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Foreign Regulatory Files and The Scope of Discovery

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The collective book of federal case law is full of quotable one-liners about the broad nature of civil discovery. These pithy passages embolden the plaintiffs' bar to request almost anything and result in a judiciary hesitant to shut down seemingly relevant but broad discovery requests. As a result, it is now commonplace for lawyers representing pharmaceutical and medical device manufacturers to get requests from plaintiffs for foreign regulatory communications – even though the product at issue is sold across the globe under dozens of regulatory schemes that have no impact on the case. Under the pre-2015 Federal Rules of Civil Procedure, manufacturers were left with difficult arguments that such requests were outside the scope of discovery. Instead, they generally had to rely on the standards for obtaining a protective order. But in 2015, Rule 26(b)(1) (which defines the scope of discovery) was amended.

The old buzzwords that gave plaintiffs a permission slip for limitless discovery were deleted and proportionality was enshrined as a critical limitation on discoverability. Still, as one court put it, "old habits die hard." Some courts conditioned to the old way of discovery continue to allow requests off the beaten path. Their justification for these rulings is often confused by the old Rule. To combat these issues, lawyers representing pharmaceutical and medical device manufacturers need to be armed with a firm understanding of the new Rule and the obligations and limitations it imposes.

Scope of Discovery

Before the 2015 Amendments, it is no surprise that courts interpreted the scope of discovery very broadly. The express language of the old Rule 26(b)(1) imposed few, if any, meaningful limitations, even though the Advisory Committee Notes suggest that the scope of discovery was intended to be more limited. Fed. R. Civ. P. 26(b)(1) advisory comm. note (2010). The 2015 amended language of Rule 26(b)(1) expressly limits the scope of discovery by considerations of proportionality – considerations that, before, had only been implicit in other parts of the Rule. Fed. R. Civ. P. 26(b)(1) advisory comm. note (2015) ("The present amendment restores the proportionality factors to their original place in defining the scope of discovery.").

Still, today some lawyers and courts continue to rely on pre-2015 Amendment case law when defining the scope of discovery. *See, e.g. Fulton v. Livingston Finan., LLC,* No. C15-0574JLR, 2016 WL 3976558, at *7 (W.D. Wash. July 25, 2016) ("Defendants cited case law that analyzed the version of Federal Rule of Civil Procedure 26(b)(1) that existed before the highly publicized amendments took effect on December 1, 2015."). That is not an inconsequential mistake given the issues with the old Rule. Thus, lawyers defending clients against broad discovery requests should be prepared to educate courts on the pitfalls of the old Rule and the importance of the 2015 Amendment.

Pre-2015 Scope of Discovery

The old Rule 26(b)[1] can be broken into three parts, each of which gave plaintiffs room to argue for an ever-expanding definition of what was discoverable:

Relevant to a Party's Claim or Defense. *"Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense."* Fed. R. Civ. P. 26(b)(1) (2010).

Setting privileged materials aside, under the old Rule, any matter that was relevant to a party's claim or defense fell within the scope of discovery. The problem with that definition is that it did not, on its own, meaningfully limit the scope of discovery because "relevance" is a sweeping concept. *See* Fed. R. Evid. 401 (a matter is relevant if it has a tendency to make a fact of consequence to the litigation more or less probable); *Cardenas v. Dorel Juvenile Grp., Inc.,* 232 F.R.D. 377, 382 (D. Kan. 2005) ("Relevancy is broadly construed, and a request for discovery should be considered relevant if there is 'any possibility' that the information sought may be relevant to the claim or defense of any party."). And in the age of electronically stored information, there is almost always a possibility that a search could turn up a "relevant" document.

