You are the new head of IP litigation for a pharmaceutical company. It seems prudent, you think, to review the patent protection on the company's weight loss drug in order to determine potential validity and unenforceability issues. While no specific litigation is pending, competition in this space has become fierce with a number of companies looking to win the battle of the bulge. One foreign, litigious competitor has a product remarkably similar to yours. The work of the original law firm in the preparation and prosecution of the patent suggests that this may be a close question. Will it be discoverable? Should you have it reevaluated by your outside litigation counsel? Will that be privileged? Is this a question of attorney-client privilege or work-product protection?

The Work-Product Doctrine and Patent Practice: When Is Counsel's Review of Materials "in Anticipation of Litigation?"

BY JOHN K. VILLA

All good questions. Let's begin by defining the question more carefully. Legal advice provided by the attorney to the client will be protected under the attorney-client privilege — that much is clear. Services performed for submission to the patent office, on the other hand, *do* not *necessarily constitute* legal advice to the client so as to qualify as attorney client privileged.[1]

To be protected from disclosure *if the attorney-client privilege is not applicable,* it must satisfy the work-product doctrine. How can any of this be work product, you muse, since there is no lawsuit and not even a threat of a suit — even now? The answer, you will find, turns on a number of factors and information may be protected even before anyone expressly threatens or brings litigation. This is an extension of the evolving work product doctrine that has been interpreted to protect legal services where sophisticated parties can reasonably predict litigation even if none has yet been filed. Whether this will protect the original patent prosecution files, however, is more troublesome. Before discussing patent-specific work product jurisprudence, let's first review the general rules underlying its application.

Work Product Doctrine, in General

First articulated by the Supreme Court in *Hickman v. Taylor,*[2] and now codified in Rule 26(b)(3) of the Federal Rules of Civil Procedure (and parallel state rules of procedure), the work-product doctrine protects from discovery documents prepared "in anticipation of litigation or for trial," unless there is a showing of substantial need or undue hardship. This is generally referred to as fact work product — i.e. the attorney's collection of facts that she believes is necessary to litigate the case. The act of collection itself reveals some aspect of an attorney's thought processes. There is also opinion work-product, which is an attorney's opinions and strategies regarding potential litigation. To obtain documents referred to as opinion work product (as opposed to fact work product) that reflect the "mental impressions, conclusions, opinions or legal theories," of an attorney or party, an adversary must ordinarily show an exceptionally high level of need and prejudice.[3]

Since the most sophisticated corporate legal departments seek to avoid or minimize the risk of litigation, all of their work is, in a sense, performed in anticipation of litigation.[4] To invoke the work product doctrine, therefore, courts have generally limited its application to those documents that "can fairly be said to have been prepared or obtained because of the prospect of litigation."[5] In determining whether a document satisfies this test, most courts follow a two-part inquiry: (1) was litigation reasonably anticipated at the time of the document's creation, and (2) was the document created because of that apprehension of litigation?[6]

Satisfaction of the first element requires a showing that the litigation is more than a "remote prospect," an "inchoate possibility" or even a "likely chance."[7] Although litigation need not have commenced at the time of the document's creation,[8] some courts require the existence of an identifiable, specific claim[9] that pertains to a particular party[10] in order for the

JOHN K. VILLA is a partner with Williams & Connolly LLP in Washington, DC. He specializes in corporate litigation (civil and criminal) involving financial services, directors', officers', and lawyers' liabilities, securities and related issues. He is an adjunct professor at Georgetown Law School and a regular lecturer for ACC. He is also the author of *Corporate Counsel Guidelines*, published by ACC and West. He can be contacted at jvilla@wc.com.

protection to apply. Other courts only require that the document have been created "with an eye toward litigation,"[11] focusing on the facts of the particular situation and on the lawyer's experience with respect to the matter at hand.[12]

With respect to the second element, the apprehension of that litigation must be the purpose underlying creation of the document.[13] While many courts deny work-product protection under this prong where the anticipated litigation is not the primary or exclusive purpose for the document's creation,[14] other courts have rejected such a rigid approach and apply the doctrine to documents that satisfy the "but for" test. Perhaps the best example of this is the test adopted by the Second Circuit in *United States v. Adlman*:[15] "[w]here a document was created because of anticipated litigation, and would not have been prepared in substantially similar form but for the prospect of that litigation, it falls within Rule 26(b)(3)."[16] Under this latter approach, a document prepared in assessing a *proposed* transaction that may likely result in litigation, will be protected by the work-product rule, even if it also serves a business purpose, unless the document would have been created in substantially the same form in the absence of any anticipated litigation.[17]

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The importance of *Adlman* is that work product protection was accorded to work for a transaction that had not even occurred let alone been the subject of a threat of litigation. The Second Circuit recognized that the high likelihood of litigation — here an IRS tax challenge — was, in these circumstances, sufficient. *Adlman,* however, reflects an unusually sophisticated approach toward the application of work product.

