

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

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In re: VIOXX PRODUCTS LIABILITY
LITIGATION

MDL NO. 1657 (EEF)

THIS DOCUMENT RELATES TO ALL CASES

SECTION L

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**MEMORANDUM OF LAW IN OPPOSITION TO MERCK'S MOTION FOR
SANCTIONS**

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INTRODUCTION

This Memorandum of Law is submitted on behalf of Dr. David Egilman in opposition to Defendant Merck Sharp & Dohme Corp.'s ("Merck") Motion for Sanctions Against Dr. David Egilman, filed on April 4, 2014. Merck's motion is without merit and must be denied for several key reasons. First, there is no factual basis to support Merck's claim for sanctions. At the time Dr. Egilman made his allegedly revealing statements, Merck already had disclosed the very same information in open court and through self-serving public statements, and the parties had provided even more detailed information through publicly accessible filings. Second, Merck fails to grapple with or even acknowledge controlling legal authority. Merck ignores the Supreme Court's well-established principle that protective orders may not prohibit the disclosure of publicly available information, and Merck pays no heed to the Fifth Circuit's stringent standards for establishing contempt by clear and convincing evidence. Merck does not even attempt to demonstrate which confidential documents were disclosed by Dr. Egilman or which private information he has revealed to the public. For all of these reasons, we respectfully request that the Court deny Merck's motion.

SUMMARY OF ARGUMENT

Merck argues that Dr. Egilman should be sanctioned for offering an opinion to *The Wall Street Journal* – bereft of any specific information about any specific document and made in the context of separate Kentucky litigation, not the MDL – about what internal Vioxx documents show about Merck's conduct. The first, and most critical, reason for rejecting Merck's contention is that, *before* Dr. Egilman's statements were made to *The Wall Street Journal*, Merck itself made public the very same statements by filing them in open court. Similarly, the parties to this litigation have made the extensively detailed expert reports of Dr. Egilman and others

available to the public by filing them on PACER, where they have remained for months if not years. Merck has never objected to the presence of these reports in open court files, even though, unlike *The Wall Street Journal* statements, they contain detailed discussion of specific internal documents. These two facts are fatal on their own to Merck's motion. Because Dr. Egilman's detailed opinions already had been publicly disclosed by Merck and the parties, no breach of confidentiality occurred. *See, e.g.*, Pretrial Order No. 13 ("PTO 13") at ¶ 23 (deeming information withdrawn from protection to the extent it becomes "publicly available"). Even if PTO 13 applied, the First Amendment protects the right to disclose information that is found in the public record, even when that material overlaps with, is identical to, or summarizes other confidential material. *See Seattle Times Co. v. Rhinehart*, 467 U.S. 20 (1984).

Merck's motion suffers from an additional fundamental flaw. Merck has not (1) identified the documents allegedly disclosed, or referred to, by Dr. Egilman, nor (2) provided any confidentiality log as required by this Court's orders. As to the first point, Merck's failure to identify the documents it thinks were disclosed deprives Dr. Egilman of the due process to which he is entitled. If Merck does not know which documents were disclosed, then it begs the question how it can establish a violation of PTO 13 by clear and convincing evidence. *See Travelhost, Inc. v. Blandford*, 68 F.3d 958, 961 (5th Cir. 1996) (movant must present "evidence so clear, direct and weighty and convincing as to enable the fact finder to come to a clear conviction, without hesitancy, of the truth of the precise facts of the case."). As to the second point, Merck's hesitance in producing a log may be related to the fact that Merck does not know the scope of what is and what is not confidential, as Merck's submissions in Kentucky state court suggest. *See* Declaration of Alexander A. Reinert ("Reinert Decl.") ¶ 12. Or perhaps Merck is aware that it has forfeited any claim to confidentiality, through multiple self-serving disclosures

to the public of its own summaries and conclusions drawn from the very same documents it now seeks to protect from disclosure. Thus, there are serious questions as to whether disclosure of any Vioxx document, let alone the unidentified subset of documents that Merck asks this Court to assume were disclosed by Dr. Egilman, is sanctionable.

Had Merck bothered to confer with Dr. Egilman prior to filing its motion, perhaps it would have realized that its efforts to sanction him were misplaced. But rather than focus on relevant law or facts, Merck attempts to impugn Dr. Egilman's integrity by accusing him of engaging in a "crusade" in which he is seeking to "attack Merck." *See* Mem. in Support of Merck's Mot. for Sanctions ("Merck Br.") at 3, 10. Dr. Egilman's professional history in Vioxx litigation rebuts Merck's character assassination. Dr. Egilman is a Clinical Professor of Family Medicine at Brown University who has published several articles (based on previously confidential Merck documents) on Vioxx-related matters, in peer-reviewed medical journals including the Journal of the American Medical Association, the British Medical Journal and the Annals of Internal Medicine. *See* Ex. E to Reinert Decl. In addition to publishing articles critical of Merck's conduct with respect to Vioxx, Dr. Egilman also served as the key medical and liability witness in the seminal Vioxx case of Ernst v. Merck. In both venues, Dr. Egilman described Merck's conduct in the same manner that he repeated to *The Wall Street Journal*. It is no surprise, then, that Merck has sacrificed reliance on facts or law for this heavy-handed play to "poison the well." But the record shows that Dr. Egilman has steadfastly abided by his confidentiality obligations in this and other Vioxx matters. On several occasions over the past seven years, when he has published material related to Vioxx, Dr. Egilman has assiduously sought and received prior permission from Merck to discuss material designated confidential. *See* Ex. F to Reinert Decl. Dr. Egilman has even gone so far as to solicit commentary on the

substance of his scholarship from Merck's counsel prior to publication. *See* Ex. F to Reinert Decl. Consistent with this behavior, in Kentucky and in this Court, Dr. Egilman has followed the court-ordered processes governing the treatment and de-designation of confidential documents. This is in contrast to Merck's behavior, which reflects a callous disregard for its obligations, found in both Protective Order No. 13 and in this Court's express instruction at a February 28, 2014, hearing. *See infra* Part IV. For all of these reasons, more fully discussed below, Dr. Egilman respectfully requests that this Court deny Merck's request for sanctions.

