

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

IN RE: XARELTO (RIVAROXABAN) PRODUCTS	*	MDL NO. 2592
LIABILITY LITIGATION	*	SECTION L
	*	
	*	JUDGE ELDON E. FALLON
	*	
	*	MAG. JUDGE NORTH
*****	*	

THIS DOCUMENT RELATES TO:

All Cases

ORDER & REASONS

Before the Court is the PSC’s Motion to Compel Discovery of Defendants’ German Employees’ Personnel Files. R. 2951. Having reviewed the parties’ briefs, the applicable law, and the matters raised during oral argument the Court now issues this Order & Reasons.

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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. The Court adopted a discovery plan and set bellwether trials to begin in February 2017.

In anticipation of the deposition phase of discovery, the PSC requested the production of the custodial files and the personnel files of Defendants' employee-witnesses. Custodial files are

maintained by the employee and include documents generated or received by the employee concerning the employee's work. R. 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. 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. *See Williams v. Roy O. Martin Lumber Co. LLC*, 51 Fed. App'x. 483, at *6 (5th Cir. 2002).

On January 14, 2016, the Court ordered the parties to file briefing concerning the deposition protocol, so that a Pretrial Order could be issued for the purpose of setting guidelines in advance of the deposition phase of discovery. R. 1914. Both the PSC and Defendants timely filed memoranda in support of their positions on the protocol. R. 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. 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. 1922 at 10.

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. 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 balancing the relevancy and importance of the material against employee privacy interests.

The Court delayed ruling on the German law issue raised by Bayer, finding that the parties failed to present sufficient briefing for the Court to determine whether a “blocking statute” such as the German Data Protection Act could trump the Federal Rules of Civil Procedure. R. 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. 2048. Meanwhile, the parties began exchanging documents and taking depositions of Janssen witnesses.

II. THE PRESENT MOTION

The present motion returns to the discovery issues presented by the German Data Protection Act. On April 1, 2016, the PSC filed a Motion to Compel Discovery of Defendants’ German Employees’ Personnel Files, In Its Entirety. R. 2951. The motion specifically addresses the discovery 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. 1951-1 at 1.

The Court issued an Order & Reasons on May 16, 2016 that ordered Bayer to produce a privacy log of the employee personnel files. R. 3237. In light of the considerable comity interests at issue, the Court sought to better understand the “character, nature, and quantity of the personal data contained in the files,” R. 3237 at 10, before evaluating the legality of production under the German Data Protection Act or conducting a balancing of interests pursuant to *Société Nationale Industrielle Aerospatiale v. United States District Court for the Southern District of*

Iowa. 482 U.S. 522, 548 (1987). Bayer filed a Notice of Filing of Privacy Logs on June 6, 2016. R. 3384. The PSC filed a Reply to Bayer’s privacy logs on May 16, 2016. R. 3560.

A. The PSC’s Motion (R. 2951)

The PSC contends that the German Data Protection Act does not trump the Federal Rules of Civil Procedure concerning the discovery of personnel files such as the ones at issue. R. 2951. The PSC takes the position that the Court has ordered the production of numerous domestic personnel files associated with employees of Janssen, and that the “effect of the so-called German blocking statute” should not lead to a different outcome. R. 2951-1 at 2.

The PSC begins by providing a particularized discussion of Dr. Misselwitz and Dr. Kubitz’s importance to the litigation. Opening with the former, the PSC notes that Dr. Misselwitz is the Vice President at Bayer AG, and leads the Cardiovascular Therapeutic Area in Wuppertal, Germany. R. 2951-1 at 4. Dr. Misselwitz directed other Xarelto development leaders, including Bayer’s Thrombosis Head, Bayer’s Cardiovascular Head, Bayer’s Hematology Head, and Bayer’s Lead for Pediatric Development. R. 2951-1 at 4. Dr. Misselwitz has a long history with Xarelto. He joined Bayer’s Strategic Drug Development—Cardiovascular Team on April 1, 2002. R. 2951-1 at 5. Dr. Misselwitz worked closely with Janssen leadership in the course of the Xarelto partnership between Bayer and Janssen. R. 2951-1 at 5. Dr. Misselwitz also acted as a public voice for Xarelto during its development by meeting with investors and authoring publications. R. 2951-1 at 5. The PSC asserts that Dr. Misselwitz was one of the two primary drivers behind the selection of once-a-day dosing for Xarelto. Lastly, the PSC points out that Dr. Misselwitz supported the use of project-specific bonuses to incentivize Bayer employees working on projects such as Xarelto. R. 2951-1 at 6–7. With the preceding in mind, the PSC takes the position that Dr. Misselwitz’s personnel files will likely contain material that reveals “strategic plans for [sic] which Dr. Misselwitz and/or his superiors felt to be of critical

importance to Xarelto development.” R. 2951-1 at 7–8.

The PSC next describes in particularity Dr. Kubitza’s role at Bayer. Dr. Kubitza’s high-level leadership role at Bayer began in 2007, when she was promoted to Group Leader Acute Care within Clinical Pharmacology. R. 2951-1 at 8. Dr. Kubitza was crucial to the assessment of the pharmacodynamics profile of Xarelto, and consulted with others at Bayer concerning inquiries involving Xarelto raised by regulatory bodies, both foreign and domestic. Dr. Kubitza participated in discussions concerning the financial consequences of potential dosing regimens in response to inquiries made by investment banking firms. R. 2951-1 at 9. The PSC also contends that Dr. Kubitza was the second primary driver of once-a-day dosing for Xarelto. Dr. Kubitza continues to be involved with Xarelto. She attends conferences and forums which discuss the ongoing debate concerning the need to measure plasma concentrations of Xarelto in an effort to appropriately dose all patients. The PSC argues that Dr. Kubitza’s personnel files may provide evidence of bias, and could bring to light additional discoverable information. R. 2951-1 at 10.

The PSC lastly turns to the German Data Protection Act and claims that it is inapplicable to the deposition requests at bar. The PSC concedes that the German Data Protection Act prohibits the transfer of “personal data” to any jurisdiction that does not provide the same level of privacy protections as the European Union. R. 2951-1 at 11. However, the PSC takes the position that the personnel files fall into an exception which allows the sharing of personal data where “the transfer is necessary or legally required on important public interest grounds, or for the establishment, exercise, or defense of legal claims.” R. 2951-1 at 11. Arguing in the alternative, the PSC cites the Supreme Court’s opinion in *Société Nationale Industrielle Aerospatiale v. U. S. Dist. Court for the S. Dist. of Iowa*, 482 U.S. 522, 546 (1987), and argues that the *Société Nationale* factors weigh in favor of disclosure even if disclosure is prohibited by German law. R. 2951-1 at 12.

B. Bayer's Opposition (R. 3146)

Bayer contends that the Court should not require the production of the documents at issue, because production would violate the German Data Protection Act. Bayer recognizes that the illegality of production under foreign law is not dispositive, but argues that the comity interests set forth in *Société Nationale* weigh against the production of personnel files due to the employee privacy interests involved.

Bayer begins by asserting that personnel files are subject to heightened protection under the German Data Protection Act, and that no exceptions to the Act allow for production. Bayer notes that the German Constitution provides for a “right to informational self-determination,” and argues that the German Data Protection Act buttresses the values of said right. R. 3146 at 8. The Defendant leans heavily on the affidavit of its German law expert, Dr. Henning Moelle. R. 3146-1. Citing Moelle, Bayer takes the position that production of personal data could “subject [Bayer] to administrative or criminal penalties, including fines and imprisonment for up to two years, and to civil liability.” R. 3146 at 8 (citing R. 3146-1 at 9).