Requests for foreign regulatory communications related to pharmaceutical or medical devices highlight the problem with the old relevance-only scope of discovery. For a single product, a pharmaceutical or medical device manufacturer may communicate with, or make formal submissions to, dozens of regulatory agencies across the globe. Even though these foreign regulatory communications are irrelevant to the claims of U.S. plaintiffs because foreign regulatory decisions do not impact patients in the U.S.[2], many courts have agreed with plaintiffs that these communications are encompassed within the sweeping concept of relevance. Specifically, courts have found that these communications could be relevant to establish what and when a manufacturer knew about a particular safety issue with a product. *See, e.g. Hardy v. Pharmacia Corp.*, No. 4:09-CV-119 (CDL), 2011 WL 2118983, at *3 (M.D. Ga. May 27, 2011) (finding that the requested foreign regulatory communications "could lead Plaintiff to discover admissible evidence regarding whether Defendants' warnings to Plaintiff's physician were adequate and reasonable under the circumstances"); *St. Jude Med. S.C., Inc. v. Sorin CRM USA, Inc.*, No. 14-cv-00119, 2014 WL 1056526 (D. Colo. Mar. 19, 2014). With the plain language of the old Rule as their sword, plaintiffs were often successful in seeking foreign regulatory communications on a whim that they might include information relevant to a U.S. plaintiff (such as notice) – a claim which is difficult for manufacturers to refute without collecting and reviewing the documents. *See Hardy*, 2011 WL 2118983, at *3.

Relevant to the Subject Matter. *"For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action."* Fed. R. Civ. P. 26(b)(1) (2010).

The relevant-to-the-claim-or-defense standard was – on its own – extremely broad, and the rest of the Rule's language did little to moderate it. In fact, it provided plaintiffs an avenue for further expanding the scope of discovery to "any matter relevant to the *subject matter* involved in the action." *Id.* (emphasis added). Though seldom invoked, the mere existence of this sentence led courts to interpret the scope of discovery more broadly than they might have otherwise done. *See, e.g. Nat'l Credit Union Admin. v. First Union Capital Markets Corp.*, 189 F.R.D. 158, 161-62 (D. Md. 1999).

Reasonably Calculated to Lead to Admissible Evidence. *"Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence."* Fed. R. Civ. P. 26(b)(1) (2010).

The final sentence of the old Rule led to the most confusion. Even though "this sentence was designed to make clear that otherwise relevant material could not be withheld because it was hearsay or otherwise inadmissible," many lawyers and courts used it to define the scope of discovery. Fed. R. Civ. P. 26(b)(1) advisory comm. note (2015). In civil litigation, it became common practice for practitioners and courts to incorporate this sentence into the definition of relevance: "Relevant information for the purposes of discovery is information 'reasonably calculated to lead to the discovery of admissible evidence.'" *See Survivor Media, Inc. v. Survivor Prods.*, 406 F.3d 625, 635 (9th Cir. 2005).

With courts allowing discovery into any matter "reasonably calculated to lead to the discovery of admissible evidence," any limitation that might have been imposed by the already-broad Rule 26(b)(1) was all but gone. *See* Fed. R. Civ. P. 26(b)(1) advisory comm. note (2015) (expressing concern that the "standard set forth in this sentence might swallow any other limitation on the scope of discovery"). Thus, manufacturers were left with few strong arguments that foreign regulatory communications were *outside the scope* of discovery. As a result, to avoid discovery into such matters, manufacturers had to rely on the standards and case law applicable to protective orders, which included considerations of proportionality.

The New Scope of Discovery

In 2015, Rule 26(b)(1) was amended to "guard against redundant or disproportionate discovery" and "encourage judges to be more aggressive in identifying and discouraging discovery overuse." P. 26(b)(1) advisory comm. note (2015). To accomplish this, the provisions improperly used by practitioners and courts to broaden the scope of discovery (i.e., "relevant to subject matter" and "reasonably calculated to lead to admissible evidence") were deleted. And the proportionality factors, which were previously a discretionary tool, were restored "to their original place in defining the scope of discovery." *Id.* Chief Justice John Roberts championed the 26(b)(1) amendments in his 2015 Year-End Report on the Federal Judiciary: "Rule 26(b)(1) crystalizes the concept of reasonable limits on discovery through increased reliance on the common-sense concept of proportionality." (Dec. 31, 2015).