I. FACTUAL BACKGROUND

A. The Opinions Expressed By Dr. Egilman To The Wall Street Journal Have Long Been Disclosed to the Public By the Parties

Several indisputable facts weigh heavily against granting Merck's motion. First, before Dr. Egilman's statements appeared in *the Wall Street Journal*, Merck itself introduced into the public record Dr. Egilman's statements describing the contents of the documents at issue in the Kentucky litigation, statements that are in sum and substance identical to Dr. Egilman's comments to *The Wall Street Journal*. On February 14, 2014, Merck submitted to a Kentucky state court a private letter written to Merck by Dr. Egilman in which he explained his request to de-designate certain Vioxx documents. *See* Exs. G & H to Reinert Decl..

That letter contained the following description of the documents Dr. Egilman sought to de-designate:

Some of these documents are evidence that Merck provided fraudulent information in testimony to the Federal District Judge in Boston when it pled guilty plea for criminal conduct related to off label marketing of Vioxx. Finally some of these documents indicate that Merck manipulated data in its drug trials. I intend to share these documents with Merck's corporate integrity officer, the FDA and the FBI. More importantly the study data and Merck's analysis of its own data which has remained secret or which Merck misrepresented in published medical literature (Advantage and 078 letters and publications and others) have important public health implications that relate to Cox-2 health effects in general.

These results are relevant to the assessment of risks associated with Cox-2 drugs that remain on the market.

See Ex. H to Reinert Decl. at 1. Thus, when Dr. Egilman told *The Wall Street Journal* that some documents revealed “information on the toxicity of the drug, . . . information that Merck published that misrepresents the health effects of the drug, . . . new information on the health hazards of the drug and evidence of fraud in the conduct of the studies,” Merck already had disclosed those very same views to the public. Merck did not seek to file Dr. Egilman’s letter under seal, nor has it argued that the letter is confidential, yet the letter expresses precisely the same opinion he voiced to *The Wall Street Journal*. Merck has made no showing that the statements to *The Wall Street Journal* revealed any additional information about the documents beyond the statement Merck itself made public.

Second, for months if not years now the expert reports of Dr. Egilman and others have been available to the public via PACER filings made in this case. In those expert reports, the contents of internal Vioxx documents are extensively disclosed and analyzed. In particular, Dr. Egilman’s original expert report, placed in publicly accessible court files associated with this proceeding on July 25, 2013, contained the following opinions: (1) that Merck was aware of data “linking increased incidents of cardiovascular events with VIOXX usage” (Expert Report by Dr. David Egilman ¶20, filed in 2:05-md-01657, Doc. No. 64508-7); and (2) that Merck “misrepresented, concealed, suppressed, and omitted material facts regarding VIOXX’s risks” of causing many serious health effects (*Id.* ¶24). Dr. Egilman’s supplemental expert report provides additional opinions regarding Merck’s attempts to mislead the public regarding the actual health effects of VIOXX. See Plaintiff’s Notice of Correction to Expert Report, at 6-8 (Nov. 11, 2013), filed in 2:05-md-01657, Doc. No. 64683. Merck has never sought to restrict the public’s access to these opinions.

The upshot of all of these publicly available descriptions of the contents of documents, none of which was entered into the public record by Dr. Egilman, is that well before *The Wall Street Journal* published its article, far more detailed descriptions of the documents that Merck claims are confidential have been made available for public consumption. For example, while this motion is pending nothing prevents a journalist from discovering and publishing these detailed descriptions for the world to see. It is black letter law that the release of information in open court “is a publication of that information and, if no effort is made to limit its disclosure, operates as a waiver of any rights a party had to restrict its future use.” *National Polymer Products v. Borg-Warner Corp.*, 641 F.2d 418, 421 (6th Cir. 1981). One need only compare the statements made by Dr. Egilman to *The Wall Street Journal* with the statements by Dr. Egilman that the parties already have placed into the public record to reach the conclusion that Dr. Egilman’s statements to *The Wall Street Journal* disclose nothing private or treated as confidential by the parties. *See* Ex. D to Reinert Decl. at Tables 2-4 (comparing specific statements in expert reports with general statements made to *The Wall Street Journal*). At most, Dr. Egilman’s statements to *The Wall Street Journal* reveal his opinion about what one would conclude from reading the documents, an opinion that has not been treated as confidential by any of the parties.

These facts are enough on their own to reject Merck’s motion, because they establish that the statements made by Dr. Egilman to *The Wall Street Journal* provides less detail about internal Vioxx documents than filings made publicly available by the parties themselves. But if one looks to the statements of others, most notably the United States in its successful prosecution of Merck, it is clear that Dr. Egilman is hardly alone in opining that Merck’s actions as reflected in the documents reflect fraud and misrepresentation. *See* United States Department of Justice,

U.S. Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx (Nov. 22, 2011 press release), available at <http://www.justice.gov/opa/pr/2011/November/11-civ-1524.html> (describing allegations that Merck made “inaccurate, unsupported, or misleading statements about Vioxx’s cardiovascular safety in order to increase sales of the drug,” defrauding the federal government and the several States). And when Merck pleaded guilty to misbranding, they agreed, with a slight modification, with the United States’ rendition of what the evidence would show. *See* Dec. 16, 2011, Transcript of Rule 11 Hearing at 13-17, attached as Ex. I to Reinert Decl.

