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UNITED STATES BANKRUPTCY COURT DISTRICT OF NEW JERSEY

In re:

INVITAE CORPORATION, et al.,

Debtors.¹

(Hon. Michael B. Kaplan)

Chapter 11

Case No. 24-11362 (MBK)

(Jointly Administered)

Hearing Date: May 6, 2024, at 10:00 a.m. (ET) Obj. Deadline: April 29, 2024

NATERA INC.'S OBJECTION TO THE PROPOSED SALE TRANSACTION

¹ The last four digits of Debtor Invitae Corporation's tax identification number are 1898. A complete list of the Debtors in these chapter 11 cases and each such Debtor's tax identification number may be obtained on the website of the Debtors' proposed claims and noticing agent at <u>www.kccllc.net/invitae</u>. The Debtors' service address in these chapter 11 cases is 1400 16th Street, San Francisco, California 94103.



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Natera Inc. ("<u>Natera</u>") hereby submits this objection (the "<u>Objection</u>") to the proposed sale of the above-captioned debtors' and debtors-in-possession's (collectively, the "<u>Debtors</u>") Assets² free and clear of liens, claims, encumbrances, and other interests (the "<u>Sale Transaction</u>" or "<u>363 Sale</u>"). In support of this Objection, Natera represents as follows:

PRELIMINARY STATEMENT

1. For over four years, Natera has fought vigorously to protect its right to exclude the Debtors from making, using, offering for sale, or selling products, including Personalized Cancer Monitoring ("<u>PCM</u>") products, which infringe Natera's patented technologies (collectively, the "<u>Infringing Products</u>"). Natera has won a substantial monetary verdict for various patent infringements and a permanent injunction against the Debtors and all persons in active concert or participation with the Debtors (the "<u>Permanent Injunction</u>") from using PCM, and any product or service that is not more than colorably different from PCM, that infringe the Natera Patents (as defined below). Notwithstanding Natera's hard-fought victories, the Sale Transaction apparently includes the Infringing Products, particularly the PCM products, as part of the Assets being sold, in clear contravention of the Permanent Injunction.

2. Although Natera does not generally object to the Sale Transaction, it objects to any "free and clear" sale of Assets, including all PCM products, that are covered by the Natera Patents and subject to the Permanent Injunction. More specifically, and as discussed in more detail below,

² Capitalized terms used but not otherwise defined herein have the meanings ascribed to them in the Debtors' Motion for Entry of an Order (I) Approving Bidding Procedures and Bid Protections, (II) Scheduling Certain Dates and Deadlines with Respect Thereto, (III) Approving the Form and Manner of Notice Thereof, (IV) Establishing Notice and Procedures for the Assumption and Assignment of Contracts and Leases, (V) Authorizing the Assumption and Assignment of Assumed Contracts, and (VI) Authorizing the Sale of Assets [Docket No. 19] (the "Bidding Procedures Motion") or the bidding procedures (the "Bidding Procedures") attached as Exhibit 1 to the Order (I) Approving Bidding Procedures and Bid Protections, (II) Scheduling Certain Dates and Deadlines with Respect Thereto, (III) Approving the Form and Manner of Notice Thereof, (IV) Establishing Notice and Procedures for the Assumption and Assignment of Contracts and Leases, (V) Authorizing the Assumption and Assignment of Assumed Contracts, and (VI) Authorizing the Sale of Assets [Docket No. 57] (the "Bidding Procedures Order"), as applicable.

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the Judgments and Injunction (as defined below) related to the Infringing Products are not "interests" under Bankruptcy Code section 363(f). And even if they are "interests," none of the conditions for a "free and clear" sale under Bankruptcy Code section 363(f) can be satisfied. Lastly, approval of the proposed sale free and clear of the Judgments and Injunction would irreparably harm Natera and could result in abuse of the bankruptcy sale process. Natera therefore requests that the Court (i) prohibit the sale of the Infringing Products free and clear of the Judgments and Injunction and (ii) require that the language in the Sale Order be amended as proposed below.

BACKGROUND

3. Founded in 2004, Natera is a pioneering molecular technology company with industry-leading healthcare products. For well over a decade, Natera has been researching and developing non-invasive methods for analyzing DNA in order to help patients and doctors manage diseases. These ongoing efforts have given rise to a number of novel and proprietary cell-free DNA ("cfDNA") testing technologies to assist with life-saving health management.

4. Natera's pioneering and ongoing innovation is especially evident in the area of cfDNA-based testing. Natera has developed unique and highly optimized processes for preparing and analyzing cfDNA that can be used to test non-invasively for a range of conditions by analyzing a patient's blood sample.

5. In detecting and monitoring cancer, the use of minimally invasive, blood-based tests offers significant advantages over older, more invasive methods, such as radiological scans or tumor biopsy. But a significant technological challenge is that blood-based testing requires the measurement of very small amounts of relevant genetic material—circulating-tumor DNA ("<u>ctDNA</u>")—within a much larger blood sample. Natera's approach combines proprietary molecular biology and computational techniques to measure genomic variations in tiny amounts

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of DNA, representing a fundamental advance in ctDNA preparation for large-scale sequencing analysis. Natera applied certain aspects of this technology to develop and commercialize its molecular residual disease ("<u>MRD</u>") test known as Signatera®. This breakthrough product is personalized to each cancer patient's DNA to monitor it and help inform treatment options. Natera pioneered the emerging personalized MRD market, applying this technology to monitor patients for the earliest signs of recurrence of various types of cancer.

