in;[62] no opportunity for the plaintiff to opt out once they've opted in if they are qualified, but with the ability to pursue their suit if they are not so qualified;[63] a requirement that the lawyers who sign the agreement recommend the deal to 100% of their Vioxx clients;[64] a requirement that signatory lawyers withdraw from representation of and forego any interest in the claim of any client who decides not to participate;[65] and, a limitation to the types of injuries for which compensation would be paid, i.e., cardiac arrest, ischemic stroke and sudden cardiac death.[66] Finally, the contract gives Judge Fallon the authority to determine attorney's fees, individually and for common benefit "upon due consideration by him in consultation with (the state court

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60 E. Burch, Judging Multi-District Litigation, 90 N.Y.U.L.Rev. 71, 79 (2015) (hereinafter "Burch").

61 Master Settlement Agreement, art. 12.

62 *Id.*, at §11.1.3.2.

63 *Id.*, at §1.2.3; §2.7.3.1.

64 *Id.*, at §1.2.8.1.

65 *Id.*, at §1.2.8.2.

66 *Id.*, at Exh. 2.2.1.1.

judges) and in accordance with established 5th Circuit precedent".[67] Given the unusual nature of this hybrid resolution mechanism, it is not surprising that it has been both praised and damned.

IV. ASSESSMENT

There have been a number of criticisms directed to the Vioxx settlement and the MDL process as utilized therein. These criticisms generally involve the scope and basis of the jurisdiction exercised by the MDL transferee judge; lawyer-client issues involving conflicts of interest and adequacy of representation; and the time, cost and expense of MDL litigation (i.e., the "Black Hole Effect"). While these criticisms raise points that do have merit, they seem a bit "ivory tower-ish" in the context of the challenges facing the trial court in mass torts such as the Vioxx matter. The trial court must deal with the problems before it, and the Vioxx judge did take care to address each of these concerns.

A. The Scope and Basis of Jurisdiction

The exercise of jurisdiction by MDL judges to oversee voluntary settlements and to appoint and compensate counsel have been described as "immature"[68] and "uncertain at best."[69] So, why didn't the Vioxx lawyers seek to use a class action proceeding or even a Chapter 11 bankruptcy proceeding -- both of which have significant law and jurisprudence governing the court's authority to handle this type matter?

The simple answer is that neither of these vehicles was available. The Plaintiffs' Steering Committee did seek class action certification in the Vioxx matter from Judge Fallon, who ruled that:

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67 *Id.*, at art. 9.

68 Silver, The Responsibilities of Lead Lawyers and Judges in Multi-District Litigation, 79 Fordham L.Rev. 1985, 1989 (2011) (hereinafter "Silver").

69 Burch, supra, at 117.

> The number, uniqueness, singularity and complexity of the factual scenarios surrounding each case predominating issue.[70]

As to Chapter 11 bankruptcy, it was not available because Merck was not insolvent. So, the MDL was the only realistic vehicle.

The actual authority for the MDL process comes from 28 U.S.C. §1407. Under that authority, the federal Judicial Panel on Multi-District Litigation determines, either on its own initiative or in response to a motion, whether matters involving common questions of fact are appropriate to be consolidated, and selects a judge to conduct such proceedings.[71] The transferee judge takes these cases for coordinated or consolidated pre-trial proceedings which have been broadly interpreted to include all pre-trial proceedings before trial, including issuing pre-trial orders, resolving pre-trial motions such as discovery motions, motions to amend, motions to dismiss, motions for summary judgment and motions for class certification, as well as attempting to facilitate settlement.[72] The transferee court cannot unilaterally transfer cases to itself or trial, but must remand any pending case to its original court.[73]

The original intent of Congress "never envisioned transferee judges concluding multi-district cases; the plan was simply to streamline the discovery and pre-trial process and then return cases to their home districts for trial."[74] Yet, real-life problems such as a need for settlement, attorney misconduct and freeriding and the lack of explicit police power persists; --

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70 *In Re: Vioxx Liability Litigation*, 239 Federal Rules Decision, 450, 462-463 (E.D. La. 2006).

71 For the MDL process generally, see *Fallon, et al*, supra, at 2327-2328.

72 *Id.*, at 2328.

