

STATE OF NORTH CAROLINA
COUNTY OF DURHAM

IN THE GENERAL COURT OF JUSTICE
SUPERIOR COURT DIVISION
18 CVS 2313

CARDIORENTIS AG

Plaintiff,

v.

IQVIA LTD. and IQVIA RDS, INC.,

Defendant.

**ORDER & OPINION ON OPPOSITION
TO DESIGNATION**

1. THIS MATTER is before the Court on Plaintiff's Opposition to Notice of Designation ("Opposition"), requiring a determination of whether this case involves a material dispute regarding the use or performance of intellectual property, including pharmaceuticals, within the scope of N.C. Gen. Stat. § 7A-45.4(a)(5) ("Section 7A-45.4(a)(5)"). The Court concludes that this action falls within the scope of Section 7A-45.4(a)(5) and additionally within the scope of section 7A-45.4(b)(2) of the North Carolina General Statutes ("Section 7A-45.4(b)(2)"). Accordingly, this action is properly designated as a mandatory complex business case.

Robinson, Bradshaw, & Hinson, P.A. by J. Dickson Phillips III, Jonathan C. Krisko, Morgan P. Abbott and Hogan Lovells US LLP by Dennis H. Tracey III (pro hac vice) and Allison M. Wuertz (pro hac vice) for Plaintiff.

Brooks, Pierce, McLendon, Humphrey & Leonard, LLP by Charles F. Marshall, III, Charles E. Coble, and Shepard D. O'Connell for Defendants.

Gale, Chief Judge.

2. Plaintiff Cardiorentis AG ("Cardiorentis" or "Plaintiff") is a biopharmaceutical company based in Switzerland that develops products focused on

treating patients with acute heart failure. (Compl. ¶ 3, ECF No. 3.) Cardioentis developed Ularitide, a pharmaceutical treatment for acute decompensated heart failure. (Compl. ¶ 18.) Ularitide has not yet received regulatory approval.

3. Defendant IQVIA RDS, Inc., formerly known as Quintiles, Inc., is a North Carolina company, and Defendant IQVIA, Ltd., formerly known as Quintiles Ltd., is an English company (collectively, “Defendants”). (Compl. ¶¶ 12–13.) Defendants provide biopharmaceutical development and commercial outsourcing services. (Compl. ¶ 5.) Cardioentis hired Defendants to perform a clinical trial of Ularitide, which would be used to create the necessary data needed for regulatory approval. (Compl. ¶¶ 20–22.) The parties entered into a General Services Agreement, detailing the scope of services Defendants were to provide, and a Quality Agreement, specifying Defendants’ quality assurance function in relation to the clinical trial. (Compl. ¶¶ 22, 24.)

4. Cardioentis initiated this action on March 23, 2018, asserting multiple claims involving the central allegation that Defendants breached the contracts, as a result of which Cardioentis suffered damages, including an inability to secure necessary regulatory approval of Ularitide in various countries.

5. Defendants timely filed a Notice of Designation on April 24, 2018, contending that this action should be designated as a mandatory complex business case pursuant to Section 7A-45.4(a)(5) and Section 7A-45.4(b)(2). (See ECF No. 12.)

6. The case was designated as a mandatory complex business case by order of the Chief Justice and assigned to the Honorable Adam M. Conrad on April 25, 2018. (See ECF Nos. 1, 2.)

7. Plaintiff timely filed its Opposition on May 21, 2018, contending that the action does not raise any material issues related to a dispute involving intellectual property.

8. The parties have filed briefs advocating their respective positions, and the issue is ripe for determination.

9. Section 7A-45.4(a)(5) provides that a party may designate a case as a mandatory complex business case if the action involves a material issue related to “[d]isputes involving the ownership, use, license, lease, installation, or performance of intellectual property, including computer software, software applications, information technology and systems, data and data security, pharmaceuticals, biotechnology products, and bioscience technologies.” N.C. Gen. Stat. § 7A-45.4(a)(5) (2015). Designation of a case within the scope of Section 7A-45.4(a)(5) becomes mandatory if the amount in controversy equals or exceeds five million dollars (\$5,000,000). See N.C. Gen. Stat. § 7A-45.4(b)(2) (2015). If a case is governed by Section 7A-45.4(b)(2), any presiding superior court judge is required to stay the proceeding and order that the case be designated as a mandatory complex business case before proceeding further. N.C. Gen. Stat. § 7A-45.4(g) (2015).

10. Cardiorentis contends that Section 7A-45.4(a)(5) must be confined to “only those pharmaceutical cases centered on intellectual property rights in, or

intellectual property aspects of, pharmaceuticals,” and that this action “does not involve material ‘intellectual property’ issues” or the “use” or “performance” of pharmaceuticals. (Reply Supp. Opp’n Notice Designation ¶ 1.d, ECF No. 39; Opp’n Notice Designation 3, ECF No. 14.) Instead, Cardioentis contends that this action is merely “[a] contract dispute regarding the efficacy of a clinical trial and the intentional misrepresentation of its results—which have no bearing on the intellectual property components of the pharmaceutical.” (Reply Supp. Opp’n Notice Designation ¶ 4.c.)

