United States Court of Appeals for the Federal Circuit

GENETIC VETERINARY SCIENCES, INC., DBA PAW PRINTS GENETICS,
Plaintiff-Appellee

v.

LABOKLIN GMBH & CO. KG, THE UNIVERSITY OF BERN,
Defendants-Appellants

2018-2056

Appeal from the United States District Court for the Eastern District of Virginia in No. 2:17-cv-00108-HCM-DEM, Senior Judge Henry C. Morgan, Jr.

SEALED OPINION ISSUED: July 29, 2019
PUBLIC OPINION ISSUED: August 9, 2019*

MARK P. WALTERS, Lowe Graham Jones PLLC, Seattle, WA, argued for plaintiff-appellee.

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* This opinion was originally filed under seal and has been unsealed in part with the remaining sealed portions modified to omit confidential information from the public opinion.

JOHANNA WILBERT, Quarles & Brady, LLP, Milwaukee, WI, argued for defendants-appellants. Also represented by MICHAEL PIERY; NIKIA L. GRAY, Washington, DC.

Before WALLACH, HUGHES, and STOLL, *Circuit Judges.*

WALLACH, *Circuit Judge.*

Appellee Genetic Veterinary Sciences, Inc., d/b/a Paw Prints Genetics ("PPG") sued Appellants LABOKLIN GmbH & Co. KG ("LABOKLIN") and the University of Bern ("the University") (together, "Appellants") in the U.S. District Court for the Eastern District of Virginia ("District Court"), seeking a declaratory judgment that claims 1–3 ("Asserted Claims") of the University's U.S. Patent No. 9,157,114 ("the '114 patent") are patent-ineligible under 35 U.S.C. § 101 (2012).[1] J.A. 50–57 (Complaint). Appellants filed a motion to dismiss the Complaint for, inter alia, lack of subject-matter jurisdiction and lack of personal jurisdiction, *see* J.A. 58–60, which the District Court denied, *see* J.A. 302–16 (Order). Following the close of the parties' evidence during a jury trial but before submitting the case to the jury, the District Court granted PPG's motion for judgment as a matter of law ("JMOL") and held the Asserted Claims patent-ineligible under § 101. *See Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co., KG*, 314 F. Supp. 3d 727, 728 (E.D. Va. 2018), *appeal dismissed*, No. 18-1625, 2018 WL 6334978 (4th Cir. June 5, 2018); *see also* J.A. 1 (Final Judgment).

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[1] Congress did not amend § 101 when it passed the Leahy-Smith America Invents Act ("AIA"). *See generally* Pub L. No. 112-29, 125 Stat. 284 (2011).

Appellants appeal the District Court's conclusions as to jurisdiction and patent-ineligibility. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (2012). We affirm.

BACKGROUND

The University is the owner of the '114 patent and an agent or instrumentality of the Swiss Confederation, "having a place of business in Bern, Switzerland." J.A. 1090. In 2013, the University granted an exclusive license of its '114 patent to the German company LABOKLIN, J.A. 1091, whose "principal place of business is in Bad Kissingen, Germany," J.A. 1090; *see* J.A. 173–218 (Confidential License Agreement). Among many conditions of the License Agreement, LABOKLIN was required to commercialize the invention in North America "within [a specific time period] of the Effective date." J.A. 214–15. Subsequently, and at the time of the filing of Appellants' Motion to Dismiss, LABOKLIN had entered into two sublicenses in the United States. *See* J.A. 309, 349–51 (referencing California and Michigan sublicensees). The License Agreement required both LABOKLIN and the University to obtain the other's consent prior to sending any cease-and-desist letter to a potential infringer. J.A. 217. The License Agreement further stated that if the infringing activity "d[oes] not abate within [a specific time period]" and the University gives LABOKLIN written notice of its election not to bring suit, LABOKLIN has a right to sue for infringement. J.A. 218.

PPG is a corporation headquartered in the State of Washington. J.A. 302. It offers laboratory services for testing for genetic variations and mutations known to cause certain diseases in dogs, including a test for "detect[ing] the presence of a mutation in the SUV39H2 gene." J.A. 302. Relevant to the facts of this case, PPG would accept a customer's request to test sample DNA received "from all over the world" and once the DNA test was concluded, would send the results back to the customer. *See* J.A. 101–02, 68.

In January 2017, after obtaining the University's consent to send PPG a cease-and-desist letter, *see* J.A. 312, 349, 353, counsel for LABOKLIN sent a cease-and-desist letter to PPG at its business location in Spokane, Washington, *see* J.A. 99–104. The cease-and-desist letter explained that "[LABOKLIN] is the exclusive license holder of [the '114 patent]," J.A. 100, as well as the exclusive licensee of the related European and German patents, *see* J.A. 99, all of which were attached as enclosures, and the letter stated that given "[PPG] make[s] use of the patent as defined in above-mentioned patent claim 1[,] . . . you [PPG] have committed an act of patent infringement," J.A. 102. After receiving the cease-and-desist letter, PPG brought suit against both LABOKLIN and the University, requesting declaratory judgment that the Asserted Claims of the '114 patent are ineligible under § 101 for failing to claim patent-eligible subject matter, and ultimately asserting that PPG therefore cannot be liable for infringing the Asserted Claims. *See* J.A. 50–57.[2]

LABOKLIN and the University moved to dismiss the Complaint under, inter alia, Federal Rules of Civil Procedure 12(b)(1) for lack of subject-matter jurisdiction and 12(b)(2) for lack of personal jurisdiction. J.A. 35. Following an evidentiary hearing, the District Court issued its Order finding jurisdiction established over both LABOKLIN and the University. *See* J.A. 302–16. First, applying Federal Rule of Civil Procedure 4(k)(2), and considering the cease-and-desist letter and LABOKLIN's licensing activities in the United States, the District Court held that it may exercise personal jurisdiction over LABOKLIN because LABOKLIN had sufficient minimum contacts with the United States to comport with due process. J.A. 310; *see*

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[2] Counsel for PPG also responded to counsel for Appellants in a letter dated after the filing of the declaratory judgment. *See* J.A. 68.