Before addressing the German Data Protection Act itself, Bayer attempts to distinguish the “1.1 million German-stored documents” they have already produced from the documents currently sought by the PSC. R. 3146 at 9. Bayer concedes that most, if not all, of the documents produced by Bayer contain some personal data within the scope of the German Data Protection Act. R. 3146 at 9. Bayer distinguishes the files by arguing that German law recognizes a distinction between custodial files and personnel files. According to Bayer, custodial files are employee-maintained documents that were “generated or received by the employee concerning the employee’s work.” R. 3146 at 10. In contrast, Bayer characterizes personnel files as a unique “compilation of personal data” that are maintained by an employer’s Human Resources department. R. 3146 at 10 (quoting R. 3146-1 at 4). In justifying this

uniqueness, Moelle contends that personnel files are “massive compilation[s] of personal data of the employee,” and that they necessarily include personal and sensitive material. R. 3146-1 at 4–5, 9.

Turning to the text of the German Data Protection Act, Bayer contends that the Act calls for a balancing of interests whenever the production of personnel files is at issue. “Under the . . . balancing test, the employees’ interest in protecting their personnel records from what would be a massive personal-data dump is extraordinarily high, even when weighed against any litigation interest.” R. 3146 at 11. Somewhat contradicting its assertion that a balancing test applies, Bayer also asserts that the Act provides that personnel files may only be disclosed “for a legitimate purpose of the *employment relationship*.” R. 3146 at 11 (citing R. 3146-1 at 7).

Moelle’s affidavit clarifies this matter. According to Moelle, the German Data Protection Act’s “legitimate purpose of the employment relationship” language does not alter the exceptions applicable to the transfer of personnel records for business purposes. R. 3146-1 at 7–8. Instead, Moelle contends that this section of the Act provide contextual evidence of the “great weight that should be afforded employee privacy interests.” Moelle takes the position that the personal records at issue may be transferred without violating the Act if the employer has a legitimate interest in transfer, and “there is no reason to assume that the data subjects have an overriding interest against such processing and transfer of their data.” R. 3146-1 at 8.

Following their discussion of German law, Bayer addresses the Supreme Court’s *Société Nationale* balancing test. Bayer concedes that this Court has the authority to compel the production of the German files, even if production violates the German Data Protection Act. R. 3146 at 13. However, Bayer correctly states that the Court must first conduct a *Société Nationale* comity analysis before ordering Bayer to violate a foreign blocking statute. Bayer takes the position that the balancing test weighs against production. Bayer interprets *Société*

Nationale to call for the use of the five factors of the Restatement (Third) of Foreign Relations. Bayer addresses each in turn, emphasizing their position that the personnel files contain highly sensitive employee data and that the PSC may find the evidence it seeks in the 1.1 million documents already produced by Bayer or by asking the witnesses at deposition. R. 3146 at 13–17.

Lastly, Bayer argues that the PSC’s motion for Dr. Kubitza’s file is untimely. Dr. Kubitza was deposed in Amsterdam on February 29 and March 1, 2016. Bayer contends that the PSC did not raise at deposition any of the issues they now argue are crucial to their case, and are therefore barred from seeking Dr. Kubitza’s personnel files.

C. The PSC’s Reply (R. 3173)

The PSC timely replies. R. 3173. The PSC refines two of its arguments in response to the Defendants’ Opposition and the affidavit of Bayer’s German law expert.

The PSC contends that the German Data Protection Act does not prevent the disclosure of the personnel files at issue. The PSC avers that Bayer’s German law expert conceded that section 4(c)(1)(3) of the Act is an exception that allows for the transfer of personal data in this case. R. 3173-1 at 3–4. The PSC further argues that Bayer wrongly distinguishes between personnel files and custodial files under German law. According to the PSC, “Personnel files are not the test; personal data is.” R. 3173-1 at 4. The PSC then cites case law where domestic courts found that personal data should be compelled despite the objections of German defendants. R. 3173-1 at 4.

The PSC also provides its *Société Nationale* comity analysis. R. 3173-1 at 4–9. Addressing the five factors of the Third Restatement of the Law of Foreign Relations, § 442 (Am. Law Inst. 1987), the PSC contends that all but one of the factors—whether the information originated in the United States—points towards the production of the personnel files. R. 3173-1

at 4–9. And with respect to this one adverse factor, the PSC emphasizes the fact that Bayer voluntarily chose to engage in extensive commerce with the United States, and avers that Bayer should not be able to hide behind German discovery protections when it purposefully availed itself of United States markets. R. 3173-1 at 7–9.

III. DISCUSSION

A. Applicable Law

The present matter presents a conflict between Rule 26 of the Federal Rules of Civil Procedure and a “blocking statute,” 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. The Relationship between the Federal Rules of Civil Procedure and Foreign Blocking Statutes

The PSC seeks the production of deponent employees’ personnel files. The PSC claims that these files likely contain information regarding compensation, performance bonuses, and other incentives that rewarded conduct which caused Xarelto to be prematurely rushed to the marketplace. Because this is a discovery issue, 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)).

At the outset, the Court notes that despite the broad scope of discovery, personnel files are generally treated with special care in the Fifth Circuit. In *Coughlin v. Lee*, the circuit court

held that a district court must consider specific factors in weighing 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), 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 court emphasized the importance of particularity, calling for a “case to case” balancing of the variables before the court. *Id.*

Furthermore, the production of discovery material such as personnel files sometimes carries civil or criminal consequences abroad. Through the use of so-called “blocking statutes,” foreign states may “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 France, China, Malaysia, the Netherlands, Canada, and Germany have enacted blocking statutes, and thereby indirectly affect 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).

The Supreme Court last addressed the relationship between blocking statutes and American discovery procedures in *Soci t  Nationale Industrielle Aerospatiale v. U.S. Dist. Court*

for *S. Dist. 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). Some courts use a three-factor test. For example, the District of Connecticut examines whether: “(1) the examination of the particular facts of the case, particularly with regard to the nature of the discovery requested; (2) the sovereign interests in issue; and (3) the likelihood that the [foreign discovery] procedures will prove effective.”¹ *Valois of America, Inc. v. Risdon Corp.*, 283 F.R.D. 344, 346 (D. Conn. 1997); see also *In re Aircrash Disaster Near Roselawn, Ind., October 31, 1994*, 172 F.R.D. 295, 309 (N.D. Ill. 1997) (employing the same factors). Others, such as the Second Circuit, have used a four-factor test, examining “(i) the competing interests of the nations whose laws are in conflict; (ii) the hardship that compliance would impose on the party or witness from whom discovery is sought; (iii) the importance to the litigation of the information and documents requested; and (iv) the good faith of the party resisting discovery.” *First Am. Corp. v. Price Waterhouse LLP*, 154 F.3d 16, 22 (2d Cir. 1998)

¹ This formulation of the comity analysis is drawn from language in *Société Nationale*. See *Société Nationale*, 357 U.S. at 545 (suggesting that a district court should consider “the particular facts, sovereign interests, and [the] likelihood that resort to . . . [foreign discovery] procedures will prove effective”).

(citing *Minpeco, S.A. v. Conticommodity Servs., Inc.*, 116 F.R.D. 517, 523) (S.D.N.Y. 1987)). *But see Strauss v. Credit Lyonnais, S.A.*, 242 F.R.D. 199, 211 (E.D.N.Y. 2007) (applying the five factors of the Restatement (Third) of the Law of Foreign Relations as well as two additional factors).

The majority of lower courts, however, perform the five-factor test used in the Restatement (Third) of the Law of Foreign Relations § 442 (Am. Law Inst. 1987) (the “Third Restatement”), citing the Court’s favorable reference to the Third Restatement in a footnote in *Société Nationale*. *See, e.g., Pershing Pacific West, 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 in 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).