B. Merck Has Made No Showing That The Documents That Form The Basis of Dr. Egilman’s Opinion Are Protected From Disclosure

Even if one treats Dr. Egilman’s statements to *The Wall Street Journal* as disclosing the specific contents of documents, and not his already publicly available opinion about what one should conclude from reading the documents, Merck’s motion is factually insufficient. For Merck has failed to provide any evidence that the documents that form the basis for Dr. Egilman’s statement to *The Wall Street Journal* are themselves protected from disclosure by PTO. 13, 13A, or 13C. Nothing in *The Wall Street Journal* statement refers to any MDL document or provides any specific information from such a document. And if one looks to Dr. Egilman’s original expert report, it is evident that his opinion that Merck engaged in fraud, misrepresentation, and a cover-up can be wholly supported by non-confidential documents. *See* Reinert Decl. at ¶ 8 and Ex. D. Merck has made no showing otherwise; indeed, it has not even attempted to describe which MDL documents Dr. Egilman allegedly disclosed. As it is Merck’s burden to establish contempt by clear and convincing evidence, *Travelhost*, 68 F.3d at 961, its failure to provide any specificity in its motion is fatal.

Finally, it is simply not clear as a factual matter that any MDL document relating to Dr. Egilman's statements to *The Wall Street Journal* is confidential and protected by PTO 13, 13A or 13C. As a separate submission by the State of Utah establishes, Merck itself has presented to the public a report summarizing millions of pages of internal documents, sometimes describing them in great detail. Although Merck may still consider these documents confidential, basic principles of waiver call this position into question. *See infra* pp. 18-19. As Merck recognized in prior submissions to this Court, it waives confidentiality whenever it discusses confidential material in public, at least to the extent of the subject matter of Merck's public disclosures. *See* April 9, 2014, Letter from John H. Beisner to Court ("April 9 Beisner Letter") at 3 n.1. And because the subject matter of Merck's self-serving statements to the public involves the very matters upon which Dr. Egilman commented to *The Wall Street Journal*, Merck cannot now argue that it has preserved confidentiality in the documents upon which its prior statements were based.

Merck's motion thus seeks to punish Dr. Egilman for offering a characterization of the same documents that Merck and others have characterized in one way or another for years. Moreover, in Kentucky state court Merck has conceded that MDL documents produced in Kentucky may be de-designated under that court's governing protective order. By operation of this Court's Protective Order, such documents become automatically removed from PTO 13's protection. *See* PTO 13 at ¶ 23 (removing from protection any document that "has its designation as Confidential Information withdrawn or judicially removed in any U.S. VIOXX action."). No principle of equity or fairness permits a sanction in these circumstances.

C. The Statements in *The Wall Street Journal* Are Much Less Specific Than Criticisms of Merck That Have Been Publicized By Other Parties

Not only have Dr. Egilman's opinions about Merck's treatment of Vioxx research been known to the public for a long period of time, but numerous other parties have commented on

Merck's conduct based on internal Merck documents. Some examples, all of which rely on and summarize documents that Merck currently claims are confidential and Dr. Egilman has asked to be de-designated, include:

- In 2008, a study was published based on documents and data that Merck claims to be confidential (and are the subject of Dr. Egilman's request in Kentucky) which concluded that Merck had failed to adequately inform the public and the FDA about mortality results in its own internal studies. *See* Bruce M. Psaty and Richard A. Kronmal, *Reporting Mortality Findings in Trials of Rofecoxib for Alzheimer Disease or Cognitive Impairment: A Case Study Based on Documents From Rofecoxib Litigation*, 299 JAMA 1813, 1816 (2008). Contemporaneous press accounts describe the study as providing evidence of fraud and deception by Merck. *See, e.g.,* *Maker of Vioxx is Accused of Deception*, WASH. POST (April 16, 2008), available at <http://www.washingtonpost.com/wp-dyn/content/article/2008/04/15/AR2008041502086.html>.
- The United States Department of Justice, in announcing Merck's plea of guilty to civil and criminal charges regarding its marketing of VIOXX, described allegations that Merck made "inaccurate, unsupported, or misleading statements about Vioxx's cardiovascular safety in order to increase sales of the drug," defrauding the federal government and the several States. *See* United States Department of Justice, *U.S. Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx®* (Nov. 22, 2011 press release), available at <http://www.justice.gov/opa/pr/2011/November/11-civ-1524.html>.
- In April 2012, the State of Utah filed an amended complaint against Merck, based in part on documents that Merck claims to be confidential, alleging that Merck failed adequately to inform the public about the dangers of Vioxx, made false statements about its efficacy and safety, and covered up information about health hazards associated with the drug. *See* Amended Complaint of the State of Utah in *In re Vioxx Products Liability Action*, MDL No. 1657 (filed April 17, 2012). Similar allegations, also based on documents that Merck purports to be confidential, were made by the State of Kentucky. *See* Complaint in *Kentucky v. Merck & Co., Inc.*, No. 09-CI-1671 (filed Sept. 28, 2009).
- On July 25, 2013, Dr. David Madigan's expert report, based in large part on documents that Merck maintains to be confidential, was made available to the public, giving anyone with a PACER account access to Dr. Madigan's conclusions that Merck made misleading statements about Vioxx's health effects, failed to disclose highly relevant evidence of cardiovascular health risks, and obscured the public's understanding of the true risk posed by Vioxx. *See* Expert Report by Dr. David Madigan ¶¶ 251-57, filed in 2:05-md-01657, Doc. No. 64508-1; *see also* David Madigan et al., *Under-Reporting of Cardiovascular Events in the Rofecoxib Alzheimer Disease Studies*, 164 Am. Heart J. 186 (2012) (providing analysis of data from three Merck studies, all of which are currently designated confidential by Merck, and concluding that Merck's published reports failed to fully disclose Vioxx risk).

Thus, it is hardly disclosing a state secret to observe that numerous parties with access to Merck's internal documents believe that they support the same opinions that Dr. Egilman offered to *The Wall Street Journal*.

In summary, these facts show: (1) that Dr. Egilman's opinion regarding what Merck's internal documents revealed had already been made publicly available in numerous venues; (2) the parties, including Merck, and not Dr. Egilman, were directly responsible for placing Dr. Egilman's specific opinions into the public record *before* he made his far more general comments to *The Wall Street Journal*; (3) Dr. Egilman's opinion can be supported by documents that Merck acknowledges to be unprotected by PTO 13, 13A, and 13C; and (4) many other parties, including the United States, have made public similar opinions about Merck's conduct, based on internal Vioxx documents. As will be established in the remainder of this Memorandum, there is no legal authority for sanctioning Dr. Egilman under these circumstances.