In short, there is a sliding scale of the likelihood of protection. Where there is a pending or expressly threatened litigation against the party, or the party is preparing or considering asserting a specific claim against another identified party, the work product privilege is well-accepted (assuming of course the document was prepared for that purpose). At the opposite end of the scale is the situation where the party is examining the

validity of its legal positions without an identifiable adversary or controversy. In that instance, the decisions have proven difficult to predict.

Work-Product Protection in Patent Litigation

So how have these general rules governing the work-product doctrine been applied in the patent law context, such as a lawyer's review of a patent portfolio?

One court has observed that "[p]atent prosecutions and other legal actions peculiar to the patent process present a unique set of difficulties with respect to the application of the attorney work product privilege."[18] The difficulties arise, in large part, because of the nature of the proceedings involved in the procurement of a patent. Most courts adhere to the view that the work-product doctrine does not ordinarily apply to materials routinely created in the preparation of a patent application for prosecution due to the non-adversarial nature of a patent prosecution.[19] As explained by one federal court:

> [C]ourts have been refining the contours of this privilege as it applies to patent prosecutions and litigation for many years, and there remains no bright line rule. In balancing the realities of patent prosecutions, which may indeed result in litigation, with the general requirement that work product protection be extended only to those documents that are produced in anticipation of identifiable litigation, many courts have come to the basic conclusion that generally, work performed by an attorney to prepare and prosecute a patent does not fall within the parameters of the work product protection. . .since the prosecution of [a] patent is a non-adversarial, *ex-parte* proceeding. Thus, work done to that end is not "in anticipation of" or ["]concerning" litigation.[20]

Although not ordinarily applicable, the work-product doctrine may apply to materials created during this stage of the patent process, that is the initial patent application — but only where circumstances exist that indicate the likelihood of *identifiable* litigation upon issuance of the patent. For example, while the mere possibility of an infringement action is insufficient to render the documents used in preparing the patent application protected attorney work-product,[21] courts have applied the work-product doctrine to these documents where, at the time of the filing of the patent application, the company believed that competitors' products would infringe its patent once issued and contemplated commencing litigation against them.[22] Similarly, courts have extended work-product protection to these materials where the company has received statutory notice from a competitor that the latter's product will not infringe the company's patent.[23]

In the patent prosecution context, therefore, the courts tend to follow a more restrictive approach in applying the work-product doctrine — requiring an identifiable claim involving a particular party or parties. In the absence of these factors, documents prepared by a lawyer in connection with a patent prosecution fall outside the protections of this doctrine.

If the IP counsel is about to commission the new analysis, however, it is likely to fare much better. There is an identifiable adversary, existing, competing products, and no obvious business purpose for the legal work other than assessment of litigation risks. While little is assured, our new IP counsel probably has a situation that is adequately concrete so that the court will uphold the privilege — especially in the Second Circuit. Indeed, even if there was no identifiable adversary, the likelihood of an infringement from one of a group of companies — the "usual suspects" — will probably be sufficient to invoke successfully the work product doctrine.

What could our IP counsel do to increase the chance of work-product protection?

- Identify in the work product the potential adversary and claim in the discussion of the litigation risks;
- Use the work product exclusively for evaluating legal risk and not for business purposes.
- Treat the product with the same confidentiality that the client would treat attorney client privileged materials.

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NOTES

1 Invention records, drafts of patent applications, and other documents submitted by clients to attorneys during the course of the patent application process are not protected by the attorney-client privilege unless they contain confidential information communicated to the attorneys for the purpose of obtaining legal advice and assistance in obtaining the patent. *See In re Spalding*, 203 F.3d 494, 501 (Fed. Cir. 2000).

2 329 US 495 (1947).

3 Fed. Rule Civ. P., Rule 26(b)(3)(A).

4 *See Restatement (Third) of the Law Governing Lawyers* § 87, cmt. I (2000) (recognizing that "because preparing documents or arranging transactions is aimed at avoiding future litigation or enhancing a client's position should litigation occur," most lawyers' work could be regarded as being in anticipation of litigation).