Fed. R. Civ. P. 4(k)(2) (explaining how personal jurisdiction is established for a federal claim outside state-court jurisdiction). Second, the District Court held that jurisdiction was established over the University as a foreign sovereign in the United States because, inter alia, the University had engaged in "commercial activity" sufficient to trigger an exception to jurisdictional immunity under 28 U.S.C. § 1605(a)(2) by "obtain[ing] a patent and then threaten[ing] PPG by proxy with litigation." J.A. 314.

Appellants subsequently asserted counterclaims for infringement of the '114 patent, J.A. 317–28; however, PPG stipulated to infringement of the Asserted Claims, and the only issue that proceeded to trial was PPG's invalidity defense, J.A. 1088, 1089–116 (containing, in a draft final pretrial order, the stipulated facts of both parties). Following the close of both parties' evidence at trial but before submitting the case to the jury, the District Court granted PPG's Motion for JMOL and held the Asserted Claims patent-ineligible under § 101. *See Genetic Veterinary*, 314 F. Supp. 3d at 728. This appeal followed.

JURISDICTION

Appellants aver that the District Court: (1) "lacks personal jurisdiction over LABOKLIN" because LABOKLIN lacks sufficient contacts with the forum; and (2) "lacks personal and subject[-]matter jurisdiction over the University because the University enjoys sovereign immunity." Appellants' Br. 16. We address each issue in turn.

I. Personal Jurisdiction Over LABOKLIN

A. Standard of Review and Legal Standards

"Personal jurisdiction is a question of law that we review de novo." *Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1016 (Fed. Cir. 2009) (citation omitted). We apply Federal Circuit law to questions of personal jurisdiction because the issue "is intimately involved with the substance of the patent laws." *Grober v. Mako Prods.,*

Inc., 686 F.3d 1335, 1345 (Fed. Cir. 2012) (internal quotation marks and citation omitted); *see Hildebrand v. Steck Mfg. Co.,* 279 F.3d 1351, 1354 (Fed. Cir. 2002) (applying Federal Circuit law to determinations of personal jurisdiction over out-of-state defendant-patentees in patent infringement cases and declaratory judgment cases). Where the district court's disposition as to personal jurisdiction is based on affidavits and other written materials in the absence of an evidentiary hearing, a plaintiff need only make a prima facie showing that defendants are subject to personal jurisdiction. *See Elecs. For Imaging, Inc. v. Coyle*, 340 F.3d 1344, 1349 (Fed. Cir. 2003). Where discovery is conducted, however, the plaintiff bears the burden of proving by a preponderance of the evidence the facts necessary to establish personal jurisdiction over the defendant. *Pieczenik v. Dyax Corp.*, 265 F.3d 1329, 1334 (Fed. Cir. 2001). We review any underlying factual findings for clear error. *Grober*, 686 F.3d at 1345. A factual finding is "clearly erroneous" only when the entire record leaves the reviewing court "with the definite and firm conviction that a mistake has been committed." *Anderson v. City of Bessemer City*, 470 U.S. 564, 573–74 (1985).

Federal Rule of Civil Procedure 4(k)(2) states, in relevant part: "For a claim that arises under federal law, serving a summons . . . establishes personal jurisdiction over a defendant if: (A) the defendant is not subject to jurisdiction in any state's courts of general jurisdiction; and (B) exercising jurisdiction is consistent with the United States Constitution and laws." Fed. R. Civ. P. 4(k)(2). In applying and interpreting Rule 4(k)(2), we therefore allow a court to exercise personal jurisdiction over a nonresident if: "(1) the plaintiff's claim arises under federal law, (2) the defendant is not subject to jurisdiction in any state's courts of general jurisdiction, and (3) the exercise of jurisdiction comports with due process." *Synthes (U.S.A.) v. G.M. Dos Reis Jr. Ind. Com de Equip. Medico*, 563 F.3d 1285, 1293–94 (Fed. Cir. 2009).

For the assertion of jurisdiction to comport with due process, a nonresident defendant must have "certain minimum contacts with [the forum] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (internal quotation marks and citation omitted). Relevant here, "if Rule 4(k)(2) supplies the due process analysis, then the forum is the United States," "as opposed to the state in which the district court sits [i.e. Virginia]." *Synthes (U.S.A.)*, 563 F.3d at 1291, 1295.

We have summarized the Supreme Court's due process jurisprudence for specific personal jurisdiction[3] as a three-part test: "(1) whether the defendant purposefully directed its activities at residents of the forum; (2) whether the claim arises out of or relates to the defendant's activities with the forum; and (3) whether assertion of personal jurisdiction is reasonable and fair." *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1360 (Fed. Cir. 2001) (internal quotation marks and citation omitted). "The first two factors correspond with the 'minimum contacts' prong of the [*International Shoe*] analysis, and the third factor corresponds with the 'fair play and substantial justice' prong of the analysis." *Id.* "We have consistently rejected attempts to satisfy the defendant-focused 'minimum contacts' inquiry by demonstrating contacts between the plaintiff (or third parties) and the forum State." *Walden*, 571 U.S. at 284.

