

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF LOUISIANA

IN RE: XARELTO (RIVAROXABAN) PRODUCTS  
LIABILITY LITIGATION

\* MDL NO. 2592  
\* SECTION L  
\*  
\* JUDGE ELDON E. FALLON  
\*  
\* MAG. JUDGE NORTH

\*\*\*\*\*

**THIS DOCUMENT RELATES TO:**

*All Cases*

**ORDER & REASONS**

Before the Court is the PSCs’ Motion to Compel Discovery of Defendants’ German Employees and their Personnel Files. R. Doc. 2951. Having reviewed the parties’ briefs, the applicable law, and hearing oral argument the Court now issues this Order & Reasons.

**I. BACKGROUND**

This matter arises from damages Plaintiffs claim to have suffered from the manufacture, sale, distribution, and/or use of the medication known as Xarelto, an anti-coagulant used for a variety of blood-thinning medical purposes. The Plaintiffs have filed suits in federal courts throughout the nation against Defendants, Bayer Corporation, Bayer HealthCare LLC, Bayer HealthCare Pharmaceuticals Inc., Bayer HealthCare AG, Bayer Pharma AG, and Bayer AG (collectively, “Bayer”), Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Janssen Ortho LLC, and Johnson & Johnson (collectively, “Janssen”). The Plaintiffs allege that they or their family members suffered severe bleeding and other injuries due to Xarelto’s allegedly inadequate warning label, among other things, as well as Xarelto’s purported lack of reliance on regular blood monitoring.

The Judicial Panel on Multidistrict Litigation determined that the Plaintiffs’ claims involved common questions of fact and that centralization under 28 U.S.C. § 1407 would serve

the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. Therefore, on December 12, 2014, the Judicial Panel on Multidistrict Litigation consolidated the Plaintiffs' Xarelto claims into a single multidistrict proceeding ("MDL 2592"). MDL 2592 was assigned to Judge Eldon E. Fallon of the United States District Court for the Eastern District of Louisiana to coordinate discovery and other pretrial matters in the pending cases. Subsequent Xarelto cases filed in federal court have been transferred to this district court to become part of MDL 2592 as "tag along" cases. The Court has appointed committees to represent the parties, and discovery has commenced.

In anticipation of the deposition phase of discovery, the PSC requested the production of the custodial files and personnel files of Defendants' employee-witnesses. Custodial files are maintained by the employee and concern the documents generated or received by the employee concerning the employee's work. R. Doc. 1922 at 2. In contrast, personnel files are maintained by the Human Resources department of an employer, and are likely to contain confidential employer evaluations which the employee may have never seen. R. Doc. 1922 at 2. The personnel file may also include sensitive information such as salary, physical or mental health data, "alimony and child support garnishment, tax records, and drug test results." *Williams v. Roy O. Martin Lumber Co. LLC*, 51 Fed. Appx. 483, at \*6 (5th Cir. 2002).

On January 14, 2016, the Court ordered the parties to file briefing concerning a discovery and deposition protocol, so that a Pretrial Order could be issued for the purpose of setting guidelines in advance of depositions. R. Doc. 1914. Both the PSC and Defendants timely filed memoranda in support of their positions on the protocol. R. Docs. 1920, 1922. In the briefing, the parties' contested the discoverability of employee personnel files. Neither Janssen nor Bayer resisted production of custodial files. However, both Janssen and Bayer asserted that personnel files did not fall within the scope of Rule 26(b), because the privacy

interests of the deponent-employees outweighed the PSC's interest in discovery. R. Doc. 1922 at 5. Bayer also objected to the production of personnel files on the grounds that the personnel files contained "personal data," and production of such data would constitute a violation of the German Data Protection Act. R. Doc. 1922 at 10.

Despite the broad scope of discovery in the United States, personnel files are treated with special care in the Fifth Circuit. In *Coughlin v. Lee*, 946 F.2d 1152 (5th Cir. 1991), the Fifth Circuit Court of Appeals held that a district court must use specific factors to weigh the competing privacy and discovery interests presented by a request for the production of personnel files. *Id.* at 1155–57. The Fifth Circuit adopted ten factors outlined in *Frankenhauser v. Rizzo*, 59 F.R.D. 339, 344 (E.D. Pa. 1973), *overruled on other grounds by Crawford v. Dominic*, 469 F. Supp. 260 (E.D. Pa. 1979), six of which are relevant in a civil case against a private defendant such as Bayer: (1) "the impact upon persons who have given information of having their identities disclosed;" (2) "whether the information sought is factual data or evaluative summary;" (3) "whether the party seeking the discovery is an actual or potential defendant in any criminal proceeding either pending or reasonably likely to follow from the incident in question;" (4) "whether the plaintiff's suit is non-frivolous and brought in good faith;" (5) "whether the information sought is available through other discovery or from other sources; and" (6) "the importance of the information sought to the plaintiff's case." *Id.* The *Frankenhauser* court emphasized the importance of particularity, calling for a "case to case" balancing of the variables before the court. *Id.*