One year after the Supreme Court’s holding in *Société Nationale*, the Fifth Circuit adopted a three-factor comity analysis. “The district court is only directed to determine whether [foreign discovery procedures] are appropriate after ‘scrutiny in each case of the particular facts, sovereign interests, and likelihood that resort to these procedures would prove effective.’” *In re Anshuetz & Co., GmbH*, 838 F.2d 1362, 1364 (5th Cir. 1988) (quoting *Société Nationale*, 357 U.S. at 545). The Fifth Circuit’s formulation of the comity analysis emphasizes the sovereignty interests of foreign states. In particular, the circuit court found that district courts should “consider, with due caution, 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.” *Id.* The *Anshuetz* opinion does not cite the Third Restatement.

Despite the *Anshuetz* court’s adoption of a three-factor comity analysis, district courts in the Fifth Circuit routinely use the five-factor test of the Third Restatement. For example, the Northern District of Texas recently employed the five factors of the Third Restatement, adding to the comity analysis a discussion of the hardship of compliance as well as the good faith of the party resisting discovery. *See S.E.C. v. Stanford Int’l Bank, Ltd.*, 776 F. Supp. 2d 323, 330 (N.D. Tex. 2011). The Eastern District of Texas has also addressed the question, finding that the five factors of the Third Restatement provide the proper framework for a comity analysis. *See Seoul Semiconductor Co. v. Nichia Corp.*, 590 F. Supp. 2d 832, 834 (E.D. Tex. 2008). While there is no district court opinion from the Eastern District of Louisiana on this subject, one magistrate judge has applied the five factors of the Third Restatement. *See Adams v. Unione Mediterranea Di Sicurta*, No. 94-1954, 2002 WL 472252, at *2–3 (E.D. La. Mar. 28, 2002). Before

embarking on any comity analysis, however, it is appropriate to consider the German Data Protection Act to determine whether the Act is applicable and if so whether there are any exceptions which may apply.

ii. The German Data Protection Act

The blocking statute at issue is the German Data Protection Act.² The roots of the Act 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 (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 protected data. BDSG, § 44(1). Violation of the Act may result in up to two years of imprisonment. *Id.*

As its name implies, the German Data Protection Act limits the disclosure of personal data. The Act defines “personal data” as any “information concerning the personal or material circumstances” of a natural person. *Id.* § 3(1). The Act does not specifically address personnel files, but scholars believe that the scope of the Act covers telephone numbers, addresses, jobs, familial status, credit information, and medical history (among others), and some of this information may well be contained in the personnel files. *See* 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, 119 (2013). The Data Protection Working Party, an independent agency tasked with advisory authority concerning EC Directive 95, has signaled that personal data should be interpreted to include subjective personal data such as “opinions or assessments.” Article 29 Data Protection Working Party, *Opinion 4/2007 on the Concept of Personal Data*, at 6, 01248/07/EN/Final WP 136 (June 20, 2007). In a 2007 advisory document, the Working Party provided several examples of subjective personal data, including “Titius is a reliable borrower,” “Titius is not expected to die soon,” and most pertinently “Titius is a good worker and merits promotion.” *Id.*; see also Article 29 Data Protection Working Party, *Opinion 8/2001 on the Processing of Personal Data in the Employment Context*, at 2 n.5, 5062/01/EN/Final WP 48 (Sept. 13, 2001) (“Examples of employment records usually involving the processing of personal data . . . [include] [p]ayroll and tax information . . . [a]nnual appraisal/assessment records, [and] [r]ecords relating to promoting, transfer, [t]raining, [and] disciplinary matters . . .”). Thus the material in the personnel files would appear to be covered by the German Data Protection Act.

Two obstacles impact the production of employee personal data for purposes of compliance with United States discovery procedures. EC Directive 95 places restrictions on both the transfer of personal data to countries outside the EU as well as on the purpose for which personal data may be used. See *Opinion 8/2001 on the Processing of Personal Data in the Employment Context, supra*, at 26. The transfer restriction appears in Article 25 of the EC Directive, and the purpose restrictions appear in Articles 6, 7, and 8. Council Directive 95/46, art. 6–8, 25, 1995 O.J. (L 281).

In harmony with EC Directive 95, the German Data Protection Act also places restrictions on both the international transfer of personal data (“the transfer restriction”) as well

² The direct translation of “Bundesdatenschutzgesetz” is “Federal Data Protection Act.” For the sake of

as the purposes for which collected personal data may be used (“the purpose restriction”). *See Förster, supra*, at 119. The transfer restriction is contained in section 4b of the Act, and provides that “Transfer shall not be effected [to foreign bodies] in so far as the data subject has a legitimate interest in excluding transfer, in particular if an adequate level of data protection is not guaranteed at the bodies stated in the first sentence of this sub-section.” BDSG § 4b(2). Enumerated exceptions to the transfer restriction are contained in section 4c of the Act. In turn, the purpose restriction is located in section 28 of the Act.

“The . . . use [of personal data] as a means of fulfilling one’s own business purposes shall be admissible . . . in so far as this is necessary to safeguard justified interests of the controller of the filing system and there is no reason to assume that the data subject has an overriding legitimate interest in his data being excluded from processing or use”³

BDSG § 28(1). Exceptions to the purpose restriction are also found in section 28.

Upon review of the transfer and purpose restrictions as well as their applicable exceptions, the Court identifies two possible legal mechanisms⁴ which may allow for the disclosure of the at-issue personnel files. Both data subject consent and the dual use of the “legal claims” and “justified interests of the controller” exceptions may allow for the litigation-related transfers at issue.

The first mechanism, data subject consent, is an exception found in section 4(c)(1)(1) of the German Data Protection Act. Under this provision, the written consent of the data subject is sufficient to negate both the transfer and purpose limitations of the Act. BDSG 4(c)(1)(1); *see also Förster, supra*, at 119–20. This exception is the simplest of the available options, but it also

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

³ Section 28(1)’s reference to transfers generally is not to be confused with the distinct restrictions on international transfers found in section 4(b)(2). BDSG §§ 4(b)(2), 28(1).

⁴ The Court finds that section 4(c)(2)’s “adequate level of protection” exception does not provide a viable method for avoiding conflict with the German Data Protection Act in this case. BDSG § 4(c)(2). This exception cannot be satisfied by a mere protective order—only a “competent [German] supervisory authority” may certify that

hinges on matters outside of the data holder’s control.

The second mechanism uses the “legal claims” exception of section 4(c)(1)(4) to nullify the transfer restriction, and the “justified interests of the controller” exception found in section 28(1)(2) to overcome the purpose restriction. Both Bayer and its German law expert concede that the “legal claims” exception is applicable to the instant matter.⁵ *See* R. 3146 at 10, 3146-1 at 6–7. Thus, only the “justified interests of the controller” exception must be examined in detail. Section 28(1)(2) provides that:

“The collection, storage, modification, or transfer of personal data . . . shall be admissible . . . insofar as this is necessary to safeguard justified interests of the controller of the filing system and there is no reason to assume that the data subject has an overriding legitimate interest in his data being excluded from processing or use”⁶

BDSG 28(1)(2). Thus, under this exception, two matters are at issue: (1) the processing and transfer of the data must be necessary to safeguard a legitimate interest of the data controller; and (2) the data subject must not have an overriding legitimate interest in preventing processing or

this level of protection exists. BDSG § 4(c)(2); *see also* Förster, *supra*, at 121–22.

