UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA

ZIMMER, INC. d/b/a ZIMMER BIOMET,	)	
Plaintiff,	)	
v.	)	CAUSE NO.: 3:15-CV-583-TLS
INFORMATICA CORPORATION,	)	
Defendant.	)	

OPINION AND ORDER

The Plaintiff, Zimmer, Inc. d/b/a/ Zimmer Biomet, filed a Complaint against the Defendant, Informatica LLC, in the Circuit Court for Kosciusko County, Indiana, asserting causes of action for breach of contract, breach of express and implied warranties, fraud in the inducement of contract, negligent misrepresentation, violation of the Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5 et seq., constructive fraud, and unjust enrichment. The Defendant removed the state court action to this Court on grounds that federal question jurisdiction existed under 28 U.S.C. § 1331 because the action "aris[es] under the Constitution, laws, or treaties of the United States." Although the Complaint involves only state law claims, the Defendant maintains that those claims necessarily involve the resolution of a substantial, disputed question of federal law, namely the meaning and application of certain U.S. Food and Drug Administration (FDA) regulations.

This matter is before the Court on Zimmer, Inc.'s Motion to Remand Action to Kosciusko Circuit Court [ECF No. 16], filed on January 5, 2016. The Plaintiff contends that removal to federal court was not appropriate, and seeks to have this case remanded to the state court where it was originally filed. The parties have completed briefing, and the matter is ripe for

this Court's consideration.

COMPLAINT ALLEGATIONS

Zimmer develops and delivers musculoskeletal orthopedic devices and products. To satisfy FDA requirements that were issued in April 2014, Zimmer invited four software companies to submit proposals for a cost effective and reliable unique device identification (UDI) and master data management (MDM) solution for use in selling its orthopedic products. Informatica submitted a proposal, representing that it had the available systems and software to provide the requested UDI and MDM solutions. The two entities entered into an agreement (the Agreement) in June 2014 for Zimmer to license these solutions. The Agreement was accompanied by a Statement of Work that outlined the software and services that Informatica would provide to Zimmer pursuant to the Agreement. According to the Statement of Work, the project had three key requirements:

- All Zimmer medical devices will be labeled and/or marked and reported according to the multi-year, class-based FDA roll-out plan starting in 2014 and ending in 2020.
- The UDI will be transmitted to FDA accredited data pools known as the FDA Global Unique Device Identification Database (GUDID).
- A Master Data Management (MDM) system and interfaces to internal Zimmer systems will be provided.

(Compl. ¶ 18 (citing Statement of Work, ECF No. 6 at 11).) Zimmer alleges that these project requirements were necessary for it to satisfy the federal labeling and registering requirements, and for it to continue to sell its devices and products. The Statement of Work also identified certain high-level goals. It provided that the "MDM solution with configured workflow processes to master UDI data," would accomplish the following:

- Provide a Single Source of Truth for mastered data;
- Be scalable beyond initial [Zimmer] UDI needs for other MDM project;
- Utilize Configuration rather the Customization including workflows, integration, business rules that are developed via GUIs;
- Require new organizational roles-Data Stewards, Data Governance, [Zimmer Business Solutions] Support;
- Provide an external data upload to FDA and accredited industry databases;
- Support future acquisition activities; and
- Team closely with Informatica and TCS to leverage their knowledge and experience and to become capable in the configuration of the Informatica products.

(*Id.* ¶ 20 (citing Statement of Work, ECF No. 6 at 13).)

Zimmer alleges that Informatica made numerous representations regarding its UDI MDM solution, including that it would manage all changes to Zimmer's product data (Compl. ¶ 25), provide workflow processes to validate and submit necessary UDI information (*id.* ¶ 27), be compliant with the record keeping requirements of FDA 21 CFR part 11 (*id.* ¶ 28), be designed for scalability and high availability and support 1 billion records (*id.* ¶ 29), be based on a UDI solution template already in existence (*id.* ¶ 30), and include integrated workflow and task management capabilities (*id.* ¶ 31). Zimmer has paid Informatica over $3 million since the inception of the project. According to the Complaint, Informatica "failed to deliver and implement a working UDI MDM solution as represented to Zimmer." (*Id.* ¶ 32.)