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[3] "Specific" jurisdiction "depends on an 'affiliatio[n] between the forum and the underlying controversy,' (i.e., an activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation)." *Walden v. Fiore*, 571 U.S. 277, 283 n.6 (2014). This case concerns the "minimum contacts" necessary to create *specific* jurisdiction because PPG relies on specific jurisdiction only. *See* Appellee's Br. 13–16, 18.

Related to the third factor regarding whether assertion of personal jurisdiction is "reasonable and fair," "[w]here a defendant who purposefully has directed his activities at forum residents seeks to defeat jurisdiction, he must present a compelling case that the presence of some other considerations would render jurisdiction unreasonable." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 476 (1985) (emphasis added). In *Burger King*, the Supreme Court identified five considerations relevant to the reasonableness inquiry:

> [C]ourts in "appropriate case[s]" may evaluate [1] "the burden on the defendant," [2] "the forum State's interest in adjudicating the dispute," [3] "the plaintiff's interest in obtaining convenient and effective relief," [4] "the interstate judicial system's interest in obtaining the most efficient resolution of controversies," and [5] the "shared interest of the several States in furthering fundamental substantive social policies."

Id. at 477 (second alteration in original) (quoting *World-Wide Volkswagen Corp. v. Woodson,* 444 U.S. 286, 292 (1980)).

B. The District Court Had Personal Jurisdiction over LABOKLIN

The District Court determined that "in addition to [sending] the cease-and-desist letter to PPG," LABOKLIN conducted business in the United States by entering into sublicenses in California and Michigan in accordance with an exclusive license granted to it on the disputed '114 patent. J.A. 309; *see* J.A. 307–09. Taken together, the District Court held that these contacts establish fair and reasonable "specific personal jurisdiction over LABO[KLIN]." J.A. 310. Appellants argue that the District Court lacks personal jurisdiction over LABOKLIN because "LABOKLIN does not have sufficient contacts to satisfy due process" and a cease-and-desist letter along

with licensing activity in the forum is not "enough to confer jurisdiction." Appellants' Br. 17, 18. We disagree with Appellants.

The District Court's exercise of personal jurisdiction over LABOKLIN comports with due process. As it relates to the application of the first and second requirements of Rule 4(k)(2)(A), the parties do not dispute the District Court's findings "that [PPG's] claim arises under federal law and that LABO[KLIN agreed it was] not subject to jurisdiction in any state's courts of general jurisdiction." J.A. 307. Thus, the dispositive inquiry is whether the exercise of personal jurisdiction here comports with a due process analysis under the third requirement of Rule 4(k)(2)(B), and, more specifically, LABOKLIN's conduct and contacts within the entire United States as the forum. *See Synthes*, 563 F.3d at 1295. We therefore turn to the three-pronged due process inquiry. *See Inamed*, 249 F.3d at 1360.

As it relates to the first two factors of the due process inquiry for specific personal jurisdiction—i.e. the "minimum contacts" prong—these factors are met based upon LABOKLIN's sending of the cease-and-desist letter together with its commercial sublicenses. Here, LABOKLIN's cease-and-desist letter was clearly directed to PPG at its United States address, and the cease-and-desist letter threatened PPG's domestic testing business by accusing PPG of "commit[ting] an act of patent infringement" when it identified its patent portfolio including the '114 patent. J.A. 102. As counsel for LABOKLIN testified, LABOKLIN sent the letter "[b]ecause it was aware that PPG *was and is still infringing* the ['114] patent and wanted to inform PPG that it was infringing." J.A. 347–48 (emphasis added). Counsel for LABOKLIN also "[sought] for PPG to either cease its conduct or enter into a licensing agreement whereby it was a sublicensee of [LABOKLIN]." J.A. 348. PPG's claim for declaratory judgement arises out of or relates to LABOKLIN's patent sublicensing and its

enforcement activities in the United States pursued in a cease-and-desist letter from LABOKLIN's counsel. *See Jack Henry & Assocs., Inc. v. Plano Encryption Techs. LLC*, 910 F.3d 1199, 1205 (Fed. Cir. 2018) (applying due process considerations and reversing a district court's determination that it did not have jurisdiction where, inter alia, "[appellee had] undertaken a licensing program, with threats of litigation, directed to the [appellants] conducting banking activity in the Northern District" of Texas); *cf. Genetic Implant Sys. v. Core-Vent Corp.,* 123 F.3d 1455, 1458–59 (Fed. Cir. 1997) (holding that the licensee of a patent assignee not being incorporated in the forum state did not preclude a finding that the assignee "had sufficient minimum contacts" with a state to support personal jurisdiction over the assignee because it nonetheless conducted business there based on its agreement with the licensee that had promoted and sold patented "dental implants" instate). Thus, the cease-and-desist letter taken together with both of LABOKLIN's successful efforts to commercialize by sublicensing the '114 patent within the United States satisfy the "minimum contacts" element of the due process inquiry for specific personal jurisdiction.