6. Natera's cfDNA technology is the product of more than a decade of hard work and investment of, on average, more than fifty million dollars per year in research and development. Natera has expended substantial resources researching and developing its technologies and establishing its reputation among physicians, insurers, and regulators as a company committed to sound science and consistently accurate, reliable results. This research, and the technological innovations resulting therefrom, are protected by a substantial patent portfolio, with over 200 patents issued or pending worldwide, including greater than 60 in the field of oncology.

7. Among these patented inventions are Natera's U.S. Patent No. 10,557,172 (the "<u>172 patent</u>"), U.S. Patent No. 10,731,220 (the "<u>220 patent</u>"), and U.S. Patent No. 10,597,708 (the "<u>708 patent</u>" and, together with the '172 patent and the '220 patent, the "<u>Natera Patents</u>"), which, as outlined herein, Debtors ArcherDX, LLC and Invitae Corporation were found to infringe through their use and sale of PCM and other products. The Debtors used Natera's patented technology and incorporated it into their products (as set forth below) without permission and in violation of patent laws.

I. <u>Natera Established That The Debtors Infringed Its Patents Prior to the Bankruptcy</u> <u>Filing.</u>

8. On January 27, 2020, Natera initiated a patent infringement action under section 271 of Title 35 of the United States Code (the "<u>Patent Act</u>") in the U.S. District Court for

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the District of Delaware (the "<u>District Court</u>") against ArcherDX, Inc.³ The complaint and subsequent amendment alleged infringement of several of the Natera Patents through manufacture, use and/or sale of several products, including PCM. On August 6, 2020, Natera filed a second suit against ArcherDX, Inc. ("<u>Archer</u>") for infringement of another Natera patent. The two actions were consolidated and later amended to join ArcherDX, LLC and Invitae Corporation as successors in interest to ArcherDX, Inc. (collectively, the "<u>Defendants</u>"). *See Natera, Inc. v. ArcherDX, Inc., et al.*, C.A. Nos. 20-cv-125-GBW and 20-cv-1047-GBW (the "<u>Infringement Litigation</u>"). The Infringement Litigation arises from the Defendants' infringement of certain claims of the Natera Patents through the use of Archer's LiquidPlex (previously called Reveal ctDNA), VariantPlex, Stratafide, FusionPlex, PCM, and other oncology products that used the same technology as the previously mentioned products. In particular, the Debtors' PCM products—both the version at issue in the Infringement Litigation and a version the Debtors launched in late 2023—compete directly with Natera's Signatera product.

9. Following protracted litigation over the next couple of years culminating in a jury trial, on May 15, 2023, a jury returned a verdict in Natera's favor with the following findings:

- (i) Defendants' use of the Infringing Products, including PCM, directly infringed the asserted claims of the Natera Patents;
- (ii) The asserted claims of the Natera Patents are not invalid;
- (iii) Defendants' use of the Infringing Products was not reasonably related to the development and submission of information to the U.S. Food and Drug Administration; and
- (iv) Natera had suffered damages of \$9,356,886 for lost profits as a result of Defendants' infringing sales of PCM, \$5,430,181 as reasonable royalty for Defendants' past sales in the United States of the Infringing Products other than PCM, and \$4,564,963 as reasonable royalty for Defendants'

³ ArcherDX, Inc. merged with Apollo Merger Sub A Inc., which then merged with Apollo Merger Sub B LLC to form ArcherDX, LLC, one of the Debtors in the Chapter 11 Cases.

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past sales outside the United States of the Infringing Products other than PCM.

See Verdict Form, Case No. 20-cv-125-GBW [ECF No. 609], attached hereto as Exhibit A (the "Jury Verdict").

10. On September 19, 2023, the District Court entered a judgment reflecting the jury's findings. *See Judgment*, Case No. 20-cv-125-GBW [ECF No. 665] (the "Judgment"), attached hereto as **Exhibit B**. Following the jury trial, Natera moved for an injunction against the Defendants' use of its PCM product, except for the continued use by 50 patients of the PCM tests. *See Plaintiff's Motion for Permanent Injunction*, Case No. 20-cv-125-GBW [ECF No. 621].

11. On November 21, 2023, the District Court entered the Permanent Injunction prohibiting Defendants and any persons in active concert or participation with them from infringing the asserted claims of the Natera Patents by using PCM and "any product or service not more than colorably different from PCM" and made several findings. *See Memorandum Order*, Case No. 20-cv-125-GBW [ECF No. 679], attached hereto as **Exhibit C** (the "Permanent Injunction Order" and, together with the Jury Verdict and the Judgment, the "Judgments and Injunction").⁴ The Permanent Injunction Order found that: (a) Natera would suffer irreparable injury if the use of PCM was not enjoined; (b) the remedies available at law were unable to adequately compensate Natera for its loss of market share, brand recognition, and customer goodwill, (c) the balance of hardships favored granting an injunction; and (d) for all but four

⁴ For the avoidance of doubt, Natera's Objection is not related to the enforcement of any monetary damages set forth in the Jury Verdict and the Judgment. Rather, Natera is seeking to (a) preserve the findings of fact and conclusions of law regarding the infringement on the Natera Patents (the "<u>Findings and Conclusions</u>"), and (b) ensure that if a sale of the Infringing Products is permitted, any purchaser takes the Infringing Products subject to these Findings and Conclusions and the Permanent Injunction. Stated differently, the Sale Order should not in any way alter or impede Natera's rights under the Judgments and Injunction with respect to any Successful Bidder *except* monetary damages that arise under the Judgments and Injunction.