Information is now only discoverable if it is (1) not privileged, (2) relevant, and (3) proportional to the needs of the case. The relevance

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language did not change, so lawyers can expect that courts will continue to interpret it broadly. The real difference with the revised Rule's language is the addition of the proportionality limitation.

The Proportionality Factors. The revised Rule 26(b)(1) provides a list of factors that the parties and the court must consider when determining whether a discovery request is proportional to the needs of the case:

- The amount in controversy
- The importance of the issues at stake in the action
- The parties' resources
- The importance of the discovery in resolving the issues
- Whether the burden and expense of the discovery outweighs its likely benefit

In determining whether the proposed discovery is proportional, and therefore within the scope of discovery, no one factor is determinative. Rather, at its core, proportionality is a balancing test, ensuring that parties receive the information they need to plead their claims and argue their defenses while curtailing expensive and time-consuming waste. *See, e.g.,* Chief Justice John Roberts, *supra,* pg. 7 ("The key here is a careful and realistic assessment of actual need."); *Lopez v. United States*, No. 15-CV-180-JAH(WVG), 2017 WL 1062581, at *4 (S.D. Cal. Mar. 21, 2017). But like the language of the Rule that preceded it, each factor in the newly-revised Rule is susceptible to being misinterpreted by plaintiffs or misapplied by courts.

Plaintiffs suing pharmaceutical or medical device manufactures for personal injury, for example, are sure to argue that when serious injuries are alleged against a large manufacturer, almost any discovery request – including a request for foreign regulatory communications that have little to no connection to the litigation – is proportional to the needs of the case. Plaintiffs may argue that (1) the amount in controversy in a personal injury lawsuit is high, (2) the serious nature of the injuries and widespread use of the product make the resolution of the issues important, and (3) the manufacturer has the resources to respond to the request. These arguments are only bolstered when made in the context of mass tort multidistrict litigation where hundreds or even thousands of cases are pending against a company.

When analyzing these factors for courts, lawyers defending manufacturers should keep them in their true context: discovery must be proportional to the *needs* of the case – it need not be proportional to the defendant's resources or the litigation's size or seriousness. If not properly put into context for courts, these plaintiff arguments have the potential to swallow the proportionality limitation on the scope of discovery.

Shared Obligation. These conclusory plaintiff arguments highlight another important piece of the proportionality limitation: the shared responsibility of ensuring that discovery is proportional. The Rules and Advisory Committee Notes make clear that plaintiffs, defendants, and the court each have an obligation and responsibility in tailoring the scope of discovery and avoiding its overuse. *See* Fed. R. Civ. P. 26(g)(1)(B)(iii) (by signing a request or response the attorney certifies that the request takes certain proportionality factors into consideration); Fed. R. Civ. P. 26(b)(1) advisory comm. note (2015) (the amendment "reinforces the Rule 26(g) obligation of the parties to consider these factors in making discovery requests, responses, or objections."); *see, e.g., Salazar v. McDonald's Corp.*, No. 14-cv-02096-RS (MEJ), 2016 WL 736213 (N.D. Cal. Feb. 25, 2016) ("[T]he revised rule places a shared responsibility on all the parties to consider the factors bearing on proportionality before propounding discovery requests, issuing responses and objections, or raising discovery disputes before the court.").

Plaintiffs, for their part, have an obligation to ensure that their discovery request is proportional. *See* Chief Justice John Roberts, *supra*, pg. 7 ("The amended rule states, as a fundamental principle, that lawyers must size and shape their discovery requests to the requisites of the case."). Even though they may have little information about the burden or expense of responding to a request for foreign documents, plaintiffs are in the best position to articulate why they believe the documents are important to resolving issues important to their claim. Fed. R. Civ. P. 26(b)(1) advisory comm. note (2015) ("A party claiming that a request is important to resolve the issues should be able to explain the ways in which the underlying information bears on the issues as that party understands them."). If plaintiffs cannot articulate how the requested discovery will resolve important issues, then it makes little sense to debate the amount in controversy, importance of the general issues, or ability of the defendant to shoulder the burden of the request. After all, the ultimate purpose of discovery is to resolve issues in dispute – not entertain plaintiffs' curiosities. *U.S. ex rel. O'Connell v. Chapman Univ.*, 245 F.R.D. 646, 648 (C.D. Cal. 2007) ("[T]he purpose of discovery is to remove

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surprise from trial preparation so the parties can obtain evidence necessary to evaluate and resolve their dispute.").