After hearing oral argument and reviewing the briefs, the Court issued an Order & Reasons requiring the PSC to provide an "individualized showing of relevancy, proportionality, and particularity," for each witness whose personnel files they sought. R. Doc. 1987 at 8. Following the Court's instruction, the PSC noticed depositions of the Janssen employees and

made a specific, particularized request for various types of material contained in the personnel files of those witnesses. The Court subsequently required Janssen to produce the files for an *in camera* examination. The Court then appropriately tailored the scale of production by material balancing the relevancy and importance of the material against employee privacy interests.

The Court delayed ruling on Bayer's argument concerning the German Data Protection Act, until the parties had an opportunity to brief the question of whether a "blocking statute" such as the German Data Protection Act could trump the Federal Rules of Civil Procedure. R. Doc. 1987 at 8 n.1. However, at the request of the parties, the Court later provided guidance on the German law issue at a telephonic discovery conference, and the parties jointly agreed to revisit the applicability of the German Data Protection Act at a later date. R. Doc. 2048. Meanwhile, the parties began exchanging documents and taking depositions of Janssen witnesses.

## **II. THE PRESENT MOTION**

Recently, the PSC noticed the depositions of several Bayer employees who are citizens and residents of Germany. In preparation for the depositions, the PSC requested that Bayer produce the personnel files of these witnesses. Bayer refused, citing the German Data Protection Act restrictions on the transfer of personal data. On April 1, 2016, the PSC filed a Motion to Compel Discovery of Defendants' German Employees and Their Personnel Files, In Its Entirety. R. Doc. 2951. The present motion returns to the discovery issues presented by the German Data Protection Act. The motion specifically addresses the personnel files of deponents Frank Misselwitz, MD, PhD, and Dagmar Kubitzka, MD. The PSC seeks to compel Xarelto-related documents associated with these witnesses' performance reviews, self-reviews, annual compensation, incentives and bonuses, or, in the alternative, to produce these documents to the Court for *in camera* inspection. R. Doc. 1951-1 at 1.

### III. DISCUSSION

#### A. Applicable Law

The present issue presents a conflict between Rule 26 of the Federal Rules of Civil Procedure and the German Data Protection Act. In seeking a resolution of this conflict that respects the discovery rights and defenses of the parties as well as the comity concerns of the United States and Germany, a review of American and German civil procedure as well as the law concerning blocking statutes is appropriate.

##### i. A Review of Discovery Practices under American Civil Procedure and Foreign Civil Procedure

The PSC seeks the production of various portions of deponent personnel files. Because this is a discovery request, and the case is lodged in a United States District Court, Rule 26 of the Federal Rules of Civil Procedure applies. Rule 26(b)(2) defines the scope of discovery as “any nonprivileged matter that is relevant to the party’s claim or defense and proportionate to the needs of the case . . . . unless otherwise limited by a court order.” The rules of discovery are to be interpreted with a “liberal spirit.” *Coughlin v. Lee*, 946 F.2d 1152, 1159 (5th Cir. 1991) (quoting *Burns v. Thiokol Chem. Corp.*, 483 F.2d 300, 305 (5th Cir. 1973)).

The breadth of United States civil discovery rules, however, often raises sovereignty concerns when parties seek international discovery. European nations typically have narrower discovery procedures than provided for in the United States, especially when compared to our civil discovery rules. Germany follows this trend. The German Rules of Civil Procedure, or *Zivilprozeßordnung*, hold that evidence shall only be taken before the court. 1877, *Reichsgesetzblatt [RGBl.]*, at 97, as amended, § 355 (Ger.). “This principle is based on the assumption that the court must get a personal impression of the evidence to give it a just and fair consideration.” Oliver Förster & Osama Almughrabi, *Managing the Conflict Between U.S. E-*

*Discovery and the German Data Protection Act*, 36 *Hastings Int'l & Comp. L. Rev.* 111, 116 (2013). Divergent discovery rules do not in and of themselves prevent international discovery, but American courts should be cognizant that “many foreign countries, particularly civil law countries, do not subscribe to our open-ended views regarding pretrial discovery, and in some cases may even be offended by our pretrial procedures.” *In re Anschutz & Co., GmbH*, 838 F.2d 1362, 1364 (5th Cir. 1988).