II. NEITHER THE CONSTITUTION NOR PTO 13 PERMITS SANCTIONING DR. EGILMAN FOR REPEATING STATEMENTS CONTAINED IN PUBLICLY-AVAILABLE DOCUMENTS

Protective orders, by definition, are not meant to and cannot prohibit the disclosure of publicly available information. The language of PTO 13, which provides that documents shall not be protected once they become publicly available, *see* PTO 13 at ¶ 23, is consistent with this axiom. And more importantly, the Supreme Court has made clear, in an opinion neither acknowledged nor addressed by Merck, that the First Amendment prohibits use of a protective order to limit disclosure of already public information. *See Seattle Times Co. v. Rhinehart*, 467 U.S. 20 (1984).

Merck's motion is in irreconcilable conflict with these fundamental principles. Merck alleges that Dr. Egilman violated PTO 13, 13A, and 13C by stating that certain documents

contain “information on the toxicity of the drug, . . . information that Merck published that misrepresents the health effects of the drug, . . . new information on the health hazards of the drug and evidence of fraud in the conduct of the studies.” See Merck Br. at 4 (quoting *The Wall Street Journal* article). At most, these statements offered Dr. Egilman’s opinion about what some of the Vioxx documents reveal about Merck’s conduct. But as established above, the public record provides even greater detail about the content of documents that Merck claims are confidential than was provided by Dr. Egilman to *The Wall Street Journal*. Whether these descriptions are found in Dr. Egilman’s October 29, 2013, letter placed into the public record by Merck, his expert reports placed in accessible court files by the parties, or his scholarly articles regarding Vioxx, nothing found in *The Wall Street Journal* cannot be found with more detail elsewhere. Neither the Constitution nor PTO 13 permits a sanction in this context.

Merck claims that it may seek sanctions even if the alleged disclosure is of publicly available information, citing a single district court case. See Motion for Sanctions at 6 (citing *Nevil v. Ford Motor Co.*, No. 94 Civ. 15, 1999 WL 1338625 (S.D. Ga. Dec. 23, 1999)). *Nevil* is fully distinguishable from this case in large part because it involved specific disclosures about specific documents. See *Nevil*, 1999 WL 1338625, at *4 (“At several points in his testimony, Mr. Carlson discloses specific information contained in General Tire studies.”). The court in *Nevil* rejected the expert’s argument that the information was in the public domain because, even were that so, the fact that the information came from protected documents was not publicly known. *Id.* at *4.¹ By contrast, in this case the public domain is awash with information about the basis of Dr. Egilman’s opinions – before Dr. Egilman made any statement to *The Wall Street Journal*, Merck introduced those statements to the public, as have other parties. Merck fails to

¹ A review of the pleadings entered in *Nevil* raises substantial doubt as to whether the expert made any showing at all that his statements could be supported by publicly available documents. See Ex. N to Reinert Decl. The expert’s brief devoted one sentence to the argument, and cited neither facts nor law in support. See *id.*

explain how it can seek sanctions for the disclosure of information that has been made public by the conduct of nearly all parties to this litigation.

More troubling, however, is Merck's failure to acknowledge or account for the United States Supreme Court's decision in *Seattle Times Co. v. Rhinehart*, 467 U.S. 20 (1984), controlling authority and the seminal case on the constitutional limits of protective orders. In *Seattle Times*, the Court observed that confidentiality orders of the kind exemplified by PTO 13 are permissible, so long as a party is free to "disseminate the identical information covered by the protective order as long as the information is gained through means independent of the court's processes." 467 U.S. at 33-34. This language has been interpreted by numerous courts to protect precisely the kinds of disclosures Dr. Egilman makes here. For instance, the District of the District of Columbia noted that a protective order could not "prevent . . . anyone . . . from disseminating the substance of information already in the public domain, *by virtue of its inclusion in the open trial record or other sources.*" *Tavoulaareas v. Washington Post Co.*, 111 F.R.D. 653, 660-61 (D.D.C. 1986) (emphasis added) (*citing Seattle Times*, 467 U.S. at 34); *cf. Bartnicki v. Vopper*, 532 U.S. 514, 544-545 (2001) ("The antidisclosure provision is based solely upon the manner in which the conversation was acquired, not the subject matter of the conversation or the viewpoints of the speakers. The same information, if obtained lawfully, could be published with impunity.") (*citing Seattle Times*, 467 U.S. at 34).

This is not an argument, as Merck appears to assume, that Dr. Egilman has a constitutional right to disclose material that is protected from disclosure by court order. *See* April 9 Beisner Letter at 4. It is a straightforward application of foundational constitutional principles: protective orders may not reach information that is publicly available. As the Northern District of Illinois explained, it would be "both unfair and unconstitutional" to find a

party in contempt for “revealing information to which the general public had access.” *Grove Fresh Distributors, Inc. v. John Labatt Ltd.*, 888 F. Supp. 1427, 1442 (N.D. Ill. 1995).² And unlike the party who ultimately was sanctioned in *Grove Fresh*, Dr. Egilman is not attempting to “claim[] as ‘public’ information he himself disclosed to the public.” *Id.* at 1442 n.22. It was Merck and other parties, not Dr. Egilman, who made his October 29, 2013 letter and his expert reports publicly available. For these reasons, Dr. Egilman cannot constitutionally be sanctioned for disclosing less information than Merck and others have made available to the public.

