UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: Seroquel Products Liability Litigation.

Case No. 6:06-md-1769-Orl-22DAB

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ORDER

This cause came on for consideration with oral argument[1] on the following motion filed herein:

MOTION:	**MOTION TO COMPEL ASTRAZENECA TO PRODUCE DOCUMENTS IMPROPERLY DESIGNATED AS PRIVILEGED AND DOCUMENTS FOR WHICH PRIVILEGE SHOULD BE DEEMED WAIVED AND FOR THE APPOINTMENT OF A SPECIAL MASTER TO REVIEW PRIVILEGE LOGS (Doc. No. 789)**
FILED:	**January 10, 2008**

THEREON it is **ORDERED** that the motion is **GRANTED in part.**

Plaintiffs seek an order finding that AstraZeneca has waived its privilege through production of insufficient privilege logs and/or an order directing AstraZeneca to produce an adequate privilege log and directing AstraZeneca to produce a copy of the documents that have been removed from the log. Plaintiffs also seek an order appointing a special master to supervise document discovery and review privilege logs, redaction logs, and any documents identified as privilege abuse by Plaintiffs on AstraZeneca's privilege logs, and/or to resolve AstraZeneca's privilege claims. Plaintiffs contend that they cannot evaluate what percent of the 18,936 documents[2] withheld to date

[1]Oral argument was held on March 24, 2008.

[2]AstraZeneca states it has claimed privilege in the log for approximately 22,000 documents. Doc. No. 908.

on the 3,710 page-log are actually privileged. Plaintiffs list AstraZeneca's failure to identify the persons making or receiving the protected communication in a large number of entries, failure to explain the relationship between persons making or receiving communications, and failure to identify individual emails in an email chain or in attachments.

AstraZeneca responds that Plaintiffs' Motion is premature and inaccurate as to the facts and law governing resolution of privilege disputes in mass tort litigation, and Plaintiffs have not responded to AstraZeneca proposals to allay their concerns. At a status conference on March 11, 2008, the Court ordered Plaintiffs to select and AstraZeneca to file under seal the documents and privilege log entries from 100 documents selected by Plaintiffs in two batches of 50 documents each on March 13 and 14, 2008. Doc. No. 893. The Court decided on 100 as the total size of the sample for rulings that would allow a fair representation to guide the parties going forward.

As Plaintiffs describe it, after they served AstraZeneca with the list of the first 50 documents on March 13, 2008, AstraZeneca informed them that 13 of the documents were pulled off the privilege log by AstraZeneca; 17 more were produced to Plaintiffs the following day. Doc. No. 916[3]. AstraZeneca allowed Plaintiffs to identify additional choices in the next selection due March 14. Doc. No. 916. Plaintiffs contend that by their count, after several submissions to AstraZeneca totaling 147 documents, 26 documents remained in dispute, but AstraZeneca ultimately chose only 75 to submit for *in camera* review. Doc. No. 916. The Court's intent in having Plaintiffs choose 100 documents was to pick a large enough sample with enough variety to provide the parties with some meaningful guidance on whether the privileges as asserted by AstraZeneca applied to the

[3]Without seeking leave of Court, AstraZeneca filed a separate twenty-two page legal memorandum "to provide the Court and Plaintiffs with the legal predicate for withholding documents submitted for *in camera* review." Doc. No. 908. The Court allowed Plaintiffs the opportunity to file an eight-page response. *See* Doc. No. 916.

chosen documents. AstraZeneca's self-selected reduction supports the inferences that it has more generally over-designated documents as privileged and that a significant number of unprivileged documents have not been produced.

Plaintiffs contend based on this "re-examination" and belated production of a high percentage of erstwhile "privileged" documents, "AstraZeneca needs a chaperone to keep an eye on yet another issue in this litigation." Doc. No. 916 at 3. Of the 46 documents pulled off the privilege log following Plaintiff's selection of 100, "more than a handful of them have led to new information that Plaintiffs will use in upcoming depositions and trials." Doc. No. 916 at 4.