5 8 Alan Wright, Arthur R. Miller, and Richard L. Marcus, Federal Practice & Procedure, § 2024, at 343 (2d ed. 1994); see In re Grand Jury Subpoena, 357 F.3d 900, 907 (9th Cir. 2004) (noting that a growing number of federal courts employ this test in determining the applicability of work-product protection); *see also McCook Metals L.L.C. v. Alcoa Inc.*, 192 F.R.D. 242, 259 (N.D. Ill. 2000) (applying test in patent litigation).

6 *See In re Gabapentin Patent Litigation*, 214 F.R.D. 178, 183-184 (D. N.J. 2003) (noting that the Second Circuit, in particular, and courts, generally, apply this two-part inquiry in determining whether the work-product protection

applies); *see generally J. Villa, Corporate Counsel Guidelines* §§2:5-2:6 (Thomson/West 2008).

7 *Gabapentin*, 214 F.R.D. at 183 (citing *Harper v. Auto-Owners Ins. Co.*, 138 F.R.D. 655, 660 (S.D. Ind. 1991, and *Leonen v. Johns-Manville*, 135 F.R.D. 94, 97 (D. N.J. 1990)).

8 *Mattenson v. Baxter Healthcare Corp.*, 438 F.3d 763, 768 (7th Cir. 2006); *In re Grand Jury Proceedings*, 73 F.R.D. 647, 653 (M.D. Fla. 1977); *see also Restatement, supra*, n. 4 (noting that the fact that litigation had not yet commenced did not affect the immunity provided by the work-product doctrine).

9 *Gabapentin*, 214 F.R.D. at 183; *In re Grand Jury Proceedings*, 73 F.R.D. at 653.

10 *McCook Metals*, 192 F.R.D. at 259.

11 *Adlman*,134 F.3d at 1196; *see also In re Sealed Case*, 676 F.2d 793, 811 (D.C. Cir. 1982); *Bituminous Cas. Corp. v. Tonka Corp.*, 140 F.R.D. 381, 389-390 (D. Minn. 1992).

12 *See, e.g., Maloney v. Sisters of Charity Hosp. of Buffalo, N.Y.*, 165 F.R.D. 26, 30 (W.D.N.Y. 1995)(involving a large reduction in staff).

13 *Binks Mfg. Co. v. Nat'l Presto Indus., Inc.*, 709 F.2d 1109, 1119 (7th Cir. 1983); *Gabapentin*, 214 F.R.D. at 184.

14 *Nat'l Union Fire Ins. Co. of Pittsburgh, PA. v. Murray Sheet Metal Co., Inc.* 967 F.2d 980, 984 (4th Cir. 1992).

15 134 F.3d 1194 (2d Cir. 1998).

16 *Adlman*, 134 F.3d at 1195.

17 *Id.* at 1204; *see also United States v. Chevron Texaco Corp.*, 241 F. Supp. 2d 1065, 1082 (N.D. Cal. 2002).

18 *Gabapentin*, 214 F.R.D. at 184.

19 *Id.*; *see also McCook Metals*, 192 F.R.D. at 260; *In re Minebea Corp.*, 143 F.R.D. 494, 499 (S.D.N.Y. 1992). Conversely, documents prepared by attorneys in connection with subsequent proceedings in the patent process, such as reexamination proceedings or appeals to the Board of Patent Appeals and Interferences, have been held to fall within the protections of the work-product doctrine. *See McCook Metals*, 192 F.R.D. at 261-262.

20 *Gabapentin*, 214 F.R.D. at 184 (quoting, in part, *In re Minebea Corp.*, 143 F.R.D. at 499)).

21 *Id.*; *see also Softview Computer Products Corp. v. Haworth*, No. 97 Civ. 8815, 2000 WL 351411, at *5 (S.D.N.Y. March 31, 2000).

22 *See Softview Computer Products*, 2000 WL 351411, at *12 (finding that *in camera* review of the documents underlying patent application "reflect that counsel's claim drafting and prosecution of the patent application were informed by Haworth's anticipation of litigation against its competitors once the '798 patent issued").

23 *See Gabapentin*, 214 F.R.D. at 185-186 (holding that documents pre-dating the filing of patent application for pioneer drug were covered by the work-product doctrine since manufacturer of pioneer drug "would reasonably anticipate imminent litigation" upon receipt of statutory notice given by competitor as to latter's intent to market a generic versions of the drug).