III. MERCK HAS NOT INTRODUCED SUFFICIENT EVIDENCE TO SUPPORT ITS HEAVY BURDEN TO ESTABLISH CIVIL CONTEMPT

Merck’s motion would fail even if this Court were to ignore all of the prior disclosures made by the parties and only consider Dr. Egilman’s statement to *The Wall Street Journal* in isolation. This is because Merck has not come close to satisfying the demanding standard required to establish contempt. Because Merck is seeking compensation for its alleged injuries, we presume that it is asking this Court to impose civil, not criminal, contempt. *In re Bradley*, 588 F.3d 254, 263-64 (5th Cir. 2009).³ To hold a party in civil contempt, a court must find “(1) that a court order was in effect, (2) that the order required certain conduct by the respondent, and (3) that the respondent failed to comply with the court’s order.” *FDIC v. LeGrand*, 43 F.3d 163, 170 (5th Cir. 1995). Merck fails to acknowledge its heavy burden to establish each of these elements by presenting “clear and convincing” evidence that Dr. Egilman has violated a “definite and specific” judicial order. *Travelhost*, 68 F.3d at 961 (internal quotation marks omitted). As the Fifth Circuit has explained, this means that Merck must present “evidence so clear, direct and

² In *Grove Fresh*, the Court imposed contempt sanctions because the alleged contemnor failed to identify the source of his information that also was available to the public. *See id.* Here, however, Dr. Egilman has provided several publicly available sources for his opinions.

³ Of course, because the standards for imposing criminal contempt are far more demanding than for civil contempt, Merck’s failure under the civil contempt standard excludes the possibility of satisfying criminal contempt.

weighty and convincing as to enable the fact finder to come to a *clear conviction, without hesitancy*, of the truth of the *precise facts* of the case.” *Id.* (emphasis added and internal quotation marks omitted).

Because of the serious nature of contempt charges, certain procedural protections, in addition to the onerous burden of proof, must be satisfied prior to issuing a judgment of civil contempt. Most critically, Dr. Egilman is entitled to notice of the grounds for the contempt and an opportunity to be heard, but is not obliged to present any evidence should Merck fail in establishing any of the three elements of contempt. *Electrical Workers Pension Trust Fund v. Gary*, 340 F.3d 373, 379 (6th Cir. 2003) (burden of proof and production rests with movant); *Alberti v. Klevenhagen*, 46 F.3d 1347, 1359 -1360 (5th Cir. 1995) (requiring notice and an opportunity to be heard); *see generally International Union, United Mine Workers of America v. Bagwell*, 512 U.S. 821, 826-34 (1994) (discussing difference in protections provided for criminal versus civil contempt). Accordingly, in no event may the movant rely on unsworn assertions to establish the critical elements of civil or criminal contempt. *Mackler Productions, Inc. v. Cohen*, 225 F.3d 136, 142 (2d Cir. 2000).

With these standards in mind, it is clear that Merck has failed to meet its burdens here. Dr. Egilman acknowledges that a court order was in effect and that it required certain conduct by him, but Merck has not introduced evidence “so clear, direct and weighty and convincing as to enable the fact finder to come to a *clear conviction, without hesitancy*,” of the “precise fact[]” that Dr. Egilman violated his obligations under PTO 13. *Travelhost, Inc.*, 68 F.3d at 961 (emphasis added and internal quotation marks omitted). Merck claims that Dr. Egilman violated PTO 13 by making three statements about “confidential VIOXX documents” to *The Wall Street Journal*: (1) “In general, there’s information on the toxicity of [Vioxx] that’s not been

previously published by Merck and there is information that Merck published that misrepresents the health effects of the drug.”; (2) The Vioxx documents “provide new information on the health hazards of the drug and evidence of fraud in the conduct of the studies.”; and (3) “I’ve been able to see documents few others have.” *See Merck Br.* at 4.

We do not take Merck to argue that Dr. Egilman breached confidentiality by disclosing that he has reviewed documents that “few others have” – after all, it is not a violation for Dr. Egilman to reveal that he is an expert in the litigation, a fact widely disclosed by the parties, and that therefore he has access to internal documents. Instead, Merck appears to argue that Dr. Egilman’s statements violated PTO 13 because they assert that certain documents contain undisclosed toxicity information and information revealing fraud and misrepresentation regarding the drug’s health effects. Merck’s first problem, however, is a profound lack of specificity on multiple levels. As Merck acknowledges, Dr. Egilman made the statements in the context of Kentucky litigation regarding the confidentiality designation of certain documents. The Kentucky litigation, however, involves numerous categories of documents: (1) documents that have been made publicly available through multiple means, but still claimed to be confidential by Merck; (2) documents disclosed in other proceedings, but not the MDL, which Merck treats as confidential; (3) documents disclosed in the MDL and treated as confidential; and (4) documents disclosed in the MDL and other proceedings and treated as non-confidential by Merck. *See Ex. A to Reinert Decl.* Dr. Egilman’s claim in the Kentucky litigation is that the allegedly confidential documents cannot be so designated either because they have been publicly disclosed or because Merck has no legitimate basis for maintaining their confidential status. With this background in mind, Merck’s lack of specificity here is fatal to meeting its burden of showing by clear and convincing evidence the “precise fact[]” that Dr. Egilman’s statements

revealed confidential information contained in documents protected by PTO 13. *Travelhost, Inc.*, 68 F.3d at 961 (requiring that finder of fact be convinced “without hesitancy” that alleged contemnor violated court order). Merck has not even shown that Dr. Egilman’s statements related to MDL documents, let alone confidential MDL documents.

There are several additional reasons that Merck has failed to demonstrate by clear and convincing evidence that Dr. Egilman violated PTO 13. First, Merck has not identified a single document or piece of information, confidential or otherwise, that it considers to contain the information allegedly disclosed by Dr. Egilman. Making matters worse, Merck’s refusal to provide Dr. Egilman counsel with a copy of an updated confidentiality log has undermined his ability to evaluate the specific documents that Merck believes have been implicated by Dr. Egilman’s statements. Basic due process requires that Dr. Egilman have some understanding of which MDL documents he is alleged to have disclosed by his statements, and whether these documents are even considered confidential under the MDL anymore.⁴ Thus, Merck has failed to provide the minimal notice required to satisfy due process before sanctions are imposed.