AstraZeneca invokes the attorney-client privilege for several categories of documents: communications seeking or relaying legal advice between in-house counsel and company personnel, including documents involving litigation matters or legal analysis of safety, scientific, technical, and regulatory matters; draft documents seeking or conveying legal advice; "mixed purpose" communications seeking or conveying legal advice; and documents created and disseminated to facilitate legal advice in the corporate context. Doc. No. 908.

I. Summary of Relevant Law

"The purpose of the attorney-client privilege is to encourage open and complete communication between a client and his attorney by eliminating the possibility of subsequent compelled disclosure of their confidential communications." *United States v. Noriega*, 917 F.2d 1543, 1550 (11th Cir. 1990). In a multi-district (MDL) case, because the MDL judge is acting as a judge of the discovery district when she uses the authority outlined in the MDL statute, appeal from the exercise of such authority generally lies in the circuit court embracing that discovery

district. *United States ex rel. Pogue v. Diabetes Treatment Centers of America, Inc.*, 444 F.3d 462, 467 (6th Cir. 2006) (citing cases).

"The party invoking the attorney-client privilege has the burden of proving that an attorney-client relationship existed and that the particular communications were confidential." *Bogle v. McClure*, 332 F.3d 1347, 1358 (11th Cir. 2003) (quoting *United States v. Schaltenbrand*, 930 F.2d 1554, 1562 (11th Cir. 1991)). Several principles relevant to the determination of privilege in this case were discussed by the Special Master deciding privilege issues in *Gutter v. E.I. Dupont de Nemours & Co.*:

> At the outset, it should be noted that the mere fact that an attorney is present at a meeting or is copied on a document does not in and of itself afford privilege protection to such a meeting or document. *Burton v. R.J. Reynolds Tobacco Co., Inc.*, 170 F.R.D. 481 (D.Kan. 1997). The mere fact that one is an attorney does not render everything he does for or with the client privileged. *Burton, supra*; *United States v. Bartone*, 400 F.2d 459 (6th Cir. 1968). The attorney-client privilege protects only communications between attorney and client where legal advice is sought.
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> The work product privilege only applies to materials prepared to aid in anticipated or pending litigation. It protects the ideas, legal theories, opinions and mental impressions of attorneys formulated in connection with preparation for trial. *Hickman v. Taylor*, 67 S.Ct. 385 (1947); F.R.Civ.Pro. 26(b)(3). Corporate house counsel are often called upon to perform tasks that go beyond the traditional tasks performed by lawyers. *United States Postal Service v. Phelps Dodge Refining Corp.*, 852 F.Supp. 158 (E.D.N.Y. 1994). Thus each document must be perused to see whether the attorney was involved in rendering legal advice or if the document contains work product information. If the attorney was performing other tasks, then the communications receive no protection from discovery.
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> Documents prepared for dissemination to third parties are not protected from discovery by either the attorney-client or the work product privilege. *United States v. (Under Seal)*, 748 F.2d 871 (4th Cir. 1984). Nor are the details, including drafts of the document to be published, protected. *United States v. (Under Seal), supra*; *In Re Grand Jury Proceedings*, 727 F.2d 1352 (4th Cir. 1983).
> * * *
> If the ultimate document is purely a business document which would not have received any protection based upon privilege in any event, draft language also receives no protection. But if there is attorney input on the draft, then the attorney-

> client or work product privileges may be implicated. Drafts may be considered privileged if they were prepared with the assistance of an attorney for the purpose of obtaining legal advice or, after an attorney's advice, contain information a client considered but decided not to include in the final version. *United States Postal Serv. v. Phelps Dodge Refining Corp., supra*. In other words, if the draft is prepared with attorney assistance, and contains words or language that do not appear in the final version, those words may be protected: if they are articulated in the context of legal advice to and from a client as to what should ultimately be disclosed, then the attorney-client privilege protects such documents. But if the final version sent to a third person contains the revisions made on the draft, those revisions are not privileged. . . .
>
> The foregoing principles are the most logical in dealing with this area. If an attorney has given advice as to what should be disclosed and what should not, then only as much of the information which is ultimately revealed to third persons is what the client intended, and what the attorney advised should in fact be disclosed. It is their ultimate concurrence which comprises the content of the waiver. "In short, whatever is finally sent to the [third party] is what matches the client's intent." *United States v. Schlegel*, 313 F.Supp. 177 (D. Neb. 1970).