⁵ Despite the plain language of the legal requirement exception, some argue that an obligation to produce protected data pursuant to a United States discovery order does not qualify as “legally required.” BDSG 4(c)(1)(1). Germany may not consider compliance with an unrecognized, foreign discovery practice to be “legally required” under the terms of its own narrow discovery laws. *See* Förster, *supra*, at 120–22. The Data Protection Working Party also concludes that “legally required” transfers pursuant to EC Directive 95 are those transfers required by an EU domestic transferor state (Germany) rather than by a foreign transferee state (the United States). The Court does not find these arguments persuasive. The plain meaning of “defense of legal claims” does not exclude international claims, and the German Data Protection Act contemplates international transfers throughout its text. Further, if the exception did not apply, the burden on international discovery would be excessive. In this litigation alone, over 1.1 million discovery documents have been produced pursuant to section (4)(c)(1)(4). A *Société Nationale* comity analysis would not look favorably upon such a weighty bar to discovery.

⁶ Section 32 of the German Data Protection Act, entitled “Data Collection, Processing, and Use for Employment-related Purposes,” does not supersede the exceptions in section 28. Moelle concedes this point in his affidavit. R. 3146-1 at 7–8. Section 32 governs the processing and use of employee personal data for employment-related purposes. Section 32 does not prevent the use of employee personal data for commercial purposes under appropriate circumstances, which is governed by section 28. “[Section 32] does not *per se* exclude the possibility that, under the circumstances of an individual case, a processing of certain personal data contained in the Personnel Records may be justified for a legitimate purpose of the employer outside the employment relationship.” R. 3146-1 at 8; *see also* *Beschlussempfehlung und Bericht des Innenausschusses, Deutscher Bundestag: Drucksache [BT] 16/13657*, <http://dip21.bundestag.de/dip21/btd/16/136/1613657.pdf> (Ger.); Franz-Josef Düwell, *Das Gesetz zur Änderung datenschutzrechtlicher Vorschriften*, Neues Aus Der Gesetzgebung, Aug. 14, 2009, http://www.hss.de/fileadmin/media/downloads/Berichte/09-9_FA_Gesetzgebung.pdf (discussing the effects of the

transfer. Bayer’s German law expert describes this exception as a balancing test. R. 3146-1 at 7–9. The Data Protection Working Party provides support for this interpretation; the corresponding component of EC Directive 95 is also characterized as a balancing test. *See* Opinion 8/2001 on the Processing of Personal Data in the Employment Context, *supra*, at 5 (citing Council Directive 95/46, art. 7.f, 1995 O.J. (L 281)).

B. Analysis of the Potential Conflict between the German Data Protection Act and the Federal Rules of Civil Procedure

If Defendants may release the German personnel files without violating the German Data Protection Act, then there is no conflict with the Federal Rules of Civil Procedure. The Court therefore must first determine whether the personnel files contain “personal data,” and if any exceptions allowing for disclosure apply in the present circumstances.

i. The Presence of Personal Data

The Court has had an opportunity to review the privilege log. Despite the PSC’s assertion to the contrary, at least some of the information in the sought personnel files qualifies as personal data for purposes of the German Data Protection Act. The personnel files contain objective personal data such as the deponents’ salary information, job titles, and email addresses. The personnel files also contain subjective personal data such as performance reviews, evaluations for promotion, and the data subject’s own self-assessments. Both objective and subjective personal data are protected under the Act. *See* Förster, *supra*, at 118–19; *Opinion 4/2007 on the Concept of Personal Data, supra*, at 6. Therefore, unless an exception applies, the German Data Protection Act and the Federal Rules of Civil Procedure are in conflict.

ii. Consent of the Data Subject

The German Data Protection Act allows for the processing and transfer of information

2009 amendments on section 28 of the BDSG).

by a data holder with the consent of the data subject. BDSG, § 4(a). However, “[c]onsent shall be effective only when based on the data subject’s free decision. Data subjects shall be informed of the purpose of collection, processing or use and, in so far as the circumstances of the individual case dictate or upon request, of the consequences of withholding consent.” *Id.* There is no indication in the record that any party has sought the consent of the specific Bayer employees at issue in this matter.

The Defendants’ German law expert, Henning Moelle, takes the position that German employers may not ask an employee to grant their consent. The Court finds Moelle’s interpretation unpersuasive. Under the BDSG, an employer may not request consent in a manner that impedes the ability of the data subject to make a “free decision.” *Id.* However, aside from Moelle’s ipse dixit, no document before the Court suggests that a mere request for consent overrides the capacity of an employee to make a free decision for purposes of section 4a. On the contrary, the text of the German Data Protect Act provides safeguards and procedures for requesting consent. The data subject must be informed of the proposed use of the data and the consequences, if any, of withholding consent. *Id.* The consent must be given in writing. *Id.* And, most importantly, the data subject’s choice to consent must be a “free decision,” i.e., free of undue pressure. *See Opinion 8/2001 on the Processing of Personal Data in the Employment Context, supra*, at 23 (“If it is not possible for the worker to refuse it is not consent.”). These safeguards are adequate to provide for meaningful consent in the context of the employer-employee relationship. The German parliament has also suggested in committee reports that employees may consent to the transfer of their personal data under the proper circumstances. *See Beschlussempfehlung und Bericht des Innenausschusses, Deutscher Bundestag: Drucksache [BT] 16/13657*, <http://dip21.bundestag.de/dip21/btd/16/136/1613657.pdf> (Ger.).

Drs. Frank Misselwitz and Dagmar Kubitzka are sophisticated, high-level employees of a

pharmaceutical company. They are capable of meaningfully providing consent for the purposes of the German Data Protection Act in the context of this litigation. *See Pershing*, 2013 WL 941617, at *9 (“[Defendant] can, and allegedly has begun to, obtain consent of its [German] employees for disclosure of documents containing the personal information.”). Therefore, the Court finds that a good faith request for data subject consent is appropriate under Bayer’s discovery obligations. If the deponents refuse to consent to such disclosures, this may raise credibility issues or at least serve as a basis for such an argument.

iii. Exceptions to the Transfer and Purpose Restrictions on Personal Data

Because the PSC seeks the international transfer of personal data, the German Data Protection Act will block unconsented production unless exceptions exist to both section 4(b)’s transfer restriction and section 28’s purpose restriction. *See Förster, supra*, at 117–20. The former exception is easily met. As the Defendants concede, they may transfer data pursuant to section 4(c)(1)(4) “for the establishment, exercise or defense of legal claims.” The Court agrees with this interpretation of German law. However, the purpose restriction requires a more in-depth discussion.

The PSC seeks the production of employee personal data for commercial purposes. Section 28(1) of the German Data Protection Act provides a few exceptions to the general proposition that personal data may only be used for the purpose for which it was collected. Of the enumerated exceptions, the Court finds that section 28(1)(2) provides the only plausible candidate for the lawful unconsented transfer of personal data under the Act. Section 28(1)(2) allows for the use of employment-related personal data for commercial purposes if such use “is necessary to safeguard justified interests of the controller . . . and there is no reason to assume that the data subject has an overriding legitimate interest in his data being excluded from processing or use.” BDSG, § 28(1)(2). Bayer’s German law expert concedes that Bayer has a

“generally legitimate interest,” R. 3146-1 at 7, so the Court must determine whether the data subject’s interests in privacy override Bayer’s interest in compliance with foreign discovery practices.⁷

German employees possess a presumptively legitimate interest in the nondisclosure of personal data to residents of countries with non-equivalent personal data protection standards. *See In re Vitamins Antitrust Litig.*, No. 99-197TFH, 2001 WL 1049433, at *9 (D.D.C. June 20, 2001). The Court cannot unilaterally certify that its data protection orders are sufficient to meet the standards of German law. The German governmental entity responsible for determining whether a receiving entity affords an “adequate level of protection,” the Bundesbeauftragte für den Datenschutz und die Informationsfreiheit, has not given an opinion regarding this Court’s Pretrial Order. BDSG, § 4(c)(2). The European Commission has certified that some non-EU countries provide adequate levels of protection under EC Directive 95, but the United States does not currently qualify. *See Förster, supra*, at 121–22. Therefore, the presumption in favor of the privacy interests of Drs. Misselwitz and Kubitza stands.