Lawyers defending manufacturers should thus meet conclusory statements by plaintiffs about the amount in controversy, importance of the issues, and ability of the defendant to shoulder the burden of the request, with pointed rebuttals that call on plaintiffs to meet their obligation to tailor proportional discovery requests. Plaintiffs do not meet that obligation by serving broad requests for foreign regulatory submissions based on nothing more than their speculation that something interesting or "relevant" might be in there. *See In re Bard IVC Filters Prods. Liab. Litig.*, 317 F.R.D. 562, 566 (D. Ariz. 2016) (concluding that it was "mere conjecture" and "more hope than likelihood" that foreign regulatory communications were relevant to the U.S. plaintiffs). That said, the revised Rule 26(b)(1) does not impose the "burden of addressing *all* proportionality considerations" on plaintiffs. Fed. R. Civ. P. 26(b)(1) advisory comm. note (2015) (emphasis added).

Defendants also have an obligation to ensure that discovery is proportional. For example, manufacturers responding to a request for foreign regulatory documents have the most information about the burden and expense of responding. *Id.* ("A party claiming undue burden or expense ordinarily has far better information – perhaps the only information – with respect to that part of the determination."). The revised Rule requires the manufacturer to demonstrate that burden – not just say that it is one. Just as conclusory statements about "important issues" will not suffice for plaintiffs to meet their proportionality burden, neither will conclusory claims by defendants about "disproportionate," "expensive," and "unduly burdensome" discovery suffice for defendants to meet theirs. *See id.* ("Nor is the change intended to permit the opposing party to refuse discovery simply by making a boilerplate objection that it is not proportional.").

Finally, the court also has a responsibility to ensure that discovery is proportional. The Advisory Committee took pains to see that the role of the judiciary in limiting the scope of discovery should not be overlooked, specifically repeating its previous guidance that the changes to Rule 26(b)(1) were "intended to encourage judges to be more aggressive in identifying and discouraging discovery overuse." *Id.* (noting that the role of the judiciary "warrants repetition"); *see also* Chief Justice John Roberts, *supra*, pg. 7 ("The [proportionality] assessment may, as a practical matter, require the active involvement of a neutral arbiter – the federal judge – to guide decisions respecting the scope of discovery. The amended rules accordingly emphasize the crucial role of federal judges in engaging in early and effective case management.").

"The court's responsibility, using all the information provided by the parties, is to consider [the proportionality factors] and all other factors in reaching a case-specific determination on the scope of discovery." Fed. R. Civ. P. 26(b)(1) advisory comm. note (2015). Judicial involvement is particularly important, as the Committee acknowledged, in the age of e-discovery. *Id.* Indeed, a seemingly straightforward request for communications with a foreign regulatory agency could require expensive and time-consuming collection efforts and the review and production of hundreds of thousands of documents, many of which could be in foreign languages. Still, courts trained in an era of limitless discovery may be hesitant to shut down broad discovery requests that seem relevant. A practitioner's role in educating courts on the true scope of discovery cannot be overstated.

A review of the pre- and post-amendment Rule reveals that the difference in the standards is important and that parties should be addressing proportionality. Plaintiffs have to draft proportionate requests, defendants have to demonstrate disproportionality, and courts have to consider proportionality and feel comfortable limiting the use of discovery devices.