No. 95-CV-2152, 1998 WL 2017926, *1, *6-7 (S.D. Fla. May 18, 1998).

Final documents sent to third parties should be disclosed, as should drafts of those documents, with the privileged exception of words that do not appear in the final version *and* were articulated in the context of legal advice to and from a client as to what should ultimately be disclosed. *See id.* This principle is clear and it appears that AstraZeneca was abiding by it in producing the documents, to some extent. At the hearing on April 10, 2008, the Court asked counsel for AstraZeneca about final drafts that went to third parties. Doc. No. 945 at 17. Counsel for AstraZeneca, Mr. Raven, stated: "The drafts and finals were treated quite differently; and if there is a final version, which there very likely is in, I would say the vast majority, if not all of these instances, then the final would have been produced." Doc. No. 945 at 17. Other AstraZeneca counsel, Mr. Feinerman, confirmed: "My understanding is that . . . if the draft was intended to be reviewed by an attorney, that that was a basis for privilege; but, again once the final version was –

the final version was completed, that final version would be produced." Doc. No. 945 at 18. However, it is unclear the extent to which intermediate drafts and commentary have been produced.

A leading treatise author, Paul R. Rice, has recognized the practice of businesses who may try to "immunize internal [business] communications from discovery by placing legal counsel in strategic corporate positions and funneling documents through counsel." 1 PAUL R. RICE, ATTORNEY-CLIENT PRIVILEGE IN THE UNITED STATES § 7:2. "There is general agreement that the protection of the privilege applies only if the primary or predominate purpose of the attorney-client consultations is to seek legal advice or assistance."*Id.* § 7:5. "There are substantial policy reasons for holding that business documents submitted for attorney review are not by that virtue automatically exempt as privileged or work product protected communications." *Visa USA, Inc. v. First Data Corp*, 2004 WL 1878209, 8 (N.D. Cal. 2004).

The structure of certain business enterprises, when their legal departments have broad powers, and the manner in which they circulate documents is broad, has consequences that those companies must live with relative to their burden of persuasion when privilege is asserted. *See, e.g.*, *In re Vioxx Products Liability Litigation*, 501 F. Supp. 2d 789, 805 (E.D. La. 2007). When the business "simultaneously sends communications to both lawyers and non-lawyers, it usually cannot claim that the primary purpose of the communication was for legal advice or assistance because the communication served both business and legal purposes." *Id.* (citing *United States v. Chevron Corp.*, 1996 WL 444597 (N.D. Cal. 1996)); *United States v. International Business Machines Corp.*, 66 F.R.D. 206, 213 (S.D. N.Y. 1974) ("If the document was prepared for purposes of simultaneous review by legal and non-legal personnel, it cannot be said that the primary purpose of the document is to secure legal advice."). Consequently, the privilege does not protect such communications. *In*

re Vioxx, 501 F. Supp. 2d at 805; ATTORNEY-CLIENT PRIVILEGE § 7.2.1 ("Because of the ease with which e-mail technology allows in-house counsel to be brought into discussions, counsel are contacted far more frequently, and through those contacts, are likely encouraged to participate in regular business matters far more frequently and broadly than was the case in the past."). Judge Fallon, incorporating the report from Special Master Rice[4], explained the reasoning:

> When these simultaneous conveyances for mixed purposes are through an e-mail message that lists the lawyers' names in the header of the e-mail message, [the defendant] Merck is revealing the contents of the single message that may have been conveyed to its lawyer primarily for legal assistance. In that circumstance, the single message could have been withheld as a privileged communication had Merck sent blind copies to the lawyers, instead of electing this format. Through a blind copy, the content of what was communicated to its attorney would have remained confidential after future discovery of the document from the other recipient's files, its purpose would have been primarily legal, and the privilege would have been applicable. Similarly, if Merck had sent a wholly separate e-mail communication with the same materials to the lawyer, the same claim could be successfully made for that single communication even though it otherwise served mixed purposes. In modern vernacular, Merck, in a variety of instances, "could have had a V-8," but it chose another format and manner of document circulation and cannot now be heard to complain about the consequences of those choices. Otherwise, Merck would be able to limit the scope of what adversaries can discover by the way in which it chooses to communicate.
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> Similarly, after a communication with its attachment has been sent to both lawyers and non-lawyers in the same e-mail communication, and its primary purpose is determined not to have been for obtaining legal advice, the lawyer's independent response can only be protected if the derivative nature of the privilege is ignored. Theoretically, the lawyer's response should be protected only if it reveals the content of prior confidential communication