Germany has expressed heightened concerns for the personal data interests of employees. The German Constitution contains a “right to informational self-determination.” *In re: Census Act*, 30 BVerfGE 1, 42–43 (Dec. 15, 1983). *But see In re Vitamins*, 2001 WL 1049433, at *7 n.12 (finding that the right to informational self-determination embodied in the German constitution does not exceed the privacy rights codified in the BDSG). The German parliament addressed this value in the context of the employer-employee relationship in 2009.

⁷ Upon review of the German Data Protection Act and the relevant secondary sources, the Court finds that German law does not recognize a procedural distinction between the production of personnel files and custodial files. Contrary to the Defendants’ assertion, custodial files containing personal data must meet the same exceptions under the German Data Protection Act as personnel files containing personal data. There is only one meaningful distinction between the two categories outside of section 32 of the BDSG: the nature of personnel files suggests that they will, on the whole, contain more sensitive personal data than custodial files. An employee’s work-related emails will raise fewer privacy concerns than his or her health records, salary information, and performance reviews. For this reason, custodial files may be transferred en masse pursuant to sections 4(b) and 28(1)(2) of the German

Responding to data protection scandals involving a number of large corporations, the German parliament amended the German Data Protection Act to strengthen employee rights regarding the usage of their personal data. See Franz-Josef Düwell, *Das Gesetz zur Änderung datenschutzrechtlicher Vorschriften*, Neues Aus Der Gesetzgebung, Aug. 14, 2009, http://www.hss.de/fileadmin/media/downloads/Berichte/09-9_FA_Gesetzgebung.pdf. While this amendment does not directly change the applicability of the section 28(1)(2) exception,⁸ it further supports the notion that German law recognizes heightened privacy interests for personal data collected in the employment context. Lastly, while the German government has been silent in this litigation, the Court finds it highly significant that the Federal Republic of Germany submitted an *amicus curiae* brief urging the *Vitamins* court to defer to Germany's privacy laws and prevent the disclosure of "employee discharge, discipline, suspension, termination, and retirement records." *In re Vitamins*, 2001 WL 1049433, at *6; see also *Volkswagen, A.G. v. Valez*, 909 S.W.2d. 900, 903 (Tex. 1995) (finding it relevant that Germany filed an *amicus curiae* brief arguing that its interests would be undermined if Volkswagen were forced to produce personal data in a corporate telephone book). The German government's efforts to intercede on behalf of German employee privacy interests, as well as the text of the German Constitution and recent amendments to the German Data Protection Act, indicate that the Court should as a matter of comity vigilantly safeguard a German employee's interest in the nondisclosure of personal information.

When considering the aforementioned privacy interests, as well as the German

Data Protection Act.

⁸ To quote the PSC, "Personnel files are not the test; personal data is." R. 3173-1 at 4. Section 32 of the German Data Protection Act regulates some aspects of personal data collected in the scope of the employer-employee relationship. However, even the Defendants' German law expert concedes that "[t]his does not *per se* exclude the possibility that, under the circumstances of an individual case, a processing of certain personal data contained in the Personnel Records may be justified for a legitimate purpose of the employment relationship [as provided for by section 28(1)(2)]." R. 3146-1 at 8.

government's repeated efforts to support and strengthen protections for personal data in the employment context, the Court finds that the wholesale production of the personnel files to the PSC would violate the German Data Protection Act. The transfer restriction of section 4(b) is satisfied by the "defence of legal claims" exception of section 4(c)(1)(4). However, there is no viable exception to the Act's purpose restriction. *See* BDSG § 28(1). Bayer has a "justified interest" in promoting its legal defense by complying with United States discovery procedures, but this interest fails to override Dr. Kubitzka and Dr. Misselwitz's weighty interests in informational self-determination. *See* BDSG § 28(1)(2). Because the purpose restriction is not satisfied, production under these circumstances would violate German law. Thus there is a clear conflict between the federal discovery rules and the German Data Protection Act.

C. Analysis of the *Société Nationale* Factors

Having found a conflict between a German "blocking statute" and the Federal Rules of Civil Procedure, the Court must now perform a *Société Nationale* comity analysis.

i. The Sought Information and the Privacy Logs

Before turning to the factors of the balancing test, the Court finds it appropriate to frame the PSC's request alongside Bayer's privacy logs of the personnel files. The PSC seeks "performance reviews and self-reviews, and compensation, incentive and bonus information for the purpose of evaluating each witness's credibility and potential bias." R. 2951-1 at 3. The PSC also contends that the personnel files are relevant to its "rush to the market" theory of liability, and "will provide Bayer's internal assessment and valuation of these employees' contributions, as well as reflect the challenges and motivations Bayer faced in bringing Xarelto to market without a monitoring requirement and with a once-daily dosing regimen." R. 2951-1 at 3. At times, it also appears that the PSC views the personnel files as a document review shortcut. "Stated simply, this information will point Plaintiffs to those areas of inquiry—both in

document review and in preparing for and following up on the depositions of Drs. Misselwitz and Kubitzka—which are most important and likely to lead to the discovery of relevant evidence” R. 2951-1 at 4.

The Court has extensively reviewed the privacy logs, the Declaration of Gudrun Lohkamp, Head of Bayer’s German Human Resources Department, and the exemplar personnel files attached to Lohkamp’s Declaration. R. 3384-1, 3384-2, 3384-3. However, the Court finds that its understanding of the privacy interests at stake would be greatly improved by an *in camera* review of the personnel files. The Court therefore turns to the question of whether the United States’ interest in the *in camera* review of the personnel files as bounded by the PSC’s asserted rationale for production outweighs Germany’s interests in protecting data subjects from the privacy concerns raised by *in camera* review.

ii. Application of the Standard

At the outset, the Court finds that the five factors of the Third Restatement provide the applicable framework for the present comity analysis. The Court is cognizant of the Fifth Circuit’s command that “[a] district court is only directed to determine whether [foreign discovery procedures] are appropriate after ‘scrutiny in each case of the particular facts, sovereign interests, and likelihood that resort to these procedures would prove effective.’” *In re Anschuetz & Co., GmbH*, 838 F.2d 1362, 1364 (5th Cir. 1988) (quoting *Société Nationale*, 357 U.S. at 545). District courts in the Fifth Circuit have consistently implemented this command by applying the five factors of the Third Restatement. *See S.E.C. v. Stanford Int’l Bank, Ltd.*, 776 F. Supp. 2d 323, 330 (N.D. Tex. 2011); *Seoul Semiconductor Co. v. Nichia Corp.*, 590 F. Supp. 2d 832, 834 (E.D. Tex. 2008); *Adams v. Unione Mediterranea Di Sicurta*, No. 94-1954, 2002 WL 272252, at *2–3 (E.D. La. Mar. 28, 2002). The Court joins these opinions. The five factors of the Third Restatement flesh out the Supreme Court’s language in *Société Nationale*, and are

applicable to the present matter.⁹

1. The Importance of the Requested Discovery to the Litigation

Jurists evaluating the “importance” of the requested discovery to the litigation have offered different formulations of the “importance” prong. Some circuits articulate an exceedingly high bar. For instance, the Ninth Circuit hesitates to compel production unless the outcome of litigation “stand[s] or fall[s] on the present discovery order.” *Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468, 1475, (9th Cir. 1992) (quoting *In re Westinghouse Elec. Corp. Uranium Contracts Litig.*, 563 F.2d 992, 999 (10th Cir. 1977)). Courts in the District of Columbia evaluate whether the sought materials are “absolutely essential” to the case. *In re Vitamins Antitrust Litig.*, No. 99-197TFH, 2001 WL 1049433, at *9 (D.D.C. June 20, 2001). The Fifth Circuit has not provided guidance regarding the degree of “importance” necessary to assuage comity concerns under *Société Nationale*, but the Eastern District of Texas has used language suggesting that the sought evidence must “be critical or compelling.” *Seoul Semiconductor Co. v. Nichia Corp.*, 590 F. Supp. 2d 832, 835 (E.D. Tex. 2008). The Court finds it appropriate to rely on in-circuit persuasive authority, and accordingly shall determine whether the PSC seeks “critical or compelling” evidence in its discovery request. *Id.*