As it relates to the third factor of the due process inquiry for specific personal jurisdiction, exercising jurisdiction over LABOKLIN is "reasonable and fair" because LABOKLIN has purposefully availed itself of the benefits and protections of U.S. laws through its commercial sublicensing as well as its enforcement of a U.S. patent. J.A. 348. In assessing such relevant factors as "the forum State's interest in adjudicating the dispute" and "the plaintiff's interest in obtaining convenient and effective relief," *Burger King*, 471 U.S. at 477, LABOKLIN's enforcement of a U.S. patent, as well as the interest of PPG in determining whether it could be potentially liable for infringement, weigh in favor of finding jurisdiction reasonable, *see Synthes*, 563 F.3d at 1299 ("[T]he United States has a 'substantial interest' in enforcing the federal patent laws."). This is

further supported by the fact that "no other . . . forum is available to [PPG] for its . . . claim." *Id.* at 1300.

Moreover, where a defendant's "activities are shielded by the benefits and protections of the forum's laws it is *presumptively* not unreasonable to require him to submit to the burdens of litigation in that forum as well." *Burger King*, 471 U.S. at 476 (emphasis added) (internal quotation marks omitted). Such is the case here. As the District Court aptly pointed out, here, "LABO[KLIN] is not merely a remote patentee assisting a U.S. company with enforcement, but instead, it *is* the U.S. enforcer." J.A. 310. For this reason, the burden placed on LABOKLIN by litigating in the United States is outweighed by the other fairness factors. *See World-Wide Volkswagen,* 444 U.S. at 294 ("[P]rogress in communications and transportation has made the defense of a suit in a foreign tribunal less burdensome." (quoting *Hanson v. Denckla*, 357 U.S. 235, 250–51 (1958))).

Appellants argue that "[m]erely sending a [cease-and-desist] letter does not create specific personal jurisdiction over LABOKLIN," while relying on *Red Wing Shoe Company v. Hockerson-Halberstadt* and *Avocent Huntsville Corporation v. Aten International Company* for the proposition that patent enforcement letters cannot provide the basis for jurisdiction without "some 'other activity' related to PPG's claim [] connect[ing] LABOKLIN to the forum beyond the letter" in a declaratory judgment action. Appellants' Br. 18 (first citing *Red Wing Shoe*, 148 F.3d 1355, 1360 (Fed. Cir. 1998); then citing *Avocent*, 552 F.3d 1324, 1334 (Fed. Cir. 2008)). This argument fails. As we have expressly stated, "*Red Wing Shoe* and *Avocent* did not create such a [bright-line] rule, and doing so would contradict the Court's directive to 'consider a variety of interests' in assessing whether jurisdiction would be fair." *Jack Henry*, 910 F.3d at 1206 (citing *Bristol-Myers Squibb Co. v. Superior Court of Cal.*, 137 S.Ct. 1773, 1780 (2017)). Here, Appellants have failed to sufficiently rebut the presumption

that personal jurisdiction would be reasonable and fair. As we have found above, the factors outlined in *Burger King* favor the establishment of jurisdiction over LABOKLIN. *Cf. Deprenyl Animal Health, Inc. v. Univ. of Toronto Innovations Found.*, 297 F.3d 1343, 1356 (Fed. Cir. 2002) ("Just as a state has a substantial interest in preventing patent infringement within its borders, it also has a substantial interest in protecting its residents from claims of patent infringement that may be unwarranted[.]"). Therefore, the facts of this case establish that LABOKLIN's activities satisfy the minimum contacts requirement without offense to due process; thus, personal jurisdiction over LABOKLIN in the District Court is reasonable and fair.

II. Personal and Subject-Matter Jurisdiction Over The University

A. Standard of Review and Legal Standard

The Foreign Sovereign Immunities Act ("FSIA") "provides the sole basis for obtaining jurisdiction" over a foreign sovereign in the United States. *Saudi Arabia v. Nelson,* 507 U.S. 349, 355 (1993); *see* 28 U.S.C. §§ 1330 *et. seq*. In reviewing a district court order regarding subject-matter jurisdiction, we apply the standard of review of the regional circuit—here the Fourth Circuit—unless the issue pertains to or is unique to patent law. *Intel Corp. v. Commonwealth Sci. & Indus. Research Org.*, 455 F.3d 1364, 1369 (Fed. Cir. 2006). The Fourth Circuit reviews the existence of sovereign immunity and subject-matter jurisdiction de novo. *In re Tamimi*, 176 F.3d 274, 277 (4th Cir. 1999). Pursuant to the FSIA, "a foreign state is presumptively immune from the jurisdiction of United States courts; unless a specified exception applies, a federal court lacks subject-matter jurisdiction over a claim against a foreign state." *Saudi,* 507 U.S. at 355. Relevant to this appeal, if a foreign state engages in "commercial activity . . . in the United States," an exception to sovereign

immunity applies. 28 U.S.C. § 1605(a)(2).[4] We have stated that a defendant's "acts of (1) obtaining a United States patent and then (2) enforcing its patent so it could reap the profits thereof—whether by threatening litigation or by proffering licenses to putative infringers—certainly" are commercial activity.[5] *Intel Corp.*, 455 F.3d at 1370. Determining whether subject-matter jurisdiction exists "entails an application of the substantive terms of the [FSIA] to determine whether one of the specified exceptions to immunity applies." *Verlinden B.V. v. Central Bank of Nigeria,* 461 U.S. 480, 498 (1983).

B. The District Court Had Personal and Subject-Matter Jurisdiction over the University

The District Court held that jurisdiction exists over the University because the University is an agent or

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[4] Specifically, 28 U.S.C. § 1605(a) provides that:

> A foreign state shall not be immune from the jurisdiction of courts of the United States or of the States in any case . . . (2) in which the action is based upon a commercial activity carried on in the United States by the foreign state; or upon an act performed in the United States in connection with a commercial activity of the foreign state elsewhere; or upon an act outside the territory of the United States in connection with a commercial activity of the foreign state elsewhere and that act causes a direct effect in the United States[.]