73 *Id.*

74 Burch, supra, at 79.

so, judges innovate and stretch common law doctrines, such as inherent judicial authority, to address these issues.[75]

In Vioxx, the need for closure and global settlement meant that the court had to exercise jurisdiction, not only over federal cases transferred by the MDL panel but also state claims, into three consolidated cases and even tolled the claims that had not been filed in the lawsuits. In the context of regulating the attorney's fees, Judge Fallon cited three different sources of his authority, which also applied to his regulation of the global settlement itself:

1. The contractual terms of the Master Settlement Agreement itself;

2. The court's equitable authority over the administration of the global settlement; and

3. The court's inherent authority to exercise ethical supervision over the parties.[76]

One or more of these bases would give the court power to oversee each of the three different type of cases.

First, the transferred federal cases were subject to the MDL statutory provisions, which allow the court to facilitate settlement. So, in these cases, there is statutory, equitable and inherent authority for power. Now it is true that federal court is a court of limited jurisdiction and the state court and tolled claims parties cannot grant such a court subject matter jurisdiction by agreement.[77] However, here Judge Fallon was careful to coordinate with the state court judges handling the state cases in overseeing the discovery process and in facilitating the

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75 Burch, supra, at 84.

76 *In Re: Vioxx Products Liability Litigation*, 574 F.Supp.2d 606 (E.D. La. 2008).

77 See *McLaughlin v. Western Union Telegraph Co.*, 7 F.2d 177, 179 (E.D. La. 1925).

settlement agreement. Because the Master Settlement Agreement was an opt-in agreement, the state cases and the tolled claims plaintiffs chose to give the court authority over the agreement by contract. Any of the three state court judges could have caused significant federalism issues if there were objections to the process. They did not do so. In the final analysis, the federal court's authority over the settlement of the state court claims was based more on the contract than on federal jurisdiction.

Still, the idea of a federal judge reaching out to oversee settlement of claims over which the court has no jurisdiction based on a private contract in order to effect a settlement of claims over which the court does have jurisdiction does seem a bit of a stretch -- or at least very innovative. This area is ripe for legislation or rulemaking. There is no direct prohibition; nor is there direct legal support. Even so, while the law in this area may be somewhat immature, the result of this exercise of authority by Judge Fallon in *Vioxx* seems fairly self-validating given that 99.9% of all eligible claimants enrolled in the settlement.[78]

B. Lawyer-Client Issues

A number of conflict-of-interest and inadequacy-of-counsel issues between lawyer and client arose out of the MDL process and the Settlement Agreement. In the MDL process, the issues arose from the prevalence of repeat players on the various plaintiff counsel committees. In the Settlement Agreement, the issues arose from the aggregate representation of multiple clients by individual lawyers or firms, from the restrictions the settling counsel were required to sign to opt into the Settlement Agreement and from an increase in the percentage of attorney's fees from the amount originally set by the court in the *Vioxx* MDL case.

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[78] See ftn. 58.

In this and other MDL cases, there a prevalence of repeat players appointed as a result of the Lead Lawyer and Steering Committee Selection process. Judges tend to select repeat players because of their expertise, cooperative tendencies and suit-financing abilities.[79] These lawyers "develop expertise, have a stable of go-to specialists, cultivate relationships with…judges and their staff, and enjoy economies of scale with low start-up costs…."[80] While this may seem valuable, there are negative effects, including encouragement of attorneys to curry favor with one another to secure future leadership posts, deterring dissent due to the goal to agree with defendants to settle, and enhancing risk of inadequate representation for plaintiffs who have "out of the norm" or "high value" cases.[81] Further, appointing repeat players may increase the possibility if collusive settlements as the lawyers scratch each other's backs and look down the road for additional opportunities.[82]

These concerns were not ignored in the Vioxx case. Judge Fallon recognized the court's "interest in broadening the range of attorney participation in MDL cases, lest the work be confined to a specialized bar of MDL attorneys which would result in exclusivity, unfairness, and discrimination, and inure to the disadvantage of litigants and their attorneys."[83] As a result, the court authorized and encouraged the Plaintiffs' Steering Committee to organize subcommittees and assign tasks for common benefit work, as well as appoint non-steering

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79 Burch, supra, at 73.