The PSC essentially requests the following: evidence of employee bias due to high rates of compensation, evidence that Xarelto was rushed to the market, evidence of Bayer’s assessments of employees on the Xarelto team, and evidence that will better prepare the PSC for

⁹ The Court does not consider the five factors of the Third Restatement to be exhaustive. The Court is mindful that the Fifth Circuit chose not to adopt the Third Restatement standard wholesale. More importantly, the *Société Nationale* Court declined to “articulate specific rules to guide this delicate task of adjudication,” in the same opinion in which it favorably cited the Third Restatement. *See Société Nationale*, 482 U.S. at 544 n. 28, 446. If the Supreme Court had intended the Third Restatement to be the definitive mechanism for “scrutiny in each case of the particular facts, sovereign interests, and likelihood that resort to [foreign discovery procedures] would prove effective,” the Court would have adopted the Restatement rather than citing it in a footnote. Therefore, the use of additional factors may be prudent under appropriate circumstances. *See, e.g., 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) (applying the Third Restatement as well as two additional factors); *S.E.C. v. Stanford Int’l Bank, Ltd.*, 776 F. Supp. 2d 323, 330

information which may be gleaned from document review and deposition. Turning to applicable precedent, the PSC's request for the production of evidence relevant to a "rush to the market" theory of liability is comparable to other cases where courts compelled the disclosure of foreign discovery materials. For example, in *In re Vitamins*, a district court was asked to produce German "employee discharge, discipline, suspension, termination, and retirement records." *In re Vitamins Antitrust Litig.*, No. 99-197TFH, 2001 WL 1049433, at *9 (D.D.C. June 20, 2001). The Plaintiffs asserted that the documents were necessary "to identify and question key conspirators and . . . to identify and elucidate the substance of meetings with competitors and to determine how defendants dealt with conspirator-employees." *Id.* at *8. The district court found that the files were highly relevant in this context. *Id.* The PSC's request for personnel files is similar. Evidence of how Bayer management "dealt with" Drs. Misselwitz and Kubitza is best gleaned from the personnel files, and this information is crucial to the PSC's theory of the case. *Id.* at *8. Guided by the holding in *In re Vitamins*, the Court finds that the first factor weighs in favor of disclosing files containing Bayer's assessment of its employees.

Pershing, cited by the PSC, is also similar to the PSC's request. *Pershing Pacific West, LLC v. MarineMax, Inc.*, Civ. No. 10-cv-1345-L (DHB), 2013 WL 941617 (S.D. Cal. Mar. 11, 2013). In *Pershing*, the plaintiffs sought rescission and damages stemming from the sale of a yacht that was allegedly defective at the time of sale. *Id.* at *1. The plaintiffs moved for the discovery of documents relating to vessels with similar engines and fuel delivery systems that were also sold by the defendant. *Id.* The defendant argued that a German blocking statute prevented disclosure, and that the information was not relevant. The district court resolved the dispute by applying the factors of the Third Restatement, and found that the first factor, the importance of the documents to the litigation, weighed in favor of disclosure. *Id.* at *7. The

(N.D. Tex. 2011).

court justified its holding by noting that “courts have often permitted a showing that, under similar circumstances, similar products manufactured or sold by the defendant have had similar failures to the product at issue.” *Id.* So too here. The PSC contends that the personnel files at issue may contain highly probative evidence that Xarelto was rushed to the market. This evidence is typically admitted in products liability cases such as the one at bar, because it may be the linchpin of the case. Therefore, as in *Pershing*, this type of evidence is critical and compelling.

The Court is skeptical of the PSC’s search for bias evidence in the personnel files. Even without evidence of compensation, skilled practitioners may find other mechanisms to suggest that a high-ranking employee of an international pharmaceutical company may be biased in favor of his or her employer. As for the PSC’s argument that the personnel files will provide for more efficient document review and depositions, these interests fall far short of the “critical or compelling” showing required by the first prong of the comity analysis. *See Seoul*, 590 F. Supp. 2d at 835.

In sum, the Court finds that some materials in the personnel files may provide critical evidence in support of the PSC’s claims that Xarelto was rushed to the market. The Court is hesitant to deny *in camera* review when the files may contain evidence of a skewed bonus compensation scheme or disciplinary files chastising guarded approaches to research and development. This type of critical information would be relevant to a finding of compelling support of the PSC’s theory of the case. Therefore, the first factor of the comity analysis weighs in favor of the *in camera* production of files containing information relevant to performance evaluations, short term incentive programs, and one-time bonuses.

2. The Degree of Specificity of the Request

The PSC’s requests are highly specific. The personnel files of a limited number of

Bayer employees are at issue. The PSC does not seek the entirety of the personnel files—the PSC instead requests the production of easily identifiable materials from the witnesses’ personnel files such as “Xarelto-related performance reviews and self-reviews, and compensation, incentive and bonus information.” R. 2951-1 at 3. The Defendants respond that they fear that production of the personnel files would lead to a “massive personal-data dump.” R. 3146 at 11. But this specter of invasive American discovery is unfounded. The Court has taken, and continues to take, all procedural efforts possible to individualize the production of the PSC’s already-specific request. The *in camera* production of the personnel files at issue is another safeguard of specificity. *See In re Vitamins*, 2001 WL 1049433, at *9. Bayer presents no persuasive argument to the contrary, such as a claim that it would be burdensome to determine which documents in the personnel files comply with the PSC’s request. *See Richmark*, 959 F.2d 1468 at 1475. For these reasons, the Court finds that this factor also weighs in favor of production.

3. Whether the Information Originated in the United States

All of the documents at issue originated outside of the United States. The documents were produced by a German entity, Bayer. The compensation information and performance evaluations of German employees are contained within the documents. And, most importantly, the documents were created in the ordinary course of business in a country that grants extensive protection to the personal data of its employees. Thus, this factor weighs against production. *See In re Baycol Prod. Litig.*, No. MDL1431, 2003 WL 22023449, at *6 (D. Minn. Mar. 21, 2003).

However, the Court concludes that this factor carries limited weight. Defendant Bayer voluntarily entered into a commercial partnership with an American corporation, Janssen. Bayer significantly benefited from availing itself of United States markets. Xarelto is sold and used

extensively in the United States, so the personnel files of the German Xarelto team have developed a somewhat international flavor. Bayer should not be caught unawares on this point—Bayer first contested the production of German personnel files in the *Baycol* litigation in 2003. *See id.* In sum, while the flow of personal data to the United States is highly contested, the transfer of blockbuster profits to Germany continues unabated. The balancing of this factor deserves minimal weight.