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limited use exceptions,⁵ the public interest weighed in favor of an injunction. Importantly, the Court explicitly avoided endorsing Defendants' representations that the version of PCM the Defendants launched in 2023 does not infringe the Natera Patents, stating that "the Court has not analyzed whether Invitae's new technology is non-infringing, nor if it is equally accurate." The Permanent Injunction Order took immediate effect on November 21, 2023, and it has not been suspended to date.

12. On December 20, 2023, the Defendants filed a notice of appeal, appealing the Permanent Injunction Order and all other orders, rulings, and judgments underlying the Permanent Injunction Order, including the Jury's Verdict and the Judgment, to the United States Court of Appeals for the Federal Circuit. *See Defendants' Notice of Appeal*, Case No. 20-cv-125-GBW [ECF No. 682] (the "<u>Appeal</u>").

13. On January 5, 2024, the Defendants filed a notice with the District Court representing that they had discontinued use of the infringing PCM for the uses prohibited by the Permanent Injunction and "are only using the legacy PCM chemistry for the purposes expressly permitted by the [Permanent Injunction Order]." *See Defendants' Notice in Response to the Court's November 21, 2023 Memorandum Order*, Case No. 20-cv-125-GBW [ECF No. 685] (the "Post-Injunction Notice"). "Defendants are not using the legacy PCM chemistry for any other purposes." *See id.*

14. Pursuant to the Permanent Injunction Order, on January 23, 2024, Natera challenged the Defendants' Post-Injunction Notice because it contained no identification of any uses and rendered it impossible for Natera to evaluate and challenge, if necessary, any use of the

⁵ The District Court granted the Defendants four limited exceptions to the injunction: (i) for use in ongoing clinical trials; (ii) for updating old studies undergoing peer review; (iii) for limited quality control to verify the accuracy of an already performed test; and (iv) for the few patients using PCM tests as of the effective date of the injunction. *See id.* at 11.

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Infringing Products (including both legacy and new versions of PCM) that violates the Permanent Injunction. See Natera Inc.'s Response to Defendants' Notice in Response to the Court's November 21, 2023 Memorandum Order Re Permanent Injunction, Case No. 20-cv-125-GBW [ECF No. 687].

15. As a result of the Debtors' chapter 11 cases (the "<u>Chapter 11 Cases</u>"), the District Court has denied all pending motions without prejudice and made no additional findings regarding whether the Defendants continue to infringe the Natera Patents, including through the sale of legacy or new versions of PCM. *See Oral Order*, Case No. 20-cv-125-GBW [ECF No. 706].

II. <u>These Chapter 11 Cases.</u>

16. On February 13, 2024 (the "<u>Petition Date</u>"), the Debtors commenced the Chapter 11 Cases by filing petitions for relief under chapter 11 of title 11 of the United States Code (the "<u>Bankruptcy Code</u>"). On the Petition Date, the Infringement Litigation was automatically stayed pursuant to Bankruptcy Code section 362. *See Notice of Suggestion of Bankruptcy for* Invitae Corporation *and Certain of Its Affiliates and Automatic Stay of Proceedings*, Case No. 20-cv-125-GBW [ECF No. 697].

17. The Chapter 11 Cases are being jointly administered pursuant to rule 1015(b) of the Federal Rules of Bankruptcy Procedure (the "<u>Bankruptcy Rules</u>"), and rule 1015-1 of the Local Bankruptcy Rules for the District of New Jersey (the "<u>Local Rules</u>"). The Debtors continue to operate their businesses and manage their properties as debtors-in-possession pursuant to Bankruptcy Code sections 1107(a) and 1108.

18. On February 14, 2024, the Debtors filed the Motion for a 363 Sale. *See* Bidding Procedures Motion.

19. On February 16, 2024, the Court approved the Debtors' proposed sale procedures and timeline. *See* Bidding Procedures Order.

OBJECTION

20. The Debtors' proposed 363 Sale should not be approved free and clear of the Judgments and Injunction because they fall outside the scope of Bankruptcy Code section 363(f) and therefore cannot be extinguished. Even assuming *arguendo* that the Judgments and Injunction are "interests," the Debtors cannot satisfy any of the free and clear conditions under Bankruptcy Code section 363(f), and Natera would be irreparably harmed by a sale free and clear of Natera's Judgments and Injunction.

I. <u>The Judgments and Injunction Are Not "Interests" That Can Be Extinguished In a</u> <u>363 Sale.</u>

21. Bankruptcy Code section 363(b) allows debtors to sell their assets outside of the ordinary course of business. Specifically, Bankruptcy Code section 363(b)(1) provides that the "trustee, after notice and a hearing, may use, sell, or lease, other than in the ordinary course of business, property of the estate...." 11 U.S.C. § 363(b). Bankruptcy Code section 363(f) further provides that any sale may be *free and clear of any "interest" in such property* if any of the conditions set forth in Bankruptcy Code section 363(f) are met.