[5] "Commercial activity" is "either a regular course of commercial conduct or a particular commercial transaction or act." 28 U.S.C. § 1603(d). The FSIA further indicates that "[t]he commercial character of an activity shall be determined by reference to the nature of the course of conduct or particular transaction or act, rather than by reference to its purpose." *Id.*

instrumentality of a foreign state that engaged in commercial activity sufficient to trigger an exception to immunity under § 1605(a)(2) as it had "obtained a [U.S.] patent and then threatened PPG by proxy with litigation." J.A. 314. Appellants argue that the University is "presumptively immune from the jurisdiction of U.S. courts" under the FSIA because "the District Court erred in finding that "[the commercial activity] exception [under the FSIA] applies to the University's immunity." Appellants' Br. 23 (capitalizations modified). We disagree with Appellants.

The University cannot claim immunity in the District Court because it obtained a U.S. patent and then participated in licensing and enforcing the '114 patent, which constitutes "commercial activity" under the FSIA. *See* 28 U.S.C §§ 1603(d), 1605(a)(2). As an initial matter, the presumption of sovereign immunity applies to the University because it is undisputedly an "agency or instrumentality of a foreign state" here, the Swiss Confederation. J.A. 303; *see* Appellants' Br. 23. The commercial activity exception of § 1605(a)(2), however, provides a basis for jurisdiction over the University within U.S. district courts. Here, the University obtained a U.S. patent and consented to LABOKLIN sending the cease-and-desist letter relating to that patent in accordance with the terms of the Licensing Agreement. *See* J.A. 353–54. These actions constitute "commercial activity" having a direct effect in the United States. *See* 28 U.S.C §§ 1603(d), 1605(a)(2). By consenting to the cease-and-desist letter, the University directly participated in the act of threatening infringement-related litigation, and did so in order to benefit from this commercial activity. The University's involvement is further underscored by the fact that it had the first option in deciding whether to proceed with litigation in the United States, and was required to notify LABOKLIN within ninety days of the sending of the cease-and-desist letter of its decision in that regard.

We have found similar conduct to fall under the "commercial activity" exception to the FSIA jurisdictional immunity. In *Intel*, we determined that the actions of Australia's national science agency constituted a commercial exception to jurisdictional immunity because it had obtained a U.S. patent and sought to enforce it against U.S. entities—"whether by threatening litigation or by proffering licenses to putative infringers"—so that it "could reap the profits thereof." 455 F.3d at 1370. We further recognized that we had previously held "that 'a patentee's attempt to conduct license negotiations is a commercial activity.'" *Id.* (quoting *Phillips Plastics Corp. v. Hatsujou Kabushiki Kaisha,* 57 F.3d 1051, 1054 (Fed. Cir. 1995), *abrogated on other grounds by MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007)). Here, LABOKLIN, on behalf of the University, admitted that it "[sought] for PPG to either cease its conduct or enter into a licensing agreement whereby it was a sublicensee of [LABOKLIN]." J.A. 348. Contrary to the University's assertion on appeal, it matters not to this analysis that it was LABOKLIN that physically wrote and sent the cease-and-desist letter to PPG, because the University conceded that it still retained substantial rights in the patent, such that the University, as the sole "patentee," ultimately controlled enforcement of the '114 patent. *See* J.A. 359–61; *see also* J.A. 360 ("[T]he [U]niversity did not transfer all substantial rights.").

Moreover, the Supreme Court has held, in the context of § 1605(a)(2), that "based on" means that a foreign state's commercial activity forms "those elements of a claim that, if proven, would entitle a plaintiff to relief under his theory of the case." *Saudi Arabia,* 507 U.S. at 357. PPG's lawsuit for a declaratory judgment on the '114 patent is based upon the University's steps to commercialize the '114 patent's claimed technology by engaging LABOKLIN as an exclusive licensee and then affirmatively consenting to LABOKLIN's threat of infringement against PPG. *See* J.A. 214–15, 348–49. The University's conduct can, and

here does, qualify under § 1605(a)(2)'s exceptions for "commercial activity carried on in the United States by the foreign state" or "an act performed in the United States in connection with a commercial activity of the foreign state elsewhere." 28 U.S.C. § 1605(a)(2); *Republic of Arg. v. Weltover, Inc.*, 504 U.S. 607, 614 (1992) (determining that a district court properly asserted jurisdiction under the FSIA and stating that actions are determined to be commercial if they "are the *type* of actions by which a private party engages in trade and traffic or commerce" (internal quotation marks omitted)). Accordingly, the commercial activity exception to sovereign immunity applies such that the District Court properly exercised subject-matter jurisdiction over the University pursuant to § 1605(a).[6]

DISCUSSION

Patent Eligibility Under § 101

I. Standards of Review and Legal Standard

We apply regional circuit law when "reviewing the grant or denial of JMOL," *ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 1354 (Fed. Cir. 2015), here, the Fourth Circuit. The Fourth Circuit reviews JMOL rulings de novo. *In re Wildewood Litig.*, 52 F.3d 499, 502 (4th Cir. 1995). Pursuant to Federal Rule of Civil Procedure 50, before submitting the case to a jury during a jury trial and after a party is fully heard on an issue, the district court may

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[6] Moreover, the University having waived service, J.A. 33–34 (evidencing, as part of the District Court's docket report, the issuance and waiver of service of summons to and by the University), the District Court's exercise of personal jurisdiction over the University was also proper, *see* 28 U.S.C. § 1330(b) (providing that "[p]ersonal jurisdiction over a foreign state shall exist as to every claim for relief over which the district courts have jurisdiction under [§ 1605(a)] where service has been made").

grant JMOL if the court finds "there is no legally sufficient evidentiary basis for a reasonable jury to have found for that party with respect to that issue." Fed. R. Civ. P. 50(a). "In deciding a JMOL motion, all reasonable inferences [are to be drawn] in favor of the nonmoving party without making credibility assessments or weighing the evidence." *ABT Sys.*, 797 F.3d at 1350 (internal quotation marks and citations omitted) (applying the Fourth Circuit standards of review when reviewing a §101 challenge).