4. The Availability of Alternative Means of Securing the Information

The PSC's request is inappropriate "if the information sought can easily be obtained elsewhere." *Pershing*, 2013 WL 941617, at *8 (quoting *Richmark*, 959 F.2d at 1475). The Court adopts the Ninth Circuit's formulation of this factor, and finds that the alternative means "must be substantially equivalent" to the requested discovery. *Id.* This articulation conforms to in-circuit precedent. *See Seoul*, 590 F. Supp. 2d at 835 (finding a viable alternative means of securing information where defendants sought one deponent, and another accessible deponent could provide the same information).

The PSC seeks evidence of employee bias as well as information suggesting that Xarelto was rushed to the market. R. 2951-1 at 3–4. The PSC also believes that the personnel files will lead to more efficient document review and depositions. R. 2951-1 at 4. Only the rush to the market evidence is cognizable under this factor. The PSC possesses no other viable method of uncovering evidence of rush to the market liability that may be contained in the personnel files. The quantity of documents already held by the PSC is irrelevant. "[T]he focus is whether the documents, if relevant, can be obtained from another source." *Brightedge*, 2014 WL 3965062, at *5; *see also Pershing*, 2013 WL 941617, at *8. Bayer holds the personnel files at issue, and they may contain highly probative materials. Accordingly, to the extent that the PSC seeks evidence

of rush to the market liability in materials such as performance evaluations and bonus compensation documents, this factor weighs in favor of an *in camera* review to better weigh the interests at issue.

In contrast, the bias and employee evaluation evidence sought by the PSC should be obtainable through depositions. *See In re Baycol Prod. Litig.*, No. MDL1431, 2003 WL 22023449, at *6 (D. Minn. Mar. 21, 2003) (“Nor can Plaintiffs show that they cannot otherwise obtain the information they need, as they may ask the Bayer A.G. employees for the information they seek in depositions.”). However, the Court notes that deponents have refused to provide salary information in at least one deposition. *See* R. 3146-1 at 29. The PSC has not presented sufficient information for the Court to conclude that the salary information is unobtainable by deposition, but the Court finds troubling the possibility of further evasive responses by deponents and weighs this possibility accordingly. As to the efficiency of document review and deposition preparation, the PSC fails to show that the 1.1 million documents already produced by Bayer in this litigation cannot satisfy their interest in devising efficient document review and deposition strategies.

5. The Balancing of National Interests

As befits a comity analysis, the balancing of national interests carries the most weight. *See Richmark*, 959 F.2d at 1476. The interests of the foreign state may be signified by “expressions of interest by the foreign state,” “the significance of disclosure in the regulation . . . of the activity in question,” and “indications of the foreign state’s concern for confidentiality prior to the controversy.” *Richmark*, 959 F.2d at 1476 (citing Restatement (Third) of Foreign Relations Law § 442 cmt. c (Am. Law Inst. 1987)). American courts must also 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 Anschuetz & Co., GmbH*, 838 F.2d 1362, 1364 (5th Cir. 1988).

As discussed *supra* in the context of the applicability of the German Data Protection Act to the present discovery request, the Court finds that Germany has a weighty national interest in protecting the personal data of German citizens in their capacity as employees. The German Constitution contains a general “right to informational self-determination.” *In re: Census Act*, 30 BVerfGE 1, 42–43 (Dec. 15, 1983). Germany’s expressions of interest in employee privacy stretch back over fifteen years. In 2001, the Federal Republic of Germany addressed the matter presently before the Court by entering the *In re Vitamins* litigation. The foreign government submitted an *amicus curiae* brief urging the *Vitamins* court to defer to Germany’s privacy laws and prevent the disclosure of “employee discharge, discipline, suspension, termination, and retirement records.” *See In re Vitamins*, 2001 WL 1049433, at *6. More recently, in 2009 the German parliament amended the German Data Protection Act to provide greater protection to personal data collected for employment-related purposes. *See Franz-Josef Düwell, Das Gesetz zur Änderung datenschutzrechtlicher Vorschriften*, Neues Aus Der Gesetzgebung, Aug. 14, 2009, http://www.hss.de/fileadmin/media/downloads/Berichte/09-9_FA_Gesetzgebung.pdf.

Still, these interests are limited. The presence of a clearly compelling state interest such as national security or state secrecy weighs most heavily under this factor. *See Seoul*, 490 F. Supp. 2d at 836–37 (finding significant foreign national interests where the discovery request implicated a citizen who was employed by an agency of a foreign government); *see also Richmark*, 959 F.2d at 1477; *Reinsurance Co. of Am., Inc. v. Administratia Asigurarilor de Stat (Admin. Of State Ins.)*, 902 F.2d 1275, 1280 (7th Cir. 1990). While Germany may have an unusually strong interest in protecting the personal data of its citizens, the quantity and character of the personal data at issue partially mitigates these concerns. The personnel files of a small number of German citizens are at issue. The Court imposed meaningful protective measures to

ensure the confidential status of produced data. Many irrelevant categories of personal data such as addresses, health information, and biometric data may be redacted prior to transfer. As a matter of judicial comity, Germany may recognize the United States judiciary's interest in personally reviewing at-issue personal data before ruling whether the balance of the equities weighs for or against production. *See Société Nationale*, 482 U.S. at 544 n.28 (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"). And, if eventually produced, evidentiary hurdles such as Rules 401 and 403 of the Federal Rules of Evidence will prevent the admissibility of irrelevant or unduly prejudicial information at trial. Under these circumstances, Germany's interest in nonproduction is inherently curtailed.

The criminal and civil penalties contained in the German Data Protection Act are also relevant to this analysis. In order for the prospect of criminal or civil penalties to weigh in favor of non-disclosure, the possibility of enforcement by the foreign nation must be more than "slight or speculative." *BrightEdge*, 2014 WL 3965062, at *5 (quoting *NML Capital, Ltd. v. Republic of Arg.*, No. 03 Civ. 8845 (TPG), 2013 WL 491522, at *11). Defendants carry the burden of providing evidence that Germany has enforced the German Data Protection Act when German personal data has been produced pursuant to a United States court order. *See Gucci Am., Inc. v. Curveal Fashion*, 2010 WL 808639, at *7 (S.D.N.Y. Mar. 8, 2010) (citing *Minpeco S.A. v. Conticommodity Servs. Inc.*, 116 F.R.D. 517, 526–27 (S.D.N.Y. 1987)). Bayer failed to meet this burden. When questioned at oral argument, counsel for Bayer failed to cite any examples of a German entity being civilly or criminally prosecuted for the production of personal data pursuant to a United States discovery order. The Court finds this telling, as United States courts have compelled the production of German personal data over the objection of counsel in the past. *See BrightEdge*, 2014 WL 3965062, at *5–6; *Pershing*, 2013 WL 941617, at *10; *In re Pradaxa*

(*Dabigatran Etexilate*) Prods. Liab. Litig., MDL No. 2385, 2014 U.S. Dist. LEXIS 10718 (S.D. Ill. Jan. 29, 2014) (ordering the production of name-redacted custodial files); *cf* Sant, *supra*, at 221 (“Foreign governments . . . have usually not punished companies that obey a U.S. court order and produce documents in violation of the law”). Thus, the interests of Germany appear to be strong, but short of overwhelming.

Turning to domestic interests, the United States has a substantial interest in “vindicating the rights of American plaintiffs.” *Pershing*, 2013 WL 941617, at *8 (citing *Richmark*, 949 F.2d at 1477). As this is a nationwide MDL, the rights of thousands of American citizens hinge on the timely production of materials that fall within the scope of the Federal Rules of Civil Procedure. The rights of the states and state court Xarelto plaintiffs are implicated as well. It is no secret that federal MDL proceedings may influence the resolution of cases outside of the federal courts. Short of the United States entering this litigation or matters of national security being at issue, few changes to the facts could result in greater United States interests in document production.