22. The Judgments and Injunction do not constitute "interests" under Bankruptcy Code section 363. The term "interest" is not defined in the Bankruptcy Code; however, the Third Circuit Court of Appeals has held that the term "any interest" under Bankruptcy Code section 363(f) is "intended to refer to obligations that are connected to, or arise from, the property being sold." *See In re Trans World Airlines, Inc.*, 322 F.3d 283, 289 (3d Cir. 2003). The court also observed that while "[s]ome courts have narrowly interpreted interests in property to mean *in rem* interests in property, such as liens . . . the trend seems to be toward a more expansive reading of 'interests in property,' which encompasses other obligations that may flow from ownership of the property." *Id.* at 288–89 (emphasis in the original) (internal citations and footnote omitted). For example,

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claims of employment discrimination may constitute "interests," but a party's right of recoupment does not. *Compare id.* at 290 *with In re Lawrence United Corp.*, 221 B.R. 661, 669 (Bankr. N.D.N.Y. 1998) ("The right of recoupment is not itself a claim and any right of recoupment . . . does not even fall under the broadest interpretation of an 'interest' in property.").

23. There is nothing to suggest that the Judgments and Injunction meet even the broadest approach to defining "any interest" in the context of Bankruptcy Code section 363(f). More specifically, the Findings and Conclusions regarding the infringement of the Natera Patents contained in the Jury Verdict and Judgment do not constitute obligations but rather address the Debtors' behavior that would be excluded.⁶ Additionally, the Permanent Injunction excludes certain of the Debtors' behavior, *i.e.*, performing the enjoined activity. For these reasons, the Judgments and Injunction are not "interests" under Bankruptcy Code section 363(f).

II. <u>Even if The Judgments and Injunction are Interests, The Debtors Cannot Otherwise</u> Satisfy Bankruptcy Code Section 363(f).

24. Even assuming the Judgments and Injunction constitute "interests," the Debtors cannot meet their burden to effectuate a sale free and clear of such interests because none of the conditions under Bankruptcy Code section 363(f) are satisfied.

25. Bankruptcy Code section 363(f) provides that a debtor may sell property free and clear of any interest in such property, but *only if one of the following conditions is met*:

- (1) applicable nonbankruptcy law permits sale of such property free and clear of such interest;
- (2) such entity consents;

⁶ Patent rights are exclusionary rights, in that a patent owner does not have a right to practice the patent, but to exclude others from practicing the patent. *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1559 (Fed. Cir. 1996) ("It is elementary that a patent grants only the right to *exclude* others and confers no right on its holder to make, use, or sell.") (emphasis in original). The patent claims at issue in the Judgments and Injunction are method claims and method claims are infringed only when the infringer performs the patented method. *See Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) ("A method claim is *directly* infringed only by one practicing the patented method.") (emphasis in original).

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- (3) such interest is a lien and the price at which such property is to be sold is greater than the aggregate value of all liens on such property;
- (4) such interest is in bona fide dispute; or
- (5) such entity could be compelled, in a legal or equitable proceeding, to accept a money satisfaction of such interest.

11 U.S.C. § 363(f).

26. As set forth below, none of these conditions are satisfied.

27. *First*, applicable nonbankruptcy law does not permit the sale of the Infringing Products free and clear of the Judgments and Injunction.

28. The Patent Act provides that "[e]very patent shall contain . . . a grant . . . of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States." *See* 35 U.S.C. § 154(a)(1). Moreover, the Patent Act provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . infringes the patent." *See* 35 U.S.C. § 271(a). A court of competent jurisdiction has already found that the Debtors have infringed the Natera Patents and that the Infringing Products are covered by the Natera Patents. *See* Judgment, at 1–2; Permanent Injunction Order, at 1. The District Court also issued the Permanent Injunction and extended the Permanent Injunction to "Defendants and each of their officers, servants, employees, attorneys, and any other persons who are in active concert or participation with them." *See* Permanent Injunction Order, at 11.

29. There is no applicable nonbankruptcy law that permits the sale of the Infringing Products free and clear of the Judgments and Injunction.⁷ Indeed, to the contrary, any purchaser

⁷ In most instances where nonbankruptcy law permits a sale free and clear of an interest, state real property law is involved. *See, e.g., In re Daufuskie Island Props., LLC*, 431 B.R. 626, 644 (Bankr. D.S.C. 2010) (holding the

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of the Infringing Products would qualify as a party "in active concert or participation" with the Debtors/Defendants. As such, this condition under Bankruptcy Code section 363(f)(1) cannot be satisfied.

30. *Second*, Bankruptcy Code section 363(f)(2) is not met because Natera has not consented and will not consent to a sale free and clear of its interest.

31. *Third*, the "interest" in question is not a lien, so Bankruptcy Code section 363(f)(3), which relates specifically to liens, is inapplicable.

32. *Fourth*, the Infringement Litigation is not a "bona fide dispute" because the District Court entered the Judgments and Injunction against the Debtors following an adjudication by a jury.

33. The phrase "bona fide dispute" is not defined in the Bankruptcy Code. The identical phrase is used in Bankruptcy Code section 303(h)(1) involving contested involuntary bankruptcy petitions, and in that context, the Third Circuit Court of Appeals explained that a bona fide dispute exists "[i]f there is a genuine issue of material fact that bears upon the debtor's liability, or a meritorious contention as to the application of law to undisputed facts. . . ." *B.D.W. Associates, Inc. v. Busy Beaver Bldg. Centers, Inc.*, 865 F.2d 65, 66–67 (3d Cir. 1989); *see also In re Elverson*, 492 B.R. 831, 835 (Bankr. E.D. Pa. 2013) (same).