Second, Dr. Egilman’s statements nowhere refer to documents that are currently confidential, let alone documents that are confidential under PTO 13. The article’s author (but not Dr. Egilman) refers to documents that “were designated confidential,” not documents that are

⁴ In *Lyn-Lea Travel Corp. v. American Airlines, Inc.*, 283 F.3d 282, 291 (5th Cir. 2002), the Fifth Circuit affirmed a contempt judgment for violation of a protective order by a party, rejecting as “disingenuous” the party’s argument that the motion for contempt failed to identify the specific confidential documents disclosed. *Id.* But the facts of *Lyn-Lea* are clearly distinguishable. In *Lyn-Lea*, the president of one of the corporations acknowledged speaking with “30 or 40” reporters about the litigation, disclosing the specific contents of various confidential documents to those journalists, and stating that he could not provide the documents because of the protective order. *See id.* at 291 & n.14; *see also* Brief of Appellees in *Lyn-Lea Travel Corp. v. American Airlines, Inc.*, at 54-55, available at 2001 WL 34388886 (Feb. 28, 2001). The Magistrate Judge found that the party was in contempt after holding that there were no “legitimate collateral sources for the confidential information . . . disclosed.” *See* Brief of Appellees in *Lyn-Lea Travel Corp. v. American Airlines, Inc.*, at 54-55, available at 2001 WL 34388886 (Feb. 28, 2001). By contrast, here the statements made by Dr. Egilman to *The Wall Street Journal* can be found in any number of collateral public sources, and there are multiple categories of potentially implicated documents, not all of which are subject to Protective Order. Nor did Dr. Egilman’s statement to *The Wall Street Journal* indicate that the documents were protected in the MDL.

currently confidential under the MDL. And in light of the Kentucky litigation, which as described above involves numerous categories of documents, nothing about this statement directly implicates documents protected under PTO 13. Merck does not even make a pretense of attempting to establish by clear and convincing evidence that Dr. Egilman's statements were directed towards MDL documents rather than documents from other litigation that are implicated in the Kentucky litigation. Indeed, to the extent that Merck believes that Dr. Egilman's statements violate an order of confidentiality, it would appear that the proper forum for such an argument is the Kentucky state court, not this Court.⁵

Third, even if Doctor Egilman's statements are interpreted as referring to documents currently protected under PTO 13, Merck has failed to show how his statements reveal any information found in those documents or even what those documents consist of. Merck presumably does not believe any of the documents reveal misrepresentation or fraud, so it appears that Merck is simply seeking to punish Dr. Egilman for mischaracterizing what the documents would reveal to a reader. The purpose of PTO 13, however, is not served by seeking to regulate the dissemination of such opinions, especially when Merck has on multiple occasions publicly characterized the documents in a self-serving way. *See supra* Part I.B.

Fourth, even if one looks to Dr. Egilman's MDL expert report for an understanding of which documents he was referring to by his statements, Merck cannot establish that he revealed any confidential information. This is because, when one focuses on the portions of his expert report that relate to Merck's fraud, misrepresentation, and failure to disclose significant health

⁵ Notably, Merck has conceded that the vast majority, about 80%, of the MDL documents sought to be de-designated by Dr. Egilman in Kentucky are not confidential under any protective order. As to the remaining small portion of documents, Merck has conceded that they are not protected from disclosure by Kentucky's governing order and have raised no objection to their de-designation by Judge Shepherd. Thus, by operation of PTO 13, at this point it appears that PTO 13 applies to none of the MDL documents sought to be de-designated by Dr. Egilman.

effects, it is apparent that his conclusions are fully supportable by documents that Merck concedes to be unprotected. See Reinert Decl. ¶ 8 and Ex. D.

Fifth, when one considers the fact that that Merck claims documents are confidential even as it has discussed them in the public record, Merck's position becomes fully untethered from reality. As the State of Utah has demonstrated, for several years, Merck made available to the public a report prepared at its request by Judge John Martin which claimed to have analyzed millions of pages of internal Vioxx documents, including MDL documents. See State of Utah's Motion in Opposition to Contempt Citation at 1-2. Utah has provided several examples in which Judge Martin "quoted, paraphrased, and otherwise published the contents of the documents that Merck now claim confidential." *Id.* at 2-5. The expert report by Dr. Lisa Rarick, filed in Kentucky state court by Merck, is to the same effect: it contains detailed analysis of internal documents to conclude that Merck adequately informed the public and the FDA of Vioxx's health effects. See Ex. J to Reinert Decl. at 2-3, 6-17. Similarly, on November 18, 2004, Merck provided testimony regarding Vioxx before the United States Senate Committee on Finance. See Ex. K to Reinert Decl. In that testimony, Merck provided its version of the events leading from the development of Vioxx to its ultimate withdrawal, claiming in its defense that it had kept the FDA and the public apprised of the dangers of Vioxx. See *id.* at 3-6. Merck has thus reserved for itself the ability to make public comments about allegedly private documents, even as it seeks to sanction Dr. Egilman for possibly discussing the same documents. Indeed, Merck's complaint that it "lacks any effective means of rebutting Dr. Egilman's statements in the public forum without discussing the very documents it seeks to keep confidential," Merck Mot. at 8, is hard to take at face value given Merck's prior disclosures.