Some of the PSC’s asserted reasons for production raise greater United States interests than others. Materials that are “vital to the case-in-chief” produce more substantial national interests than ancillary materials. *See Reinsurance*, 902 F.2d at 1280. The PSC seeks documents such as performance evaluations and self-evaluations for the purpose of obtaining evidence that Xarelto was rushed to the market. The PSC also moves to produce the personnel files so that it may discover whether an aggressive bonus compensation scheme created incentives for Xarelto to be rushed to the market. Such evidence would certainly be relevant to the PSC’s case-in-chief.

However, the PSC also seeks the personnel files for less compelling reasons such as obtaining evidence of employee bias. This rationale for production raises weaker national interests. For example, evidence that a high-level employee of an international pharmaceutical

company is well-compensated supports a finding that the employee may be biased, but denying the production of such evidence would not lead to a grave domestic injustice. And to the extent that the PSC seeks the materials in order to more efficiently prepare for deposition and conduct document review, the United States' interest is at its nadir. The federal courts value the efficient and inexpensive resolution of disputes, *see* Fed. R. Civ. P. 1, but these interests pale in comparison to Germany's asserted interests in the protection of personal data.

After reviewing the interests of both Germany and the United States, the Court finds that Germany's interests outweigh the interests of the United States regarding the following categories: materials which may contain evidence of bias; (2) materials which may aid document review; and (3) materials which will better prepare the PSC for deposition. German law favors the privacy of German employees, and the German government proved its commitment to these rights by entering United States litigation numerous times. *See In re Vitamins*, 2001 WL 1049433, at *7; *Volkswagen, A.G. v. Valez*, 909 S.W.2d. 900, 903 (Tex. 1995). Pursuant to the Fifth Circuit's guidance in *Anschuetz*, 838 F.2d at 1364, the Court also considers the fact that Germany does not provide for pre-trial discovery, *see Zivilprozeßordnung* [ZPO] [German Rules of Civil Procedure], 1877, Reichsgesetzblatt [RGBl.], at 97, as amended, § 355 (Ger.), and that Germany may be offended by the breadth of the United States' asserted discovery interests.

However, Germany's interests cannot override the United States' interest in obtaining the discovery of evidence relevant to the PSC's case-in-chief when the claims of thousands of United States citizens hang in the balance. Simply put, Drs. Misselwitz and Kubitz's personnel files may contain some evidence relevant to the argument that Bayer management pressured or aggressively incentivized its employees to unsafely accelerate the Xarelto research and development timeline. The production of a relative handful of sensitive documents may be critical to a just outcome in this matter.

Germany's interests are also mitigated to the extent that this Court is merely conducting an *in camera* review of the personal data, and has already issued protective orders which take into account the strong foreign interests at issue. The Court may further limit intrusions on employee privacy by ordering the redaction of irrelevant personal data prior to transfer. With these safeguards in place, the United States may vindicate its interests without unduly disturbing German rights.

iii. Weighing the Factors

For the aforementioned reasons, the balance of the factors leans towards the production of personnel file materials containing evidence relevant to the argument that Xarelto was rushed to the market.¹⁰ Such evidence may be found in employee performance evaluations and files discussing short term incentive programs or one time bonuses. These documents may be decisive to the PSC's case, and the PSC lacks a viable alternative mechanism to uncover the records at issue. *In camera* review by the Court is proper pursuant to *Coughlin v. Lee*, 946 F.2d 1152, 1157–60 (5th Cir. 1991), and will ensure that only appropriate materials are produced.

D. Timeliness of the Request

The PSC has not waived its right to request portions of Dr. Kubitza's personnel files under Rule 26(b). The PSC may have declined to ask questions concerning the personnel files because they have encountered non-answers or incomplete answers to these questions in other depositions. *See* R. 3146-1 at 24–29. More importantly, declining to investigate a matter at deposition is not a waiver of the right to discoverable information under the plain language of

¹⁰ The Court notes that at least one deponent has evaded answering questions regarding salary information. *See* R. 3146-1 at 29. If this behavior persists, it may indicate that, contrary to *Baycol*, there is no alternative means for the PSC to obtain this evidence of bias. *See In re Baycol Prod. Litig.*, No. MDL 1431, 2003 WL 22023449, at *6 (D. Minn. Mar. 21, 2003) (“Nor can Plaintiffs show that they cannot otherwise obtain the information they need, as they may ask the Bayer A.G. employees for the information they seek in depositions.”). Presently the Court will not require the production of salary information in the personnel files. But if deponents continue to refuse to answer these questions without explanation as to cause, the Court may entertain a request to revisit the comity analysis.

Rule 26(b), and the Defendants point to no positive law that suggests otherwise. The PSC's request is therefore timely.

IV. CONCLUSION

For the aforementioned reasons, **IT IS ORDERED** that the PSC's Motion to Compel is **GRANTED IN PART AND DENIED IN PART**. The motion is **GRANTED** insofar as it requests *in camera* review of the following personnel files. The Court **DEFERS JUDGMENT** on the PSC's Motion to Compel insofar as it requests delivery of the personnel files to the PSC.

IT IS FURTHER ORDERED that Bayer shall produce the following documents from Dr. Kubitza's personnel file for *in camera* review on or before Wednesday, July 27, 2016: (1) all Performance Management Process forms for calendar years 2006–2016; (2) the April 1, 2015, information letter regarding short term incentives; (3) the April 1, 2016, information letter regarding short term incentives; (4) the April 1, 2016, merit increase information letter; (5) the November 29, 2005, application for one time payment, (6); the December 9, 2005, information letter regarding one time payment; (7) the February 21, 2008, information letter regarding one time payment; and the November 27, 2014, information letter regarding one time payment.

IT IS FURTHER ORDERED that Bayer shall produce the following documents from Dr. Misselwitz's personnel file for *in camera* review on or before Wednesday, July 27, 2016: (1) all Performance Management Process forms for calendar years 2006–2016; (2) the November 10, 2005, agreement on additional incentive opportunity¹¹; (3) all letters, applications, emails and screenshots identified in the privacy log regarding one time payments to Dr. Misselwitz; (4) the June 25, 2003, agreement regarding retention program; (5) the August 12, 2005, email regarding promotion; (6) the August 17, 2005, merit increase approval; (7) the December 22, 2005, email

¹¹ The privacy log indicates that Dr. Misselwitz's employment contract was modified twice within months of this agreement. The Court may order the production of the 2005 contract and its amendments following review of the substance of the 2005 agreement on additional incentive opportunity.

regarding merit increase; (8) the June-September 2007 emails and supporting documentation regarding salary proposal; (9) the September 3, 2007, approval of salary proposal; (10) the September 19, 2007, merit increase information letters; (11) the May 30, 2008, agreements on salary increase and additional incentives; (12) the April 2010 information letter regarding short term incentive (yearly bonus); (13) the May 2010 merit increase information letter; (14) the September 2011 merit increase information letter; (15) the June 2013 merit increase information letter; and (16) the July 2011, July 2012, and July 2013 notional salary increase notifications.

IT IS FURTHER ORDERED that prior to *in camera* production that Bayer shall redact all addresses, social security numbers, health information, biometric data, monthly or annual salary calculations, and pension information from the above-referenced personnel files.

IT IS FURTHER ORDERED that Bayer shall request that Dr. Kubitz and Dr. Misselwitz consent to the transfer and production of their personnel files. The request shall not through duress or other inappropriate means interfere with Dr. Kubitz and Dr. Misselwitz's ability to make a "free decision" as to their employee privacy rights. The request shall in all respects comply with the requirements of the German Data Protection Act. *See* BDSG, § 4(a).

New Orleans, Louisiana, this 20th day of July, 2016.


UNITED STATES DISTRICT JUDGE