Specifically, Informatica's solution "does not have the capability to capture electronic signatures so is not compliant with the record keeping requirements of FDA 21 CFR part 11" (*Id.* ¶ 36), it is not able to process 30,000 records, much less 1 billion (*id.* ¶ 38), and its integrated workflow and task management capabilities do not work (*id.* ¶ 39). Additionally, Informatica did

not have a UDI solution template, but created the template while working for Zimmer. According to Zimmer's Complaint, it continues to experience serious performance issues even with base UDI components, which require multiple daily resets.

Zimmer has sued Informatica on grounds that it misrepresented its capabilities, as well as its products, when it responded to Zimmer's request for proposal, and that it has breached its Agreement with Zimmer.

ANALYSIS

A. Federal Jurisdiction

"[A]ny civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending." 28 U.S.C.A. § 1441(a). The federal removal statute provides, in relevant part, that "[i]f at any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case shall be remanded." 28 U.S.C. § 1447(c); *see also Townsquare Media, Inc. v. Brill*, 652 F.3d 767, 768 (7th Cir. 2011).

Federal courts "are courts of limited jurisdiction and may only exercise jurisdiction where it is specifically authorized by federal statute." *Evers v. Astrue*, 536 F.3d 651, 657 (7th Cir. 2008) (internal citations omitted); *see also Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 552 (2005). A district court has original jurisdiction for all civil cases "arising under the Constitution, laws, or treaties of the United States," otherwise known as federal question jurisdiction. 28 U.S.C. § 1331. A district court also has original jurisdiction for all civil cases

where there is diversity of citizenship and where the matter in controversy exceeds a certain sum, 28 U.S.C. § 1332, but the parties agree that there is no diversity of citizenship between them.

Although federal question jurisdiction ordinarily requires a cause of action created by federal law, a narrow exception exists for "state-law claims that implicate significant federal issues." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005). The doctrine allows a federal court to "hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Id.* There is no "'single, precise, all-embracing' test for jurisdiction over federal issues embedded in state-law claims between nondiverse parties." *Id.* at 314. Considerations include whether there is a disputed federal issue, as well as whether exercising federal jurisdiction would be "consistent with congressional judgment about the sound division of labor between state and federal courts." *Id.* at 313. Therefore, federal jurisdiction over a state law claim will lie if four requirements are met: "a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn v. Minton*, 133 S. Ct. 1059, 1065 (2013); *Grable*, 545 U.S. at 314.

Informatica asserts that the Supreme Court's *Grable* standard is satisfied here "because the parties dispute whether the product that Informatica delivered satisfied FDA regulations." (Informatica's Opposition 3, ECF No. 19.) Informatica points to Zimmer's allegation that, although Informatica represented that its MDM solution was compliant with Part 11 record-keeping requirements (Compl. ¶ 28), the solution is not compliant because it cannot capture electronic signatures (*id.* ¶ 36). With respect to these allegations, Informatica provides the

following defense: Informatica acknowledges that § 4 of the Global Unique Device Identification Database (GUDID), Guidance for Industry and Food and Drug Administration Staff (Jun. 27, 2014) (GUDID Guidance), provides that "[i]t is the legal responsibility of the labeler (or data owner) to meet the records requirements for 21 CFR 830.360 and the requirements of 21 CFR 11." However, it submits that the FDA's GUDID Guidance also states that GUDID Structured Product Labeling (SPL) submissions, geared for high volume submitters, do not require a signature and that, "therefore, part 11 requirements specific to electronic signatures (21 CFR 11 Subpart C), do not apply." (GUDID Guidance § 4 at 31.) Informatica argues that "if [the] FDA interprets its regulations not to require electronic signatures for GUDID submission compliance, it does not matter whether the product had the ability to capture electronic signatures, or not." (Informatica's Opposition 4–5.) Accordingly, "[a] determination of whether Informatica breached its contract or made misrepresentations as Zimmer alleges hinges on the interpretation of the FDA's requirements for UDI compliance." (*Id.* at 5.)