Application of the New Rule 2b(b)(1) to Requests for Foreign Regulatory Communications

Case law emerging in the wake of the amendments is a mixed bag, which makes the thorough Advisory Committee Notes an important tool for lawyers advocating to shape the new Rule. Many courts are requiring plaintiffs to show why a request is proportionate and requiring defendants to show disproportionality. But courts are still reluctant to limit discovery. Some have failed to properly analyze proportionality while others continue to rely on the old Rule's language.

In re Bard IVC Filters

In re Bard IVC Filters is the post-amendment Rule 26(b)(1) gold standard for opposing requests to foreign regulatory communications. The judge – who happens to be the former chair of the Advisory Committee on Federal Rules of Civil Procedure that drafted the changes to Rule 26(b)(1) – concluded that the defendants would not have to produce foreign communications under the new civil rules of discovery. *In re Bard IVC Filters Prods. Liab. Litig.*, 317 F.R.D. 562, 566 (D. Ariz. 2016).

In making this determination, the court emphasized the "collective responsibility" to consider proportionality. *Id.* The court required plaintiffs to show why the requested discovery was needed, ultimately finding the explanation insufficient and concluding that it is "mere conjecture that communications between foreign entities and foreign

regulators might be inconsistent with Defendants' communications with American regulators." *Id.* The court also required defendants to articulate the specific burdens they would experience if required to search the ESI of foreign entities. *Id.* ("To comply with Plaintiffs' requests, Defendants assert that they would be required to identify the applicable custodians from these foreign entities for the last 13 years, collect ESI from these custodians, and search for and identify communications with foreign regulators.").

Importantly, relevance also played a role in the outcome. The court noted that the relevance of communications with foreign regulatory agencies is uncertain. *Id.* Even if marginally relevant, however, the court concluded that the burden and expense of discovery was not proportional to the needs of the case. *Id.*

Schueneman v. Area Pharms., Inc.

Schueneman v. Area Pharms., Inc. takes a close second to *In re Bard IVC Filters.* In denying plaintiffs' request seeking all documents related to an application the company submitted to the European Medicines Agency (EMA), the court in *Schueneman* held plaintiffs to their burden of demonstrating why the discovery sought was necessary. No. 10cv1959-CAB (BLM), 2017 WL 3118738, at *4 (S.D. Cal. July 21, 2017) (Magistrate order), *aff'd* 2017 WL 3587961 (S.D. Cal. Aug. 21, 2017). The court noted the "different standards utilized by the EMA and the FDA" and required plaintiffs to "explain how documents presented to the EMA…are relevant to the issue in this case." *Id.*

Plaintiffs provided the court with a boilerplate explanation, suggesting that the documents were relevant because "the EMA's objections and discussions…directly bear on the issue of Defendant's interpretation of the nonclinical studies and whether Defendants had a 'good faith' basis to make their misstatements." *Id.* at *4. The court did not bite, finding plaintiffs' explanation insufficient and denying their request. *Id.* ("Given the extremely broad discovery requests…the minimal relevance of the statements made after the class period in an application in the European Union involving drug standards that are different from those in the United States, and the large number of potentially responsive documents, the Court find that [the requests] are not proportional to the needs of the case.").

Hodges v. Pfizer

Hodges v. Pfizer is an example of a case with minimal analysis on proportionality. In this case, the court upheld a magistrate's order requiring defendants to produce certain foreign regulatory documents. No. 14-4855 ADM-TNL, 2016 WL 1222229 (D. Minn. Mar. 28, 2016).

In its analysis, the court cited language from the old rule and concluded that the foreign regulatory documents were relevant to defendants' knowledge of the risks of the drug at issue, "which in turn is relevant to [plaintiff's] claim." *Id.* at *2–3 ("Federal Rule of Civil Procedure 26 is to be construed broadly and encompasses 'any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case.'"). Focusing only on relevance, the court did not do an independent analysis of the proportionality factors, concluding that the magistrate must have considered the proportionality factors because he had narrowed the required production to seven countries and three subject areas. *Id.*

In re Johnson & Johnson Talcum Powder Prod. Mktg.