34. More recently, the Third Circuit applied similar reasoning with respect to Bankruptcy Code section 363(f)(4), and in interpreting the provision, the Third Circuit explained, ""[b]ona fide dispute' in the § 363(f)(4) context means that there is an objective basis—either in

trustee could sell the debtor's real property free and clear of a restrictive covenant running with the land that required the debtor to convey the property back to the original seller upon the occurrence of certain events because the applicable South Carolina law renders a restrictive covenant unenforceable where it is "valueless to the covenantee and oppressive and unreasonable to the covenantor."); *In re Rose*, 113 B.R. 534, 538 (W.D. Mo. 1990) (affirming the bankruptcy court's approval of a trustee's sale of the debtors' farm free and clear of the life estate over the farm property because applicable Missouri statutory law authorizes the sale of land subject to life estates where the party seeking the sale uses and maintains the land). Here, federal patent law is at issue.

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law or fact—to cast doubt on the validity of [the interest in question]." *In re Revel AC, Inc.*, 802 F.3d 558, 573 (3d Cir. 2015). Not any alleged dispute satisfies Bankruptcy Code section 363(f)(4); rather, a bona fide dispute entails "some sort of meritorious, existing conflict." *In re NJ Affordable Homes Corp.*, 2006 WL 2128624, at *10 (Bankr. D.N.J. June 29, 2006) (citing *Atlas Mach. & Iron Works, Inc. v. Bethlehem Steel Corp.*, 986 F.2d 709, 715 (4th Cir.1993)).

35. Indeed, the mere existence of a pending appeal is not typically viewed as a "meritorious conflict" and, as such, it will not usually be deemed to create a bona fide dispute. For example, in analyzing whether appeal rights create a bona fide dispute, "the majority rule when interpreting the term 'bona fide dispute' in the context of section 303 indicates that an unstayed judgment on appeal is not subject to a bona fide dispute" such that a creditor could not join in to force an involuntary bankruptcy. In re Southland Royalty Co. LLC, 623 B.R. 64, 99 (Bankr. D. Del. 2020); see also In re Drexler, 56 B.R. 960, 967 (Bankr. S.D.N.Y. 1986) (finding a claim based on an unstayed final judgment from which an appeal by the debtor has been taken and is pending when the petition is filed was not the subject of a bona fide dispute). "Once entered, an unstayed final judgment may be enforced in accordance with its terms and with applicable law or rules, even though an appeal is pending." Id. Additionally, "[i]t would be contrary to the basic principles respecting, and would effect a radical alteration of, the long-standing enforceability of unstayed final judgments to hold that the pendency of the debtor's appeal created a 'bona fide dispute' within the meaning of [Bankruptcy] Code [section] 303." Id. Finally, the conclusion is supported by the fact that judgments do not "hang in limbo pending appeal." Id. at 678 (citing U.S. v. Verlinsky, 459 F.2d 1085, 1089 (5th Cir.1972)).

36. While the Appeal has been automatically stayed in this case due to the filing of the Chapter 11 Cases, Natera's Permanent Injunction took effect immediately upon its entry and remains in place. The District Court reached the Judgment on the merits following proceedings in

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which the Debtors had ample opportunity to participate and were aggressively represented by counsel. The Debtors also did not seek to stay the Permanent Injunction pending appeal. Additionally, the Debtors have the ability to continue the Appeal by lifting the automatic stay and have chosen not to do so. Thus, the Judgments and Injunction are not in bona fide dispute.

37. *Fifth*, Natera cannot be compelled to accept a monetary satisfaction of its interests in the Assets to be sold.

38. Bankruptcy Code section 363(f)(5) concerns whether the interest holder can be compelled, in a legal or equitable proceeding, to accept monetary satisfaction of their interests. 11 U.S.C. § 363(f)(5); *In re Beker Indus. Corp.*, 63 B.R. 474, 478 (Bankr S.D.N.Y. 1986) (stating that section 363(f)(5) is to be interpreted as referring to those "*few interests* in property that can, by operation of law, be reduced to dollars.") (emphasis added). Accordingly, if a holder of an interest cannot be compelled to accept a cash award in lieu of equitable relief, the sale cannot proceed under Bankruptcy Code section 363(f)(5). Where equitable relief, such as an injunction, is the remedy, monetary relief is insufficient. *See, e.g., Gouveia v. Tazbir*, 37 F.3d. 295, 299 (7th Cir. 1994) (where a restrictive covenant that ran with the land existed, there was nothing that could force the landowner to forego equitable relief in favor of a cash reward); *In re 523 E. Fifth Street Hous. Preserv. Dev.* 't *Fund Corp.*, 79 B.R. 568, 576 (Bankr. S.D.N.Y. 1987) (same). Here, Natera's potential interest involves the Judgments and Injunction.

39. In issuing the Judgments and Injunction, the District Court applied a four-factor test that was set forth by the Supreme Court in *eBay Inc. v. MercExchange L.L.C.* 547 U.S. 388, 391 (2006). In *eBay*, the Supreme Court reasoned that a party seeking a permanent injunction must demonstrate that: (1) it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and the defendant, a remedy in equity is warranted; and

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(4) that the public interest would not be disserved by a permanent injunction." *See id.* Furthermore, "[t]he decision to grant or deny permanent injunctive relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion." *Id.* In applying these equitable factors, the District Court found that all four factors favored granting the Permanent Injunction in Natera's favor. Permanent Injunction Order, at 5.