80 E. Burch & M. Williams, Repeat Players in Multi-District Litigation: The Social Network, available at http:\\ssrn.com\abstract=2724637, pg. 7.

81 *Id.,* at pg. 14.

82 Burch, supra, at 101.

83 Ftn. 28, at pgs. 8-9.

committee members, including those lawyers representing plaintiffs in state court cases to do that work.[84] Over 100 firms or lawyers participated in the common benefit work as a result.[85]

The first conflict issue regarding the Settlement Agreement arose from the aggregate representation of multiple parties by an individual lawyer or firm. One big issue in these situations is whether a settlement which is good and acceptable for the group is also good and acceptable for each individual client in the group. The concern is that the lawyer's economic incentive (contingency fee recovery) is tied more to the global settlement amount than to any individual settlement amount.

ABA Model Rule 1.8(g) requires that the lawyer inform each client of all material terms of the settlement, including what the lawyer's other clients will receive if the settlement offer is accepted. This is to ensure that each client exercises informed consent as required by AMB Model Rule 1.7(b).

The *Vioxx* Settlement Agreement addressed this issue in several ways. A unique aspect of *Vioxx* was that the plaintiffs did not agree to a particular settlement amount to dismiss their individual cases as is the norm. Plaintiffs who accepted the settle offered agreed to a settlement process to evaluate and compensate cases, but with the knowledge that Merck was going to put up a total of $4.85 million and plaintiffs who accepted the settlement, but didn't qualify during the process, could continue with their suits. So, no plaintiff knew what individual compensation would be received either by that plaintiff or any other when accepting the Settlement Agreement.

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84 *Id.*, at pg. 9.

85 *Id.*

The evaluation process was actually individualized with the compensation based on the evidence each plaintiff produced to navigate the Injury, Duration and Proximity "Gates" described hereinabove. This was not a one-size-fits-all compensation system. This individualization of compensation tended to disaggregate the claims, because each plaintiff's compensation was based on the individual evidence produced by that plaintiff. This also presents the lawyer involved with economic incentives to maximize each individual plaintiff's recovery.

Additionally, the Master Settlement Agreement itself contained language to enforce the lawyer's ethical obligations here. Section 1.2.2 of the Amendment to Settlement Agreement amended Section 1.2.8.1 of the Settlement Agreement to provide that "Each Enrolling Counsel is expected to exercise his or her independent judgment in the best interest of each client individually before determining whether to recommend enrollment in the Program." Given this language and the individualization of the claims process, the *Vioxx* settlement did about as good a job as is practical in addressing the conflict of interest concern and still obtaining a global settlement.

Another lawyer-client issue was the alleged "self-enriching actions" of counsel in the Vioxx matter.[86] Initially, Judge Fallon awarded 2% of the gross recovery for common benefit fees and costs, and the Master Settlement Agreement negotiated by the plaintiffs' committee with a defendant and which plaintiffs were required to sign raised that amount to 8%, and provided that it would be paid from the fees the lawyers received from their clients rather than from the clients themselves.[87] However, in his ruling on the Plaintiffs' Liaison Counsel's

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86 Silver, at 1985.

87 *Id.*, at 10992.

Motion for an Award of Plaintiffs' Common Benefit Counsel Fees and Reimbursement of Expenses, Judge Fallon exhaustively reviewed the basis for the fee request, interpreted the Master Settlement Agreement to allow for a common benefit fee of "up to" 8%, compared the request to several other fee calculation methodologies and decided the appropriate percentage was 6.5%.[88] This was not a dark-in-the-night grab by the plaintiffs' counsel. It was a request for additional fees based upon additional work done, which was extensively reviewed and ruled upon by the court.

Still another area of criticism arose from the requirement that lawyers who signed the Master Settlement Agreement must agree to recommend the settlement to 100% of his or her clients and withdraw from representation of any clients who declined the settlement. These provisions were the enforcement mechanism of the agreement as defendants sought closure.[89] These requirements were argued to be in violation of the lawyers' ethical obligation prohibiting the lawyer from offering or entering into an agreement restricting the lawyers' right to practice as part of a settlement under Rule 5.6 of the American Bar Association Model Rules of Professional Conduct. A close examination of §1.2.8 (as amended) of the Master Settlement Agreement sets out the intent of the agreement not to operate as a "restriction" under the model rules, but requiring the individual counsel to "exercise independent judgment in the best interests of each client individually before determining whether to recommend enrollment in the program."[90] Clearly, the settlement agreement recognizes the issue and attempts to address it. Under ABA

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88 *In Re: Vioxx Products Liability Litigation*, Order & Reasons, MDL 1657 (10/19/10 E.D. La.)