11. Defendants contend that this action is properly designated because the disputes necessarily involve the “use” and “performance” of a pharmaceutical, explaining that Plaintiff’s claims assert that Defendants allowed ineligible users to ingest Ularitide and, as a result, did not sufficiently test the drug’s performance. (*See* Defs.’ Resp. Opp’n Notice Designation 2, ECF No. 16.) To challenge Plaintiff’s narrow statutory interpretation, Defendants rely on this Court’s prior holding that Section 7A-45.4(a)(5) does not require that an action involve “a dispute regarding ownership of the intellectual property or another dispute that may require application of principles of the body of law known as intellectual-property law.” *Se. Auto., Inc. v. Genuine Parts Co.*, No. 16 CVS 1186, 2016 NCBC LEXIS 63, at *9 (N.C. Super. Ct. Aug. 17, 2016). Rather, this Court held that Section 7A-45.4(a)(5) extends to disputes related to the use or performance of intellectual property that may be governed by more general law. *See id.* at *8–9.

12. The Court concludes that Section 7A-45.4(a)(5) is not as narrow as Plaintiff contends nor is it as expansive as Defendants contend. On the one hand, the Court agrees with Plaintiff's assertion that "all cases involving pharmaceuticals are not mandatory complex business cases." (Reply Supp. Opp'n Notice Designation ¶ 1.d.) But it disagrees with Plaintiff's contention that Section 7A-45.4(a)(5) requires that a dispute must revolve around specific intellectual property rights in a pharmaceutical. (See Reply Supp. Opp'n Notice Designation ¶ 1.d.) On the other hand, the Court agrees with Defendants that Section 7A-45.4(a)(5)'s inclusion of "use" and "performance" necessarily extends its scope beyond a determination of specific intellectual property rights in a pharmaceutical. (See Defs.' Resp. Opp'n Notice Designation 5–6.) But the Court disagrees with the suggestion that a claim related in any way to the use or performance of a pharmaceutical falls within the statute's purview.

13. When seeking to implement the legislature's intent, the Court must, if possible, harmonize each of the phrases within the statute. The Court concludes that it is clear that the statute classifies a pharmaceutical as embodying intellectual property. See N.C. Gen. Stat. § 7A-45.4(a)(5). It is equally clear that the legislature intended for certain cases involving the "use" or "performance" of pharmaceuticals to be properly designated as mandatory complex business cases. See N.C. Gen. Stat. § 7A-45.4(a)(5). However, the legislature expressly stated that designation does not extend to "actions for personal injury grounded in tort," which would include pharmaceutical products liability cases. N.C. Gen. Stat. § 7A-45.4(a)(h) (2015).

14. The Court concludes that the legislature intended for the use or performance upon which designation is to be based to be closely tied to the intellectual property aspects of the pharmaceutical. Stated otherwise, a case may be designated if it contains disputes involving the use or performance of pharmaceuticals, but only if such dispute is closely tied to the underlying intellectual property aspects of the pharmaceutical.

15. It is, however, difficult to define a bright line test to determine when a dispute is closely tied to the intellectual property aspects of a pharmaceutical. Rather, the determination requires an allegation-specific inquiry that will vary from case to case.

16. The Court concludes that the specific allegations of this case bring the dispute within the scope of Section 7A-45.4(a)(5) because the underlying disputes are clearly related to the use and performance of Ularitide and ultimately affect its value as intellectual property.

17. The parties executed the contracts at issue in an effort to obtain data necessary for Ularitide to be approved for use by the regulatory bodies in various countries. The clinical trials were necessary to test and prove the performance and efficacy of the drug before it could be approved for potential use. Plaintiff contends that Defendants' numerous breaches of the contracts resulted in data that cannot be used to demonstrate "the efficacy and safety of Ularitide." (Compl. ¶ 81.) At its core, the dispute involves issues materially related to Plaintiff's ability to use its intellectual property because satisfactory completion of the clinical trial was

necessary for regulatory approval and, therefore, for the successful commercialization and marketing of Ularitide. Those issues have a sufficient nexus to the intellectual property aspects of the pharmaceutical to cause this action to fall within the scope of Section 7A-45.4(a)(5). Because the amount in controversy exceeds five million dollars, this action is also within the scope of Section 7A-45.4(b)(2).

18. Accordingly, the Court finds that, based on the specific allegations in the Complaint, this action involves material disputes regarding the use or performance of intellectual property, including a pharmaceutical, and therefore is properly designated as a mandatory complex business case.

19. The Opposition is OVERRULED. The action shall continue as a mandatory complex business case before the Honorable Adam M. Conrad.

IT IS SO ORDERED, this the 27th day of June 2018.

/s/ James L. Gale

James L. Gale
Chief Business Court Judge