ns from the client. Since those communications are no longer confidential, nothing the lawyer discloses in her edits reveals protected communications of the client.

501 F. Supp. 2d at 805-06.

[4]Judge Fallon selected as Special Master for privilege document discovery Professor Paul R. Rice, author of the treatise, ATTORNEY-CLIENT PRIVILEGE IN THE UNITED STATES.

ANALYSIS

AstraZeneca provided the unredacted documents from four individuals for the Court's *in camera* review: Michelle Dillione, Julia Manning, Enid Stebbins, Laura Davies. All four individuals are in-house counsel for AstraZeneca Pharmaceuticals LP. *See* Declarations, filed under seal. AstraZeneca filed in the public docket a listing of the document numbers for each of the withheld documents, divided into the categories that apply.

The first reason claimed for withholding the documents, because they are "communications seeking or relaying legal advice between in-house counsel and company personnel . . .whether they involve litigation matters or legal analysis of safety, scientific, technical, and regulatory matters," AstraZeneca alleges for every single one of the seventy-five documents withheld from production. Doc. No. 909. AstraZeneca alleges the vast majority (sixty-eight) of the documents are privileged because they are "draft documents seeking or conveying legal advice" and/or because they (fifty-five documents) are "mixed purpose" communications seeking or conveying legal advice. Doc. No. 909. Nearly two-thirds (forty-eight) are additionally privileged, AstraZeneca contends, because they are corporate committee communications involving legal advice. Doc. No. 909. AstraZeneca also contends the work-product doctrine applies to more than half (forty) of the seventy-five documents as well. Thus, AstraZeneca's attempts to categorize the documents for which it is asserting attorney-client or work-product privileges does not assist the Court because the majority are asserted to fall within five categories. The Court will discuss these categories together.

Communications concerning legal advice, drafts conveying legal advice, "mixed purpose" communications, or corporate committee communications

AstraZeneca seeks protection for communications providing or relaying legal advice between in-house counsel and company personnel, including documents AstraZeneca characterizes as the

very broad category of "involving litigation matters or legal analysis of safety, scientific, technical, and regulatory matters." AstraZeneca cites, as an example, the need for advice for "compliance with the extensive statutory and regulatory requirements applicable to prescription drugs that requires legal advice at every stage of development, including pre-marketing clinical trials, preparing and gaining approval of the new drug application with FDA, and post-marketing issues with respect to labeling and marketing." AstraZeneca further contends that "in-house attorneys provide legal advice regarding product safety and efficacy issues and related scientific developments, which have profound legal implications for risk assessment and analysis, as well as regulatory advice, and advice regarding actual or potential litigation."

AstraZeneca argues it is entitled to attorney-client privilege for draft documents that seek or convey legal advice, even if final versions of those documents are later made public. AstraZeneca contends this protection is in keeping with the desire to encourage the free flow of information between attorney and client, and freedom for the attorney to advise the client before the client acts. AstraZeneca also argues the attorney-client privilege applies to "mixed purpose" communications – those sent both to legal and non-legal personnel for simultaneous legal and non-legal review, as long as the transmission seeks or conveys legal advice. Fourth, AstraZeneca also seeks privilege protection for documents created and disseminated to facilitate legal advice where the client is a corporation, including documents widely disseminated within the corporate structure to responsible parties, as well as to third-party agents and consultants assisting counsel in providing a legal response. AstraZeneca argues the privilege also protects corporate committee communications involving legal advice and the communication of otherwise non-privileged information to counsel, even if the underlying factual information itself is not privileged.