"We review issues unique to patent law, including patent eligibility under § 101, consistent with our circuit's precedent." *Smart Sys. Innovations, LLC v. Chi. Transit Auth.*, 873 F.3d 1364, 1367 (Fed. Cir. 2017) (internal quotation marks and citation omitted). Although a district court's determination of patent eligibility under § 101 is typically an issue of law, which we review de novo, *see Intellectual Ventures I LLC v. Erie Indem. Co.*, 850 F.3d 1315, 1325 (Fed. Cir. 2017), "[t]he patent eligibility inquiry may contain underlying issues of fact," *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1365 (Fed. Cir. 2018).

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of" Title 35 of the United States Code. 35 U.S.C. § 101. "The Supreme Court, however, has long interpreted § 101 and its statutory predecessors to contain an implicit exception: 'laws of nature, natural phenomena, and abstract ideas' are not patentable." *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, 776 F.3d 1343, 1346 (Fed. Cir. 2014) (quoting *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014)).

The Supreme Court's *Alice* and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* decisions provide the two-stage framework by which we assess patent

eligibility under § 101. *See* 573 U.S. at 216–18; 566 U.S. 66, 70–80 (2012). A patent

> claim falls outside § 101 where (1) it is "directed to" a patent-ineligible concept, *i.e.*, a law of nature, natural phenomenon, or abstract idea, and (2), if so, the particular elements of the claim, considered "both individually and 'as an ordered combination,'" do not add enough to "'transform the nature of the claim' into a patent-eligible application."

Elec. Power Grp., LLC v. Alstom S.A., 830 F.3d 1350, 1353 (Fed. Cir. 2016) (quoting *Alice*, 573 U.S. at 217). It is against this framework that we analyze the Asserted Claims.

II. The Asserted Claims

Entitled "Method of Determining the Genotype Relating to Hereditary Nasal Parakeratosis [('HNPK')] and Nucleic Acids Usable in Said Method," the '114 patent generally relates to in vitro methods for genotyping Labrador Retrievers, in order to discover whether the dog might be a genetic carrier of the disease HNPK. *See* '114 patent col. 1 ll. 15–20. HNPK is a disease that causes "crusts and fissur[es]" to appear on the nose of dogs "at a young age," but the dogs are otherwise considered healthy. *Id.* col. 1 ll. 27–28. HNPK is a "recessive" condition that only passes to a puppy when both of the dog's parents are "carriers" of the gene that causes HNPK. *Id.* col. 1 ll. 34, 38–39. Therefore, "a genetic test method that can discriminate the three genotypes" of "free," "carrier," and "affected" is "highly valuable for dog breeding as well as for veterinary medicine to confirm the diagnosis of suspicious cases." *Id.* col. 1 ll. 46–50; *see id.* Abstract ("The invention also concerns polypeptide[-]based methods for determining said disorder. Further, nucleic acids, polypeptides and antibodies usable in said method are disclosed."). The '114 patent describes how the University's professor discovered that the presence

of HNPK in Labrador Retrievers resulted from a point mutation in gene SUV39H2. *See id.* col. 7 ll. 8–21.

Claims 1–3 of the '114 patent recite:

> 1. An in vitro method for genotyping a Labrador Retriever comprising:
>
> a) obtaining a biological sample from the Labrador Retriever;
>
> b) genotyping a SUV39H2 gene encoding the polypeptide of SEQ ID NO: 1[;] and
>
> c) detecting the presence of a replacement of a nucleotide T with a nucleotide G at position 972 of SEQ ID NO: 2.
>
> 2. The method according to claim 1, wherein the genotyping is achieved by [polymerase chain reaction ("PCR")], real-time PCR, melting point analysis of double-stranded DNA, mass spectroscopy, direct DNA sequencing, restriction fragment length polymorphism (RFLP), single strand conformation polymorphism (SSCP), high performance liquid chromatography (HPLC), or single base primer extension.
>
> 3. The method of claim 1, wherein the genotyping utilizes a primer pair compris[ed] of a first primer and a second primer, each compromising a contiguous span of at least 14 nucleotides of the sequence SEQ ID NO: 2 or a sequence complementary thereto, wherein:
>
> a) said first primer hybridizes to a first DNA strand of the SUV39H2 gene;
>
> b) said second primer hybridizes to the strand complementary to said first DNA strand of the SUV39H2 gene; and

> c) the 3' ends of said first and second primers are located on regions flanking the position 972 of SEQ ID NO: 2, or of nucleotide positions complementary thereto.

Id. col. 15 l. 11–col. 16 l. 14.