Because the *Grable* standard for exercising federal jurisdiction is stringently applied, the Court is not persuaded that an actually disputed and substantial question of federal law supports subject matter jurisdiction over this case. Zimmer alleges that Informatica made misrepresentations and breached the parties' contract when it did not provide the software solution as agreed. One of the specific allegations is that Informatica represented that its UDI MDM solution was compliant with the record keeping requirements of 21 CFR Part 11, but that the solution was not compliant because it was not able to capture electronic signatures. Whether Zimmer was excused from capturing electronic signatures to be compliant with record keeping requirements appears to be one issue that may arise in this litigation. But it is just one of several

instances of contractual breach that Zimmer alleges. It is not the entire claim. The breach of contract claim is also predicated on conduct that is unrelated to any specific FDA reporting regulation. Likewise, Zimmer alleges a series of misrepresentations that are wholly independent of any requirements under the FDA regulations. Thus, the litigation does not "necessarily raise" an issue of federal law.

Even if resolution of the FDA's requirements is necessary to Zimmer's breach of contract case and is actually disputed on the merits, it is not substantial. "The substantiality inquiry under *Grable* looks . . . to the importance of the issue to the federal system as a whole." *Gunn*, 133 S. Ct. at 1066 (holding that it is not enough to meet the substantiality element "that the federal issue be significant to the particular parties in the immediate suit" because that will "*always* be true" when the state claim satisfies the separate inquiries of being necessarily raised and actually disputed). Applying this substantiality standard, the Court in *Gunn* concluded that a legal malpractice case could not be removed even though the question of whether the lawyers had provided competent patent law work could not be decided without considering the substance of the ex-client's contention that their former lawyers should have made particular patent-specific arguments.

The circumstances in *Grable*, which met the substantiality requirement, stand in contrast. There, the Internal Revenue Service had seized property from the plaintiff and sold it to satisfy the plaintiff's federal tax delinquency. 545 U.S. at 310–311. Five years later, the plaintiff filed a state law quiet title action against the third party that had purchased the property, alleging that the IRS had failed to comply with certain federally imposed notice requirements, so that the seizure and sale were invalid. *Id.*

> In holding that the case arose under federal law, [the Supreme Court in *Grable*] primarily focused not on the interests of the litigants themselves, but rather on the broader significance of the notice question for the Federal Government. [The Court] emphasized the Government's "strong interest" in being able to recover delinquent taxes through seizure and sale of property, which in turn "require[d] clear terms of notice to allow buyers . . . to satisfy themselves that the Service has touched the bases necessary for good title." The Government's "direct interest in the availability of a federal forum to vindicate its own administrative action" made the question 'an important issue of federal law that sensibly belong[ed] in a federal court."

Gunn, 133 S. Ct. at 1066 (citations omitted); *see also Empire Healthchoice Assur., Inc. v. McVeigh*, 547 U.S. 677 (2006) (noting that, in *Grable*, the only issue was whether Grable received notice under the applicable federal statute; thus, the only issue contested in *Grable* was a federal issue where "its resolution was both dispositive of the case and would be controlling in numerous other cases"); *see also Bennett v. Sw. Airlines Co.*, 484 F.3d 907, 910 (7th Cir. 2007) (describing *Grable* as holding that Grable's state law claim arose under federal law "because, apart from the procedural device (a quiet-title action), there was *nothing* in it but federal law, with the potential to affect the national government's revenues"). The Supreme Court has clarified that *Grable* should apply to a "slim category" of cases that would have a lasting impact on the law, not to cases that are "fact-bound and situation-specific." *Empire*, 547 U.S. at 701 (finding that the ultimate issue was not a discrete matter of federal law, but rather the share of the settlement owed to Empire under the insurance contract, for which there was no reason why the state court was not competent to apply whatever federal law was necessary).