Beyond providing for different evidence-taking methods, some foreign nations impose civil and criminal penalties on those who transfer personal data abroad for discovery purposes. Through the use of so-called “blocking statutes,” foreign states often “prohibit[] the disclosure, copying, inspection, or removal of documents located in the territory of the enacting state in compliance with the orders of foreign authorities.” Restatement (Third) of Foreign Relations Law § 442 (Am. Law Inst. 1987). Countries such as Germany, France, China, Malaysia, the Netherlands, and Canada have enacted blocking statutes, and thereby have attempted to narrow the relatively broad scope of American discovery. *See id.*; John T. Yip, *Addressing the Costs and Comity Concerns of International E-Discovery*, 87 *Wash. L. Rev.* 595, 615 (2012).

ii. The Comity Analysis of *Société Nationale*

Litigation resulting from international commerce often produces discovery disputes which present a conflict between American discovery procedures and blocking statutes. The Supreme Court last addressed the relationship between blocking statutes and American discovery procedures in *Société Nationale Industrielle Aerospatiale v. United States District Court for the Southern District of Iowa*. 482 U.S. 522, 548 (1987); *see also Société Internationale Pour Participations Industrielles et Commerciales, S.A. v. Rogers*, 357 U.S. 197, 204–06 (1958). In *Société Nationale*, a foreign litigant argued that American discovery procedures must yield to the discovery procedures of the Hague Convention, as required by French penal law. *See Société*

*Nationale*, 482 U.S. at 526. The Court disagreed and adopted a balancing “comity analysis,” reasoning that “foreign tribunals will recognize that the final decision on the evidence to be used in litigation conducted in American courts must be made by those courts.” *Id.* at 542, 544 n.28. The Court declined to articulate the factors of the test. *Id.* at 546.

In the wake of *Société Nationale*, courts have devised numerous mechanisms for performing the Court’s unarticulated “comity analysis.” See Geoffrey Sant, *Court-Ordered Law Breaking: U.S. Courts Increasingly Order the Violation of Foreign Law*, 81 Brook. L. Rev. 181, 186–87 (2015). The majority of lower courts perform the five-factor test found in section 442 of the Restatement (Third) of the Law of Foreign Relations (the “Third Restatement”), citing the Court’s favorable reference to the Third Restatement in a footnote in *Société Nationale*. See, e.g., *Pershing Pacific W., LLC v. Marinemax, Inc.*, Civ. No. 10-1345, 2013 WL 941617, at \*6–7 (S.D. Cal. Mar. 11, 2013); see also Sant, *supra*, at 186–87 (taking the position that “a greater number” of lower courts employ this test). Under the Third Restatement, a court deciding whether to order the production of information protected by a blocking statute should consider:

the importance to the . . . litigation of the documents or other information requested; the degree of specificity of the request; whether the information originated in the United States; the availability of alternative means of securing the information; and the extent to which noncompliance with the request would undermine important interests of the United States, or compliance with the request would undermine important interests of the state where the information is located.

Restatement (Third) of Foreign Relations Law § 442 (Am. Law Inst. 1987). These five factors expand to seven in the Ninth Circuit. Relying on *Société Nationale*’s holding that the Third Restatement’s factors are not exhaustive, the Ninth Circuit also considers “[1] the extent and the nature of the hardship that inconsistent enforcement would impose upon the person, and [2] the extent to which enforcement by action of either state can reasonably be expected to achieve

compliance with the rule prescribed by that state.” *Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468, 1475 (9th Cir. 1992) (citing *Société Nationale*, 357 U.S. at 543–44 n.28).

In the present case the PSC seeks the production of the personnel files pertaining to the two witnesses noticed for deposition. Bayer opposes the production, arguing that these files contain certain personal data which is prohibited from distribution by the German Data Protection Act.

iii. The German Data Protection Act

The roots of the German Data Protection Act<sup>1</sup> stretch back to 1990 when the Act was first codified to protect “the individual against his right to privacy being impaired through the handling of personal data.” Bundesdatenschutzgesetz [BDSG] [Civil Code], § 1(3), *translation at* [http://www.gesetze-im-internet.de/englisch\\_bdsch/englisch\\_bdsch.html#p0008](http://www.gesetze-im-internet.de/englisch_bdsch/englisch_bdsch.html#p0008) (Ger.). The Act was updated in 1995 in order to comply with the European Council and Parliament’s passage of Directive 95/46/EC (“EC Directive 95”). Council Directive 95/46, 1995 O.J. (L 281). EC Directive 95 protects the privacy of personal data within the European Union. As a member of the European Union, Germany was compelled to enact privacy protection laws that enabled the EC Directive’s principles. The amended Act includes civil and criminal penalties for parties who unlawfully disclose “personal data.” BDSG, § 44(1). Violation of the Act may result in up to two years of imprisonment. *Id.* As such, the German Data Protection Act functions as a “blocking statute,” and efforts to produce German personal data implicate the *Société Nationale* comity analysis. *See, e.g., In re Baycol Prod. Litig.*, No. MDL1431, 2003 WL 22023449, at \*6 (D. Minn. Mar. 21, 2003) (applying *Société Nationale* when plaintiffs sought the production of the performance evaluations of Bayer’s German employees). It appears that only personal data

is covered by the German Act, and that certain personal data is given greater protection than others.