Merck might argue that these public submissions somehow do not constitute a disclosure of the subject documents, but this position is untenable. First, basic principles of waiver compel the conclusion that public discussion by Merck of the subject documents forfeits any claim of their confidentiality. *See e.g. Watkins v. U.S. Bureau of Customs and Border Protection*, 643 F.3d 1189, 1196 (9th Cir. 2011) (government waived confidentiality for FOIA purposes when it disclosed material to public); *Sherman v. United States Dep't of Army*, 244 F.3d 357, 364 (5th Cir. 2001) (government can waive its own interest in keeping material confidential by disclosing it to public); *cf. Industrial Clearinghouse, Inc. v. Browning Mfg. Div. of Emerson Elec. Co.*, 953 F.2d 1004, 1007 (5th Cir. 1992) (attorney-client privilege can be waived through public disclosure). Simply the references by Merck to confidential documents, when made to the public, constitute a sufficient publication to waive confidentiality in the documents themselves. *See Matter of Continental Illinois Securities Litigation*, 732 F.2d 1302, 1312-13 (7th Cir. 1984) (failure to read aloud entire report at trial is not determinative, because references and scattered quotes sufficient to support public access); *Charter Practices Intern., LLC v. Robb*, 12 Civ. 1768, 2014 WL 273855, *2-3 (D. Conn. Jan. 23, 2014) (holding that party waived confidentiality objection by discussing matter in public and in briefs filed with the court). Second, if Merck claims that its own detailed discussion of the documents did not constitute disclosure, it cannot also *simultaneously* maintain that Dr. Egilman's even more general statements disclosed confidential Vioxx documents. Merck simply cannot have it both ways.

Not only has Merck discussed the relevant documents in the public record, but the documents have been referenced in great detail by litigants in other actions and publicly available court decisions. For instance, the securities class action filed against Merck in the District of New Jersey contains specific allegations about Merck's fraud, misrepresentation, and

cover-up of health effects, many based on Merck's internal documents. *See* Ex. L to Reinert Decl at 17-74. Merck answered the complaint, disputing the allegations, but not disputing the existence of the documents; nor did Merck seek to seal the complaint because it contained descriptions and, in some cases, full excerpts, from internal Merck documents. *See* Ex. M to Reinert Decl. And a court decision denying in part Merck's motion to dismiss that action also contains a detailed discussion of the plaintiffs' allegations and the basis therefor. *See e.g., In re Merck & Co., Inc. Securities, Derivative & "ERISA" Litigation*, MDL No. 1658, 2011 WL 3444199, *9 (D.N.J. Aug. 8, 2011) (discussing plaintiffs' allegations that Merck failed to disclose information about links between Vioxx and cardiovascular events even as internal documents suggested that Merck was concerned about such risks); *id.* at *11 ("The Complaint sets forth numerous communications about evidence that Vioxx might be prothrombotic and the deliberate and/or reckless failure to explore such a connection."); *see also* *McDarby v. Merck & Co., Inc.*, 949 A.2d 223, 230-49 (N.J. App. Div. 2008) (discussing in great detail internal documents regarding development, approval, and ultimate withdrawal of Vioxx). Therefore, not only has Merck failed to satisfy its burden of specifically demonstrating that Dr. Egilman's statements referred to some MDL-protected document; it has failed even to establish that any of the MDL documents conceivably implicated by Dr. Egilman's statement are protected by the MDL or were protected at the time Dr. Egilman made his statement. Under these circumstances, an award of sanctions would deviate from the available facts and the governing law.

Finally, even if Dr. Egilman's statements can be considered to be made with respect to specific MDL documents that continue to be protected under PTO 13, Merck has provided no legal authority for the proposition that the general statements made by Dr. Egilman are sufficient to meet its heavy burden of establishing by clear and convincing evidence that he breached

confidentiality. The only cases to which it has cited are those in which the contemnor disclosed actual documents, or disclosed specific contents of confidential documents. Unlike the one case upon which Merck places heavy reliance, *Nevil v. Ford Motor Co.*, in the instant matter Dr. Egilman did not disclose any specific information contained within the documents. In *Nevil*, the plaintiff's expert was found to have disclosed specific information about identifiable protected documents. For instance, the expert disclosed to third parties that the confidential documents revealed that certain manufacturers used a specific kind of design for specific kinds of tires, and that they did so "to control separation problems in their plants." *Nevil*, 1999 WL 1338625, at *2-3.⁶ Moreover, the expert disclosed to third parties that the reason that some manufacturers had failed to implement design changes to prevent tire separation was "purely a cost issue," again referencing the confidential documents as his source. *Id.* at *3. Similarly, the expert disclosed that confidential memos revealed that a specific kind of engineering change would reduce tire separation. *Id.* at *3-4. The district court therefore concluded that at "several points," the expert had disclosed "specific information" contained in the documents. *Id.* at *4. Even so, the Court found that this violation of the protective order warranted only a "reprimand." *Id.* at *4. Dr. Egilman, by contrast, revealed nothing specific about any document except his general impressions of what a large set of documents, both protected and unprotected, revealed. And, as

⁶ The following is the excerpt of the deposition in which the expert revealed this specific information:

Q: Now, what did you look at historically to find out about various manufacturers? . . . What studies have you done about tire manufacturing from the late 1980s through the 80s in terms of the use of nylon cap plies and ultimately why a manufacturer stopped using them in most instances?

A: I've seen a lot of papers by manufacturers. For instance, General calls it the Legacy Plus. They put out a series of tires called the Legacy and the Legacy Plus. The only difference is that they put a zero-degree belt in there, and some manufacturers have indicated that they have used it to control separation problems in their plants.

Q: Okay. Who? Who said that?

A: It's in part of the documents here, General did.

Q: Oh, the protected documents?

A: Yes.

Nevil, 1999 WL 1338625, at *2-3.

established *supra* Part I.A, Dr. Egilman’s impressions have been made public on multiple occasions, unlike the impressions of the expert in *Nevil*.⁷

Nor are other cases cited by Merck applicable here. For instance, in *Pyramid Real Estate Servs., LLC v. United States*, 95 Fed. Cl. 613, 621-22 (Fed. Cl. 2010), the party against whom contempt was found violated the protective order in two ways: (1) it used specific information from confidential documents and (2) it did so for purposes other than litigation of the case in which the material was produced, violating an explicit provision of the governing protective order. And in *Smith & Fuller, P.A. v. Cooper Tire & Rubber Co.*, 685 F.3d 486, 487 (5th Cir. 2012), the sanctioned party provided compact discs containing confidential documents to a group of personal injury attorneys attending a conference.