89 Nagareda, at 1154.

90 Ftn. 53; Amendment available at http://www.officialvioxxsettlement.com\documents\Amendments%20to%20Master%20Settlement%20Agreement.pdf

Model Rule 5.6, both Merck's lawyers and the particular plaintiff's lawyer would be in violation of these provisions under the rule if this agreement operated as such a restriction. The language of the agreement seems designed to give "wiggle room" to both sides. The question remains as to whether it is enough.

Regardless of the language of the settlement as to its "intent", the restriction facially seems to violate the provisions of ABA Model Rule 5.6(b). However, one wonders if the rule was ever intended to address the issue as it arises in aggregate representation. The rule contains no prohibition of lawyers entering into agreements restricting their right to use or reveal information relating to a specific case.[91] If this language in the Settlement Agreement were designed to prevent a settling lawyer from using information learned while representing a settling party while continuing to represent the non-settling party, it would make sense and not be prohibited. Given this, the lawyer could not adequately represent the non-settling party under the circumstances and a prohibition from doing so would follow. So, such a restriction may not be as prohibitive as it appears, although clearer language could have been used.

Also missing from the academic criticisms is any reference to the main formal inhibitor to lawyer ethical breaches: the disciplinary committees of the various state bars and/or supreme courts throughout this country. If any individual client felt harmed by any unethical behavior on the part of their counsel (repeat player or not), that client has a right to complain to disciplinary counsel and the matter will be investigated. Being disciplined and/or disbarred is a huge deal and greatly influences lawyer behavior. As mentioned above, the agreement appears to be self-validating given that 99% of the eligible claimants enrolled and no known claims of malpractice have arisen out of the settlement.

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91 ABA, Annotated Model Rules of Professional Conduct, at 497 (5th Edition 2003).

C. Black Hole

As Judge Fallon has written, "The strongest criticism of the traditional MDL process is that the centralized form can resemble a 'black hole', into which cases are transferred never to be heard from again".[92] As he further points out though, the comparison to be made is not between an MDL and an average case; but rather, an MDL and thousands of similar cases when it comes to judicial efficiency.[93] Here, the MDL was conferred on February 16, 2005, and the last payment to plaintiffs was made on June 29, 2010 in a case involving approximately 50,000 claimants. In this case at least, there was no "black hole" in the sense that plaintiffs' claims were not addressed timely.

V. CONCLUSION

This was an incredibly complicated litigated matter, without much in the way of direct statutory or jurisprudential guidance for the court. The unique resolution methods used worked as efficiently as possible under the circumstances. Most of the criticism, while raising valid points, seemed to fall into the category of "making the perfect be the enemy of the good." The court system faced significant docket overload if a resolution wasn't reached in this large-scale litigation. This court was creative and energetic, and worked with counsel for both sides, as well as the state court judges, to make it work. As Professor Issacharoff has argued:

> The *Vioxx* settlement, in order to provide closure to claims premised on the epidemiological risk faced across the cohort of users of the drug, had to devise a private arrangement to overcome the dysfunctionality of the formal procedural system. Independent of any considerations of the structure of the ultimate fairness of the settlement terms, the fact remains that there was no way to achieve

92 82 Tulane Law Review 2323, 2330 (2008).

93 *Id.*

> closure within any of the established pathways of the formal joinder devices available in aggregate litigation.[94]

Who came out ahead? While nothing is 100% perfect, all sides gained. Merck obtained closure of a major exposure at a price it could pay. Those plaintiffs with the most solid cases obtained decent recoveries (sometimes significant) without running an expensive causation gauntlet at trial with the risk of obtaining nothing. Those others with claims that did not qualify for the settlement were allowed to proceed. The court system resolved a huge potential backlog. So, no cave in and no giveaway. That's some pretty tasty boudin.

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94 Supreme Court Review 183 at 219 (2008).