40. Moreover, in granting Natera's request for the Judgments and Injunction, the District Court found that the remedies available at law were unable to adequately compensate Natera for its loss of market share, brand recognition, and customer goodwill. *See* Permanent Injunction Order, at 8–9. Accordingly, Natera cannot be compelled to accept monetary satisfaction in lieu of the injunctive relief that has already been awarded by the District Court.

III. <u>Natera Would Be Irreparably Harmed by a Sale Free and Clear of the Judgments</u> <u>and Injunction.</u>

41. Approving the proposed Sale Transaction free and clear of the Judgments and Injunction regarding the Infringing Products, including the Permanent Injunction, would irreparably harm Natera and could result in abuse of the 363 sale process.

42. Bankruptcy Code section 105(a) codifies a bankruptcy court's inherent equitable powers to "issue any order, process, or judgment that is necessary or appropriate to carry out the provisions of this title." 11 U.S.C. § 105(a). The Court also may "tak[e] any action or mak[e] any determination necessary or appropriate to enforce or implement court orders or rules, or to prevent an abuse of process." *Id.*

43. As previously discussed, the District Court held that Natera would suffer irreparable injury if the Defendants' use of the PCM tests was not enjoined. *See* Permanent Injunction Order, at 5. The District Court found that, due to the Defendants' infringement, Natera lost market share and suffered irreparable reputational harm. *Id.* Additionally, "Invitae's

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infringing competitive product threatens to erode prices, by increasing the number of competitors and limiting the ability of Natera to charge a profit-maximizing monopoly price." *Id.* Similarly, the District Court found that the remedies available at law are unable to adequately compensate Natera. *Id.* at 8–9. Finally, the District Court held that "the public interest weighs in favor of an injunction." *Id.* at 10. None of these findings would change should a third-party purchaser step into the shoes of the Debtors. Thus, the sale of any Infringing Products cannot be free and clear of Natera's interests. Any buyer should be held to the terms of the Permanent Injunction and not be permitted to infringe the Natera Patents.

44. The relief requested by Natera is of a very limited nature and necessary to prevent abuse of the 363 sale process. Allowing a sale free and clear of the Judgments and Injunction would be in direct conflict with section 363's promotion of sales in good faith. As an adjudicated infringer, the Debtors' and any purchasers' infringement is willful, subject to treble damages, and potentially an exceptional case finding in a subsequent case. Indeed, honoring Natera's Permanent Injunction is necessary and appropriate to prevent an abuse of the 363 sale process. Accordingly, the Court should exercise its powers under Bankruptcy Code section 105(a) by denying the sale of Infringing Products free and clear of the Judgments and Injunction and ensuring any buyer is subject to Natera's Permanent Injunction.

RESERVATION OF RIGHTS

45. Natera reserves its right to amend, supplement, and/or otherwise modify this Objection and to raise other and further objections to the Sale Order and associated applicable asset purchase agreements. Natera further reserves its right to enforce its intellectual property rights against the Debtors and any purchasers of the Debtors' Infringing Products, including but not limited to PCM, as well as against any products "not colorably different" from the Infringing Products to the fullest extent permitted under law.

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NOTICE

46. Copies of the within Objection have been provided to: (i) the Debtors, Invitae Corporation, 1400 16th Street, San Francisco, California 94103, Attn: Tom Brida (tom.brida@invitae.com); (ii) proposed co-counsel to the Debtors, Kirkland & Ellis LLP, 601 Lexington Avenue, New York, New York 10022, Attn.: Nicole L. Greenblatt, P.C. (nicole.greenblatt@kirkland.com); Francis Petrie (francis.petrie@kirkland.com); and Nikki Gavey (nikki.gavey@kirkland.com) and Kirkland & Ellis LLP, 300 North LaSalle, Chicago, Illinois 60654, Attn.: Spencer A. Winters, P.C. (spencer.winters@kirkland.com); (iii) proposed co-counsel to the Debtors, Cole Schotz P.C., Court Plaza North, 25 Main Street, Hackensack, New Jersey 07601, Attn.: Michael D. Sirota (msirota@coleschotz.com); Warren A. Usatine (wusatine@coleschotz.com); Felice R. Yudkin (fyudkin@coleschotz.com); and Daniel J. Harris (dharris@coleschotz.com); (iv) the Office of the United States Trustee for the District of New Jersev, 1085 Raymond Boulevard, Suite 2100, Newark, New Jersey 07102, Attn: Jeffrey Sponder (jeffrey.m.sponder@usdoj.gov); and Lauren Bielskie (lauren.bielskie@usdoj.gov); (v) proposed co-counsel to the Official Committee of Unsecured Creditors, White & Case LLC, 1221 Avenue of Americas, New York, New York 10020, Attn.: J. Christopher Shore the (cshore@whitecase.com); Harrison Denman (harrison.denman@whitecase.com); Andrew Zats (azats@whitecase.com); Samuel P. Hershey (sam.hershey@whitecase.com); Ashley Chase (ashley.chase@whitecase.com); and Brett Bakemeyer (brett.bakemeyer@whitecase.com); and (vi) proposed co-counsel to the Official Committee of Unsecured Creditors, Porzio, Bromberg & Newman, P.C., 100 Southgate Parkway, P.O. Box 1997, Morristown, New Jersey 07962, Attn.: Warren J. Martin Jr. (wjmartin@pbnlaw.com); John S. Mario (jsmairo@pbnlaw.com); and Christopher P. Mazza, Esq. (cpmazza@pbnlaw.com) via electronic mail, and all parties having formally requested notice in this proceeding electronically via the Court's CM/ECF system.