And although Merck relies on *Quinter v. Volkswagen of America*, 676 F.2d 969, 971-72 (3d Cir. 1982), that case actually supports Dr. Egilman. In *Quinter*, the sanctioned party disclosed a protected document to several individuals, including by holding up the protected document up to television news cameras. Even so, the Court found that as to this instance of unlawful disclosure, there was insufficient evidence to hold the party in contempt because, even though the cameraman and the television news narrators “probably” could read the document, this was not enough to conclude that the “actual contents” of the document were disclosed. *Id.* at 974. Merck has not even demonstrated that Dr. Egilman discussed, let alone showed to *The Wall Street Journal*, any specific document protected by PTO 13.

Even if Merck has satisfied its burdens of establishing civil contempt, the Court may forego contempt sanctions in the presence of “mitigating circumstances.” *Whitfield v. Pennington*, 832 F.2d 909, 914 (5th Cir. 1987). Here, Merck’s failure to even confer with Dr.

⁷ And unlike the protective order that controlled the outcome in *Nevil*, the protective order in the instant matter specifically states that documents lose their protective designation once they become publicly available. Compare PTO 13 ¶ 23 with *Nevil* Protective Order (attached as Ex. O to Reinert Decl.).

Egilman prior to filing its motion, its refusal to provide any detail regarding its charges against him, and its longstanding disclosure of identical information to the public all counsel in favor of denying Merck's motion, or at least withholding this Court's contempt power.

IV. MERCK'S MOTION IS A TRANSPARENT ATTEMPT TO AVOID THE CONSEQUENCES OF ITS OWN FAILURE TO ABIDE BY THE LETTER AND SPIRIT OF PTO 13.

Once one clears away the vitriol and audacity of Merck's motion, it is worth remembering how this matter was brought to the Court's attention. On March 25, 2014, Merck wrote the Court seeking its intervention because Dr. Egilman had taken the position that his deposition and exhibits attached thereto in the Utah case had not been designated confidential under PTO 13. Merck claims that the entire deposition is confidential because it stated so at the beginning of the deposition before any questions had been asked. Merck acknowledges that it failed, pursuant to PTO 13, to send a letter within 30 days of the deposition designating which portions of the deposition should be considered confidential. And as with other information it claims to be secret, Merck disclosed portions of the deposition transcript to the public by summarizing the contents in a filing with the Kentucky court. *See Ex. G to Reinert Decl.* at 5.

Merck has offered different explanations at different times for its failure to abide by PTO 13. It first claimed that its attorney was too busy to comply with the pretrial order. *See* March 26, 2014, Letter from Alexander A. Reinert to Court at 1-2. Next it claimed that it was the "usual practice" in the MDL to ignore the provisions of PTO 13. *See id.* at 2. Finally and most recently, it has claimed that the provision of PTO 13 requiring designation within 30 days only of deposition testimony, not exhibits, and that there is no need to send the letter when it has designated the entire deposition confidential. *See* April 9 Beisner Letter at 2.

Merck's shifting explanations for its failure to follow PTO 13's plain language should raise suspicions on its own, but there are other reasons to reject the most recent one. First, even

if the relevant provision of PTO 13 applies only to the deposition transcript and not the exhibits, Merck has yet to explain how it could, in good faith, designate Dr. Egilman's entire deposition as confidential under PTO 13. Obviously, to protect itself against inappropriate disclosures, Merck was free to designate the entire deposition at the outset, but the purpose of PTO 13's 30-day provision is plainly to compel parties to examine discovery closely to determine which portions should remain confidential. That Merck believes it is appropriate to continue to hold Dr. Egilman's entire deposition confidential, including portions that clearly involve absolutely no information that is even arguably confidential, is just one indication of Merck's conviction that it is bound by no obligations other than those it chooses to follow.

And although Merck concedes that it has disclosed portions of Dr. Egilman's deposition to the public through its filing in Kentucky state court, it maintains that the disclosure only constitutes a limited waiver of its claim to confidentiality. *See id.* at 3 n.1. The problem with Merck's argument, however, is that it disclosed Dr. Egilman's deposition transcript for the purpose of arguing that Dr. Egilman had ulterior motives in seeking to de-designate documents in Kentucky. *See Ex. G to Reinert Decl.* at 5. For Dr. Egilman to defend against this claim, however, it requires far more than merely disclosing portions of Dr. Egilman's deposition transcript that relate to his intention to publish an article; it also requires disclosing those portions that describe in detail how Merck's documents demonstrate the company's fraud, misrepresentation, and cover-up of health effects.

We also note that Merck has yet to produce a confidentiality log to any party as required by PTO 13. Merck has offered no real explanation for its failure, other than that Dr. Egilman is not a proper party to make this objection. *See April 9 Beisner Letter* at 4. We reemphasize that, given Merck's request that this Court sanction Dr. Egilman for disclosing allegedly confidential

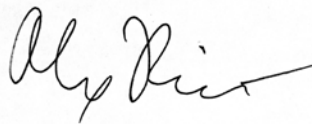
information, Merck's simultaneous insistence that Dr. Egilman has no right to request a confidentiality log is passing strange. But even if Dr. Egilman has no right to make the request, Merck was clearly ordered by this Court to provide an updated log to the parties. Merck somehow finds a lack of clarity in this Court's description of the log as "necessary," stating that it would "need" a log to determine which documents should remain under protective order. Tr. of Feb. 28, 2014 Hearing at 19 ("I will need a log showing *which documents should continue, according to the moving party*, under protective order and what they are and why they should remain under the protective order."). Its continued failure to comply with this Court's orders is inconsistent with its attempt to hold Dr. Egilman accountable for nothing more than repeating publicly available statements about non-confidential documents.

CONCLUSION

For the foregoing reasons, Dr. Egilman respectfully requests that the Court deny Merck's motion for sanctions.

Dated: May 28, 2014
New York, New York

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the attached **MEMORANDUM OF LAW IN OPPOSITION TO MERCK'S MOTION FOR SANCTIONS** was sent to the following parties and Counsel of Record via electronic mail on May 28, 2014:

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