III. The District Court Did Not Err in Granting JMOL Because It Correctly Determined that the Asserted Claims Are Patent-Ineligible Under § 101

A. The Asserted Claims Are Directed to a Natural Phenomenon

The District Court held that the Asserted Claims, both individually and in combination, are "directed to patent ineligible subject matter, namely the discovery of the genetic mutation that is linked to HNPK." *Genetic Veterinary*, 314 F. Supp. 3d at 730. Appellants argue that the Asserted Claims "are directed to a patent-eligible application" of the discovery of the "underlying natural phenomenon" because the Asserted Claims "claim a man-made laboratory procedure." Appellants' Br. 37–38. They further contend that "[n]o one in the industry was even studying the SUV39H2 gene, let alone developing genotyping methods for Labrador Retrievers." *Id.* at 45. We disagree with Appellants.

We begin our analysis by examining previous eligibility determinations. *See, e.g.*, *Mayo*, 566 U.S. at 72, 74–77 (evaluating eligibility by comparing the challenged claims "in light of the Court's precedents" and holding that the claims were directed to the relationship between the concentration of metabolites in the blood and the likelihood that a drug dose will be ineffective, which it referred to as a law of nature). We have applied the Supreme Court's guidance in *Alice* and *Mayo* to find claims "directed to a patent-ineligible concept when they amounted to nothing more than observing or identifying the ineligible concept itself." *Rapid Litig. Mgmt. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048 (Fed. Cir. 2016) (internal quotation marks

omitted). For example, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, we held that claims reciting methods for detecting paternally inherited cell-free fetal DNA ("cffDNA") mutations were directed to a patent-ineligible law of nature because they were "generally directed to detecting the presence of a naturally occurring thing or a natural phenomenon, cffDNA in maternal plasma or serum." 788 F.3d 1371, 1376 (Fed. Cir. 2015). Similarly, in *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation*, we concluded that the claims were directed to a patent-ineligible law of nature because the claims' "methods, directed to identification of alterations of the gene, require[d] merely comparing the patient's gene with the wild-type gene and identifying any differences that ar[o]se." 774 F.3d 755, 763 (Fed. Cir. 2014). In each of these cases, "the end result of the process, the essence of the whole, was a patent-ineligible concept." *CellzDirect*, 827 F.3d at 1048.

In contrast, we held that the claims in *CellzDirect* were not directed to "an observation or detection of the ability of [liver cells] to survive multiple freeze thaw cycles" but, instead, were directed to a "new and improved technique[] for producing a tangible and useful result," i.e., preserving those cells for later use. *Id.* at 1048, 1050. Therefore, we recognized that the claims fell "squarely outside those categories of inventions that are directed to patent-ineligible concepts." *Id.* at 1050 (internal quotation marks omitted). Similarly, in *Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International Ltd.*, we held that a claimed method of treating schizophrenia with the drug iloperidone was directed to patent-eligible subject matter because it taught "a specific method of treatment for specific patients using a specific *compound* at specific *doses* to achieve a specific *outcome*." 887 F.3d 1117, 1136 (Fed. Cir. 2018) (emphases added). There, the representative claim taught "'a new way of using an existing drug' that is safer for patients," *id.* at 1135, specifically involving the steps of determining a particular genotype in a patient and then

"administering specific dose ranges" of the drug based on that genotype, *id.* at 1134. Finally, in *Natural Alternatives International, Inc. v. Creative Compounds, LLC*, we held that a patent claiming methods for use of dietary supplements, dietary supplements, and uses of beta-alanine in manufacturing a human dietary supplement to increase the anaerobic working capacity of muscle and other tissue was directed to patent-eligible subject matter. 918 F.3d 1338, 1346–47 (Fed. Cir. 2019). We explained that the claims were not directed to a law of nature or a natural product because the claims "require[d that] specific [claimed] steps be taken in order to bring about a change in a subject, altering the subject's natural state." *Id.* at 1345.

Here, the Asserted Claims are not directed to a new and useful method for discovery because they begin and end with the point discovery of the HNPK mutation in the SUV39H2 gene. *See, e.g., Ariosa*, 788 F.3d at 1380 ("We do not disagree that detecting cffDNA in maternal plasma or serum that before was discarded as waste material is a positive and valuable contribution to science. But even such valuable contributions can fall short of statutory patentable subject matter[.]"). The parties do not dispute that the mutation itself is a naturally occurring phenomenon. *See* Appellants' Br. 39; Appellee's Br. 37.

Looking to the claim language, claim 1 breaks down, into three parts, the "in vitro method for genotyping a Labrador Retriever"[7] for detection of this mutation. '114 patent col. 15 l. 11. As explained by the parties' experts, first,

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[7] The scientific term "in vitro means outside of the main organism . . . in a petri dish or in a test tube," J.A. 1365 (deposition testimony of PPG's expert), and "genotyping . . . refers to determining the order or the composition of the nucleotides or bases in DNA," J.A. 1493 (deposition testimony of LABOKLIN's expert).

step (a) "obtaining a biological sample" requires a sample of DNA from a dog, which both parties' experts testified usually requires obtaining a blood sample or cheek swab from the dog, *see* J.A. 1366, 1493; second, step (b) "genotyping a SUV39H2 gene encoding the polypeptide of SEQ ID NO: 1," identifies the location of the genetic mutation, *see* J.A. 1496; and third, step (c) "detect[ing] the presence of a replacement of a nucleotide" at a specific base pair position identifies the location of the equivalent normal gene, *see* J.A. 1496, 1598; *see also* '114 patent col. 15 ll. 14–19. In other words, claim 1 simply states that the search for the mutation involves the laboratory examination of Labrador Retriever DNA, which resulted in the revelation of the mutation. *See id*. col. 15 ll. 11–19. The mutation location itself and the fact that it is inherited through male and female dog carriers mating are both natural phenomena. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590 (2013) ("Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them."). Taken together, the plain language of claim 1 demonstrates that it is directed to nothing more than "observing or identifying" the natural phenomenon of a mutation in the SUV39H2 gene. *See CellzDirect*, 827 F.3d at 1048. Claims 2 and 3 depend from independent claim 1 and add only generic methods of detecting the natural phenomenon. Thus, the Asserted Claims are directed to natural phenomenon at *Alice* step one.