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CONCLUSION

WHEREFORE, Natera requests that the Court find that the Judgments and Injunction are not "interests" that can be extinguished by or subjected to the Debtors' 363 Sale. In the alternative, if the Judgments and Injunctions are "interests," Natera requests that the Court find that the Debtors cannot satisfy Bankruptcy Code section 363(f) with respect to the Judgments and Injunction. As such, to the extent the Court approves any 363 Sale that includes the Infringing Products, Natera requests that the Court condition such approval upon amending the Sale Order to include the

following language:

Nothing in this Sale Order, the APA, or any other Transaction Document shall limit, modify, or in any way affect Natera Inc.'s rights and the Debtors' (or any purchaser's) obligations under that certain permanent injunction set forth by the United States District Court for the District of Delaware in *Memorandum Order* [ECF No. 679] (the "Permanent Injunction Order") in the case styled *Natera, Inc. v. ArcherDX, Inc., et al.*, C.A. No. 20-cv-125-GBW. Nothing in this Sale Order, the APA, or any other Transaction Document shall permit a sale free and clear of that certain jury verdict in *Verdict Form* [ECF No. 609] (the "Jury Verdict"), that certain judgment reflecting the jury's findings in *Judgment* [ECF No. 665] (the "Judgment"), or the Permanent Injunction Order, and any purchaser of the Infringing Products shall be bound by the Permanent Injunction Order, the Jury Verdict, and the Judgment to the extent such purchaser would be so bound under applicable non-bankruptcy law; *provided, however*, that the Sale Transaction shall be free and clear of all monetary damages provided in the Jury Verdict and Judgment.

Natera further requests that the Court grant such other and further relief as the Court deems

just and proper.

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Dated: April 1, 2024 Newark, New Jersey

GIBBONS P.C.

<u>/s/ Robert K. Malone</u> Robert K. Malone Kyle P. McEvilly One Gateway Center Newark, New Jersey 07102-5310 Telephone: (973) 596-4500 Email: rmalone@gibbonslaw.com kmcevilly@gibbonslaw.com

-and-

MCDERMOTT WILL & EMERY LLP

Darren Azman (*pro hac vice* pending) Deanna D. Boll One Vanderbilt Avenue New York, New York 10017-3852 Telephone: (212) 547-5400 Email: dazman@mwe.com dboll@mwe.com

Co-Counsel for Natera Inc.

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EXHIBIT A

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Read In Open Court 5/15/23 00

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NATERA, INC.,)	
Plaintiff,)	
V.)))	C.A. No. 20-125 (GBW) (CONSOLIDATED)
ARCHERDX, INC., ARCHERDX, LLC and INVITAE CORP.,)))	JURY TRIAL DEMANDED
Defendants.)	

VERDICT FORM

Instructions: When answering the following questions and completing this Verdict Form, please follow the directions provided and follow the Jury Instructions that you have been given. Your answer to each question must be unanimous. Some of the questions contain legal terms that are defined and explained in the Jury Instructions. Please refer to the Jury Instructions if you are unsure about the meaning or usage of any legal term that appears in the questions below.

As used herein:

- 1. "Natera" refers to Plaintiff Natera, Inc.
- 2. "Defendants" refers to Defendants ArcherDX, Inc., ArcherDX, LLC and Invitae Corp.
- 3. The "'172 Patent" refers to U.S. Patent No. 10,557,172.
- 4. The "'708 Patent" refers to U.S. Patent No. 10,597,708.
- 5. The "220 Patent" refers to U.S. Patent No. 10,731,220.

We, the jury, unanimously find as follows.

DIRECT INFRINGEMENT

1. Has Natera proven by a preponderance of the evidence that Defendants directly infringed any asserted claim of the '172 patent? (a "YES" answer is a finding for Natera; a "NO" answer is a finding for Defendants):

CLAIM	YES	NO
1	\checkmark	
5	\checkmark	
В		

2. Has Natera proven by a preponderance of the evidence that Defendants directly infringed any asserted claim of the '220 patent? (a "YES" answer is a finding for Natera; a "NO" answer is a finding for Defendants):

CLAIM	YES	NO
1	\checkmark	
3	\checkmark	
4	\checkmark	
6		
7	\checkmark	

3. Has Natera proven by a preponderance of the evidence that Defendants directly infringed any asserted claim of the '708 patent? (a "YES" answer is a finding for Natera; a "NO" answer is a finding for Defendants):

CLAIM	YES	NO
1		
19		

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SAFE HARBOR

4. Have Defendants proven by a preponderance of the evidence that use of the PCM products was reasonably related to the development and submission of information to the U.S. Food and Drug Administration (also known as the FDA)? (a "YES" answer is a finding for Defendants; a "NO" answer is a finding for Natera).