Much like *Hodges v. Pfizer*, the court in *In re Johnson & Johnson Talcum Powder Prod. Mktg.* focused on relevance rather than proportionality. No. 3:16MD02738, 2017 WL 5196741 (D.N.J. Nov. 6, 2017). The court's sole focus was on whether the documents "may possibly lead to the discovery of admissible evidence." *Id.* ("I believe the request

may possibly lead to the discovery of admissible evidence. Communications between the Defendants and the Third Parties have the potential to show Defendants' knowledge of the risks of talc and/or its products, as well as any effort by Defendants to sway the studies. Because the request may lead to the discovery of admissible evidence, this request is proper."). This decision highlights (1) how the language of the old rule still lingers in the case law, and (2) that an independent analysis of the proportionality considerations is key to resisting requests for foreign regulatory documents.

Strategies for Resisting Requests for Foreign Regulatory Files

Lawyers defending pharmaceutical and medical device manufacturers from broad requests for foreign regulatory communications should be well-versed in the newly revised Rule and the confusion that still lingers from the old Rule. Below are some strategies lawyers should consider when resisting these types of requests:

▶ **Educate the court on the proper scope of discovery.** Defense lawyers should sound the alarm bells when plaintiffs or courts use any language that resembles "reasonably calculated to lead to the discovery of admissible evidence." The use of that language to define the scope of discovery – even under the old Rule – has been sharply criticized by courts and the Advisory Committee. And it was deleted with the 2015 amendment. Under the new Rule, relevance alone is not enough to bring requests within the scope of discovery; it must also be proportional.

▶ **Force plaintiffs to explain how foreign communications are relevant to their U.S. legal claim.** Even if a foreign regulatory communication deals with the same product or subject, plaintiffs must show how those communications are likely to support their legal claims as laid out in the complaint. Demonstrating that foreign communications have minimal relevance to U.S. legal claims will help defense lawyers show why the request is disproportionate.

▶ **Put the proportionality factors in their true context.** Discovery must be proportional to the *needs* of the case – not proportional to defendant's resources or the size or seriousness of the litigation.

▶ **Hold plaintiffs to their proportionality burden.** Plaintiffs have an obligation to draft proportional discovery requests, which means they must be able to articulate a specific and reasonable need for foreign regulatory documents. Plaintiffs should not be allowed to generalize and speculate. Failure to comply with this obligation is sanctionable. *See* Fed. R. Civ. P. 26(g).

▶ **Rely on the Advisory Committee Notes.** Post-2015 courts have not been consistent in holding plaintiffs to their proportionality burden, but the Advisory Committee Notes are quite clear. Plus, the Rule is still in its infancy so the Committee Notes are persuasive.

▶ **Demonstrate disproportionality.** When resisting a request for foreign regulatory documents, defense lawyers must do the legwork of demonstrating disproportionality. Conclusory claims of disproportionality will not suffice. Lawyers representing manufacturers should therefore provide the court facts that demonstrate the burden and expense of responding to requests for foreign documents.

Consider answering these questions for the court. Where are the documents located? How much time or money will it take to access them? Are they likely to be in another language? What is the volume of documents? Approximately how much time would it take to collect, review, and produce the documents and what would be the associated cost? Has ongoing discovery already captured this information (i.e., is the requested information duplicative)? What will have to be done to comply with foreign data-privacy laws? If forced to comply, will discovery be delayed? Consider supporting these facts with signed declarations or affidavits.

▶ **Educate the court on its role in curtailing the overuse of discovery.** Defense lawyers should rely heavily on the Advisory Committee Notes to Rule 26(b)(1), which explicitly encourage judges to play an active role in limiting discovery and keeping it proportional. ■

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[1] Fed. R. Civ. P. 26(b)(1) (2000) ("Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense – including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter. For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.").

[2] *See, e.g. In re Seroquel Prods. Liab. Litig.,* No. 6:06-md-1769-Orl-22DAB, 2009 WL 223140, at *6 (M.D. Fla. Jan. 30, 2009).