Plaintiffs, of course, argue that drafts of marketing materials, reports, memoranda, training materials, and study protocols are not privileged. Plaintiffs also challenge AstraZeneca's assertion of privilege for "mixed purpose" communications and documents widely distributed to non-legal personnel.[5]

AstraZeneca appropriately cites the principle that when in-house attorneys are asked to provide or relay legal advice to the client corporation or its agents, the communications are protected by the attorney-client privilege, citing 1 PAUL R. RICE, ATTORNEY-CLIENT PRIVILEGE IN THE UNITED STATES § 3:14 (2d ed. 2008). AstraZeneca argues its privilege claims must be evaluated, "in light of the central role lawyers necessarily play in the FDA regulatory process for prescription medications like Seroquel." Doc. No. 908 at 5. Therefore, AstraZeneca claims the privilege for all documents created in the very broad context of seeking FDA approval, correspondence pertaining to FDA review or approval, wording of package inserts, product advertising, promotional materials considered labeling, oral promotional activities, including presentations to physicians; distribution to physicians of reprints of scientific articles or textbook chapters; and press releases to investors. As AstraZeneca argues, "Virtually everything a pharmaceutical company says about its products is governed by statutes and regulations, and therefore must be reviewed and approved by counsel before it is made public." Doc. No. 908 at 6.

AstraZeneca argues:

> Counsel must be closely consulted on such matters to ensure that all legal requirements are met. Legal advice on such matters is particularly important because violations of the FDCA and related statutes and regulations can result in criminal penalties and other serious ramifications. Legal considerations therefore are an essential focus of the company's deliberations and the communications on these

[5]Not having seen the documents provided to the Court for *in camera* review, Plaintiffs necessarily can make only generalized arguments on these subjects.

> matters. In addition to FDA regulatory considerations, prescription drug companies must constantly navigate a number of additional complex legal regimes, including, *inter alia*, federal securities, trademark, antikickback, "best price," and privacy (including HIPAA) laws, state consumer protection and product liability laws, and countless numbers of equally complex foreign laws and regulatory regimes.

Doc. No. 908 at 7.

This argument goes way too far. Almost any act by a business (or an individual for that matter) carries the potential for running afoul of some law or regulation or giving rise to a civil action. The pharmaceutical industry is subject to more regulation and more complex regulation than some other industries (though less than some others). The fact of extensive or pervasive regulation does not make the everyday business activities legally privileged from discovery. Routine inclusion of attorneys in the corporate effort of creating marketing and scientific documents does not support the inference that the underlying communications were created and transmitted primarily to obtain legal advice as is required to justify a privilege.

"No misconception seems to be more common . . . than the belief that if a document or draft has been through the hands of an attorney, it thereby automatically becomes enshrouded in privilege's veil of secrecy . . . . Nothing is further from reality. . . . . Insulation from discovery cannot be so readily or fraudulently obtained."[6] The great bulk of AstraZeneca's privilege claims suffer from this approach of simply relying on an attorney's tangential involvement in the process of creating a document to shield the entire process of gathering information and drafting and revising the document. "[T]his 'collaborative effort' argument, if successful, would effectively immunize all internal communications of the drug industry, thereby defeating the broad discovery authorized in the Federal Rules of Civil Procedure." *In re Vioxx*, 501 F.Supp.2d at 803.

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[6]Edna Selan Epstein, *The Attorney-Client Privilege and the Work Product Doctrine*, Vol. I at 342.

The result and analysis set forth in *In re Vioxx* are persuasive and compelling as applied to the issues presented here. When documents concern business decisions or are the product of corporate committees responsible for business decisions in the area of "technological, science, public relations, or marketing," *see id.*, it is the party claiming the privilege who has the burden of showing the communications at issue are more than simply grammatical, editorial, technological, scientific, public relations, or marketing suggestions, and are specifically in the nature of legal advice.

In this case, upon review of all of the documents selected by Plaintiffs based on privilege log entries and provided to the court by AstraZeneca, the Court finds that for the great bulk of them, AstraZeneca has failed to establish that communication to attorneys of "technological, science, public relations, or marketing" documents, including a manual for sales representatives, "Dear Healthcare Provider" letters, draft press statements, and "questions and answers" for the sales representatives to use were made primarily to facilitate the rendition of legal advice.