B. The Asserted Claims Do Not Recite an Inventive Concept

Because the Asserted Claims are directed to a natural phenomenon, the second step of the *Alice* § 101 analysis requires us to determine whether the subject patent's claims—when viewed individually and as an ordered combination of elements—contain "an inventive concept sufficient to transform the claimed [natural law] into a patent-

eligible application." *Alice*, 573 U.S. at 221 (internal quotation marks omitted). A claim contains an inventive concept if it "include[s] additional features," *id.*, that are more than "well-understood, routine, [or] conventional activities," *id.* at 225 (internal quotation marks, brackets, and citations omitted).

The District Court determined "the additional steps and claims [of the '114 patent]" lack "any inventive concept to transform it from patent ineligible subject matter to patent eligible subject matter." *Genetic Veterinary*, 314 F. Supp. 3d at 733. Appellants argue that "the claimed methods . . . apply a new discovery" of the SUV39H2 gene and develop novel "genotyping methods for Labrador Retrievers." Appellants' Br. 45. We disagree with Appellants.

The Asserted Claims do not recite an inventive concept that transforms the observation of a natural phenomenon into a patentable invention. Nothing in claim 1's language suggests the invention of a new *method* for genotyping. *See* '114 patent col. 15 l. 16 (claiming "genotyping" but not explaining specific steps of *how* to genotype). Rather, instructive to our analysis is that LABOKLIN's expert agreed that the genotyping method in claim 1 uses conventional or known laboratory techniques to observe the newly discovered mutation in the SUV39H2 at position 972. *See, e.g.*, J.A. 1520 (agreeing with counsel that claim 1 is "not talking about a particular way to genotype the [SUV39H2] gene encoding"). Conducting conventional detection in a laboratory does not transform the discovery of a natural phenomenon into patent eligible subject matter. Rather, similar to the claims at issue in *Mayo*, a natural phenomenon, together with well-understood, conventional activity, is not patent-eligible under § 101. *See Mayo*, 566 U.S. at 73, 79–80.

Claims 2 and 3 also do not move the natural phenomenon into eligible § 101 territory. For example, claim 2 limits the method of claim 1 to specific techniques, including

"genotyping achieved by PCR, [and] real-time PCR," *see* '114 patent col. 15 l. 21; however, we have recognized that laboratory techniques, such as using "[PCRs] to amplify and detect cffDNA," are well-understood, routine, conventional activities in the life sciences when they are claimed in a merely generic manner (e.g., at a high level of generality) or as insignificant extra-solution activity, *Genetic Techs. v. Merial LLC*, 818 F.3d 1369, 1377–78 (Fed. Cir. 2016); *see id.* at 1379–80 (finding claims patent-ineligible and stating that the physical steps of "detecting a coding region of a person's genome by amplifying and analyzing a linked non-coding region of that person's genome" did not provide an inventive concept necessary to render the claim patent-eligible). Additionally, LABOKLIN's expert confirmed that claim 2 contained techniques that "have been around for years," J.A. 1521, and had no specific order or requirement to use these techniques a particular way, *see* J.A. 1526–27; *see also* J.A. 1368–75, 1429, 1490–91, 1498. As for claim 3, which recites "utiliz[ing] a primer pair" as the means for locating the mutation, '114 patent col. 15 l. 28, LABOKLIN's expert testified that while he had never used primer pairs to genotype base pair position 972 in the SUV39H2 gene, primer pairs is a "decades old" technique "just like boiling or baking," J.A. 1528–29. As the Supreme Court explained in *Mayo*, "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." *Mayo*, 566 U.S. at 82. Therefore, the Asserted Claims are patent-ineligible at *Alice* step two.

We are unpersuaded by Appellants' primary counter-argument that the District Court erred because the Asserted Claims "do not merely recite the underlying natural phenomenon, the causative mutation of HNPK, but instead recite a particular application of that discovery." Appellants' Br. 39. Appellants argue further that the "claimed steps of obtaining a biological sample, genotyping a

SUV39H2 gene, and detecting the presence of the replacement nucleotide do not recite or even mention the correlation between the point mutation and HNPK." *Id.* Appellants rely heavily upon our precedent in *CellzDirect*, to argue that "[s]imilar to the inventors in *CellzDirect*, [the '114 patentee] discovered that the existence of the replacement nucleotide at position 972 of a specific gene indicates [that] the Labrador Retriever is a carrier of HNPK." *Id.* at 40 (citing 827 F.3d at 1052). However, any reliance on *CellzDirect* is misguided. As we stated above, the claims at issue in *CellzDirect* were directed to a "new and improved technique[] for producing a tangible and useful result," i.e., *preserving* those cells for later use. *CellzDirect*, 827 F.3d at 1048. Here, the Asserted Claims provide no tangible result save the observation and detection of a mutation in a dog's DNA. While a positive and valuable contribution, these claims fall short of statutory patentable subject matter.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. Accordingly, the Final Judgment of the U.S. District Court for the Eastern District of Virginia is

AFFIRMED