### **B. Discussion**

Upon review of the briefing, record, and statements made by counsel at oral argument, the Court finds that it is unclear what information and materials are contained within the personnel files at issue, and whether all, some, or none of the material constitutes personal data covered by the German Data Protection Act. The *Société Nationale* balancing test, as embodied in the Third Restatement, calls for an analysis of the importance of the documents to the litigation as well as balancing the foreign nation's interests against those of the United States. These two factors of the Third Restatement's five-factor test are difficult to weigh without some conception of the type or nature of the material at issue.

At this stage, the Court may only conjecture as to what is contained in the files. The Court is hesitant to begin a *Société Nationale* analysis without using all available means to discover the importance of the documents to the litigation. Analysis of the significance of the personnel files would be best conducted through *in camera* review of the documents at issue, but *in camera* production of the files may itself constitute a violation of the German Data Protection Act. Therefore, as an alternative, the Court finds that a privacy log would be helpful in ascertaining the nature or type of information contained in the files. An American court should employ all of the tools at its disposal before treading on the laws and policies of a foreign nation. A privacy log is one such tool.

The interest of the Federal Republic of Germany in “informational self-determination,” *see In re: Census Act*, 30 BVerfGE 1, 42–43 (Dec. 15, 1983), as codified in the German Data Protection Act would also be better understood after viewing a privacy log. Because the goal of

---

<sup>1</sup> The direct translation of “Bundesdatenschutzgesetz” is “Federal Data Protection Act.” For the sake of

the German Data Protection Act is to preserve the privacy of German citizens, the interests of Germany are inherently linked to the character, nature, and quantity of the personal data contained in the files. For example, Germany's interest in preventing hypothetical employee data such as "Employee A started a carpooling program" from being discovered is less compelling than its interest in preventing the discovery of data such as "Employee B took a leave of absence for a health issue," or "Employee C sought an advance on her salary for personal reasons," or "Employee D is genetically predisposed to substance abuse." Similarly, a personnel file with one stray reference to personal data does not raise the same comity concerns as a file replete with sensitive employee information. With the preceding in mind, the production of a privacy log will aid the Court's analysis of the significance of Germany's interests in the personnel files. This log should adequately describe the document without disclosing its contents. Some files may contain no personal data. Others may be entirely composed of highly sensitive information. In addition to aiding the Court, a privacy log may shed light on categories of personal data which the PSC agrees should be redacted prior to transfer, such as addresses, social security numbers, health information, or biometric data. This process should partially mitigate Bayer's concerns that production will result in a "massive personal-data dump." R. Doc. 3146 at 11.

In the meantime, however, the PSC should continue with depositions and attempt to obtain the sought information from the witnesses. Bayer concedes that employee consent is an exception to production under the German Data Protection Act, *see* R. Doc. 3146-1 at 5-6, and Pretrial Order 20 already grants extensive protection to documents produced in this litigation. The deponents may consent to the production of their personnel files, thereby mooting the present issue. On the other hand, a refusal to consent alongside evasiveness during deposition

---

clarity, the Court refers to the German law as the "German Data Protection Act."

may impact the *Société Nationale* comity analysis. The availability of alternative means to obtain data protected by a blocking statute is one of the factors of the Third Restatement, and gamesmanship at deposition is relevant to the usefulness of depositions as a mechanism to accomplish the PSC's discovery goals.

In sum, a privacy log would aid the Court's *Société Nationale* comity analysis, and the parties agree that the production of a privacy log is within Bayer's power. *Accord In re Vitamins Antitrust Litig.*, No. 99-197TFH, 2001 WL 1049433, at \*9 (D.D.C. June 20, 2001) (ordering the production of a privacy log of German documents before proceeding with a *Société Nationale* comity analysis). With such a log in hand, the Court may proceed with the balancing test, and determine what material if any should be produced.

#### IV. CONCLUSION

Accordingly, **IT IS ORDERED** that Bayer shall produce a privacy log of the personnel files of Dr. Dagmar Kubitzka and Dr. Frank Misselwitz on or before twenty-one days of the filing of this Order & Reasons. Bayer shall detail the character and quantity of the personal data contained within each file without disclosing its content.

New Orleans, Louisiana, this 11th day of May, 2016.

  
UNITED STATES DISTRICT JUDGE