A pharmaceutical company "cannot reasonably expect judicial officers to make this assessment for it . . . universally through a presumption that everything in-house counsel comments upon is legal advice." *In re Vioxx*, 501 F.Supp.2d at 805. AstraZeneca chose, as part of its business organization, to mix legal consultation with many other sources for creating final documents. This choice makes it difficult to determine the primary purpose in creating the communication and to determine whether the attorneys' roles were primarily providing legal (rather than business) advice.

> Modern technology has made it possible for the attorneys to electronically respond with their advice on the non-privileged attachments to the original mixed purpose communications. This is done through electronic line edits that reveal the lawyers' proposed additions and deletions with explanatory comments where desired. Through the line edits, Merck has claimed that what was otherwise discoverable, as a mixed purpose communication, is now made non-discoverable because of the manner in which its lawyers chose to reveal their advice. This is not acceptable. Merck cannot be permitted to deprive adversaries of discovery by voluntarily choosing to

> electronically superimpose that legal advice on the non-privileged and, therefore, discoverable communications. Of course, where the client's communications were found to be privileged, the line edits on those documents were found to be privileged also, when the other elements of the privilege, namely "primarily for legal advice," were found to be satisfied.
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> There are instances, of course, where legal advice is the primary purpose behind lawyers' comments and where these comments are complemented by grammatical and editorial changes that could reasonably be considered inextricably intertwined with the advice. It is Merck's burden, however, to demonstrate this, and that burden is made more difficult by the fact that often the legal department's comments seem to be exclusively editorial. While limited editorial and grammatical changes are an expected part of a lawyer's services (particularly in a corporate context where the client is this amorphous legal entity, and the various departments and employees who man those departments rely on one another in the development of a product for public dissemination), too often we discovered lawyers inserting new paragraphs, introducing references to different drugs, or eliminating entire sections of proposed articles, reports, and presentations. In these instances, in particular, we concluded that Merck had a responsibility to explain how this related to legal services allegedly being provided. *When non-legal departments of a corporation primarily concerned with technology, science, public relations or marketing make comments among themselves about matters within their corporate responsibilities, those communications are not protected by the attorney-client privilege. When lawyers make the same comments about technology, science, public relations, or marketing, a different result is not warranted unless Merck demonstrates that those comments are primarily related to legal assistance.* When it failed to do this on a document-by-document basis, its claims were denied. *Merck cannot reasonably expect judicial officers to make this assessment for it on either a document-by-document basis or universally through a presumption that everything in-house counsel comments upon is legal advice.*

In re Vioxx, 501 F.Supp.2d at 805-07 (emphasis added).

Applying these principles to the sample documents produced by AstraZeneca, the Court finds most of the claims of privilege not sustained, with the possibility that AstraZeneca may yet provide sufficient support as to some few of them. The documents grouped with the Dillione and Manning submissions demonstrate the attorneys' roles to be incidental at best. This is largely true with respect to the Stebbins' documents as well, though a few of those documents may qualify for work product production. Some of the Davies' documents, in form and context, suggest that discrete

requests for legal advice was being sought, apart from routine business activity. As to several documents, however, the attorney involvement looks to be largely editorial (such as, for example, deleting a comma), rather than legal. Some of her documents may also qualify as work product.

AstraZeneca may also be entitled to a privilege with respect to any actual legal advice rendered as part of the drafting effort, even though the rest of the process is not protected. As to such items, AstraZeneca could redact the request for legal advice and the attorney's response.[7]

To allow final separation of wheat and chaff and to provide guidance as to reclassification of the other documents withheld, the Court will undertake a final *in camera* review of the selected documents with a designated AstraZeneca representative to provide context for documents that, as noted above, have some possible basis for a privilege or work product claim. The logistics and timing of this session will be determined at the next status conference.

DONE and **ORDERED** in Orlando, Florida on May 7, 2008.

David A. Baker

DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE

Copies furnished to:

Counsel of Record

[7]The Court recognizes that such a production might effectively reveal the advice by comparing different drafts. To the extent this may occur, it is the result of how AstraZeneca chose to mix its legal consultations with regular business operations.