In the Seventh Circuit, *Evergreen Square of Cudahy v. Wisconsin Housing and Economic Development Authority*, 776 F.3d 463 (7th Cir. 2015), represents the rare case where a breach of contract claim has met the *Grable* standard for federal jurisdiction. The court held that the case was distinguishable from a typical breach-of-contract case because the contract at issue was one

to which a federal agency "prescribes both the form and content." *Id.* at 468 (noting that a Housing Assistance Payments contract "must be approved by HUD and their terms are administered pursuant to federal laws and regulations"). Because the "only disputed issues involved the proper interpretation of Section 8 of HUD's implementing guidance" *id.* at 467, and the federal government had a strong interest in the issue that was being litigated nationwide by Section 8 property owners being decided according to uniform principles, *id.* at 468, the court found that the case fit "within the 'special and small category of cases' in which federal 'arising under' jurisdiction lies over a complaint raising state-law causes of action." *Id.* (quoting *Gunn*, 133 S. Ct. at 1064).

The Court does not find this case to be like the litigation in *Evergreen*, such that the Court should assume jurisdiction over the dispute. This case does not involve a "context-free inquiry into the meaning of federal law." *Bennett*, 484 F.3d at 910. The parties' Agreement has defined their obligations to each other, not FDA regulations or guidance documents. Generally, the rights and obligations under the parties' contract are governed by state law. *See Volt Info. Scis., Inc. v. Bd. of Trs.*, 489 U.S. 468, 474 (1989). Indiana courts recognize the freedom of parties to enter into contracts, and presume that contracts represent the freely bargained agreement of the parties. *Weaver v. Am. Oil Co.*, 276 N.E.2d 144, 147 (Ind. 1971). Under Indiana law, contracts are interpreted to ascertain and effectuate the intent of the parties as reasonably manifested in the agreement, and if the language of the contract is clear and unambiguous, it should be given its plain and ordinary meaning. *Reuille v. E.E. Brandenberger Constr., Inc.*, 888 N.E.2d 770, 771 (Ind. 2008). The determination of whether Informatica breached its Agreement with Zimmer is fact-bound and situation-specific. There is no reason a

state court cannot determine what the parties' Agreement required, even if it also involves some interpretation of FDA regulations. The FDA regulations did not actually prescribe the UDI MDM solution or the contract between the parties, as was true in *Evergreen*. Moreover, even if the interpretation of such regulations is an issue, it is not the only material issue, as it is not the sole basis for the allegation that the software solution Informatica provided was not as agreed or promised. In other words, Zimmer is not required to prove what the federal regulations require in order to prevail on its state law claims because even if Informatica provided a software solution that complied with a particular aspect of federal law, its solution could have still failed to meet the terms of the Agreement. Nor will the federal government be vitally concerned about the outcome of this litigation, as it was in *Grable* where an adverse outcome would have undercut its ability to collect taxes. While the new FDA regulations may be important to efforts to track medical devices, the particular provision at issue is not important to the federal system as a whole. Expanding federal-question jurisdiction to encompass this case would have an exponentially greater effect on the federal-state division of labor than the unusual circumstance present in *Grable*.

Because Informatica has not carried its burden to show that this case is properly before this Court, it must be remanded.

B. Costs and Expenses

Zimmer asserts that it is entitled to recover its costs and actual expenses, including attorney fees, under 28 U.S.C. § 1447(c) because Informatica's removal was improper. "Absent unusual circumstances, courts may award attorney's fees under § 1447(c) only where the

removing party lacked an objectively reasonable basis for seeking removal. Conversely, when an objectively reasonable basis exists, fees should be denied." *Martin v. Franklin Capital Corp.*, 126 S. Ct. 704, 711 (2005). While the Court does not ultimately agree with Informatica's arguments, it does not find them to be frivolous. This case does not involve unusual circumstances that would warrant an award of fees in light of Informatica's objectively reasonable basis for seeking removal.

CONCLUSION

For the reasons stated above, the Court GRANTS Zimmer, Inc.'s Motion to Remand Action to Kosciusko Circuit Court [ECF No. 16]. The Clerk is DIRECTED to REMAND this case to the Kosciusko Circuit Court, thereby closing the case here.

SO ORDERED on March 29, 2016.

s/ Theresa L. Springmann
THERESA L. SPRINGMANN
UNITED STATES DISTRICT COURT
FORT WAYNE DIVISION