YES: _____

NO: ____

INDIRECT INFRINGEMENT

5. Has Natera proven by a preponderance of the evidence that Defendants indirectly infringed any asserted claim of the '172 patent either by induced infringement or contributory infringement? (a "YES" answer is a finding for Natera; a "NO" answer is a finding for Defendants):

CLAIM	INDU INFRING			BUTORY GEMENT
	YES	NO	YES	NO
1		\checkmark		\checkmark
6		\checkmark		\checkmark
8		\checkmark		\checkmark

6. Has Natera proven by a preponderance of the evidence that Defendants indirectly infringed any asserted claim of the '220 patent either by induced infringement or contributory infringement? (a "YES" answer is a finding for Natera; a "NO" answer is a finding for Defendants):

CLAIM	INDUCED INFRINGEMENT		CONTRIBUTORY INFRINGEMENT	
	YES	NO	YES	NO
1		\checkmark		\checkmark
3		\checkmark		\checkmark
4		\checkmark		\checkmark
6		\checkmark		
7				\checkmark

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7. Has Natera proven by a preponderance of the evidence that Defendants indirectly infringed any asserted claim of the '708 patent either by induced infringement or contributory infringement? (a "YES" answer is a finding for Natera; a "NO" answer is a finding for Defendants):

CLAIM	INDU INFRING		A STATE AND A STATE AND A STATE AND A STATE	BUTORY GEMENT
	YES	NO	YES	NO
1				\checkmark
19		\checkmark		

VALIDITY: ANTICIPATION AND OBVIOUSNESS

8. Have Defendants proven by clear and convincing evidence that any of the following claims of the '172 patent are invalid because it would have been anticipated based on Iafrate? (a "YES" answer is a finding for Defendants; a "NO" answer is a finding for Natera):

CLAIM	INVALID DUE TO ANTICIPATION
	YES NO
6	
8	

9. Have Defendants proven by clear and convincing evidence that any of the following claims of the '220 patent are invalid because it is anticipated based on Iafrate? (a "YES" answer is a finding for Defendants; a "NO" answer is a finding for Natera):

CLAIM	INVALID DUE TO ANTICIPATION	
	YES NO	
1		
3		
4		
6	\checkmark	
7		

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10. Have Defendants proven by clear and convincing evidence that any of the following claims of the '708 patent are invalid because it would have been obvious to a person of ordinary skill in the art based on Blomquist in view of Forshew? (a "YES" answer is a finding for Defendants; a "NO" answer is a finding for Natera):

	LID DUE TO /IOUSNESS
YES	NO
1	
19	\checkmark

VALIDITY: WRITTEN DESCRIPTION, DEFINITENESS, OR FAILURE TO CLAIM WHAT THE INVENTORS REGARDED AS THEIR INVENTION

11. Have Defendants proven by clear and convincing evidence that any of the following claims of the '172 patent are invalid because the patent lacks adequate written description, or fails to claim what the inventors regarded as their invention? (a "YES" answer is a finding for Defendants; a "NO" answer is a finding for Natera):

CLAIM	INVALID DUE TO LACK OF WRITTEN DESCRIPTION		INVALID FO FAILURE TO CLAIM WHA THE INVENTOR REGARDED THEIR INVENTION	
	YES	NO	YES	NO
1				1
6		\checkmark		
8		\checkmark		

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12. Have Defendants proven by clear and convincing evidence that any of the following claims of the '220 patent are invalid because the patent lacks adequate written description, or fails to claim what the inventors regarded as their invention? (a "YES" answer is a finding for Defendants; a "NO" answer is a finding for Natera):

CLAIM	INVALID DUE TO LACK OF WRITTEN DESCRIPTION		THE INV REGAR TH	RE TO WHAT ENTORS
	YES	NO	YES	NO
1	at all fait ann an an Ann An An Ann An Ann An An Ann An			\checkmark
3		\checkmark		1
4		\checkmark		5
6		\checkmark		\checkmark
7				\checkmark

13. Have Defendants proven by clear and convincing evidence that any of the following claims of the '708 patent are invalid because the patent is indefinite? (a "YES" answer is a finding for Defendants; a "NO" answer is a finding for Natera):

	INVALID DUE TO INDEFINITENESS		
CLAIM	YES	NO	
1			
19			

INVENTORSHIP

14. Have Defendants proven by clear and convincing evidence that any of the following claims of the '172 patent are invalid for failing to name the proper inventors? (a "YES" answer is a finding for Defendants; a "NO" answer is a finding for Natera):

CLAIM	IMPI	D DUE TO ROPER FORSHIP
	YES	NO
1		V
6		\checkmark
8		\int

15. Have Defendants proven by clear and convincing evidence that any of the following claims of the '220 patent are invalid for failing to name the proper inventors? (a "YES" answer is a finding for Defendants; a "NO" answer is a finding for Natera):

CLAIM	IMPRO	INVALID DUE TO IMPROPER INVENTORSHIP	
	YES	NO	
1		\checkmark	
3			
4		\checkmark	
6		\checkmark	
7		\checkmark	

DAMAGES

You are only to answer Question Nos. 16-18 below if you have found an Asserted Claim of the Patents-in-Suit to be infringed <u>and</u> not invalid.

16. What is the total amount of damages Natera has proven by a preponderance of the evidence that it is entitled to be paid for lost profits as a result of Defendants' infringing sales of PCM?

Amount: \$ 9,356,886

17. For any PCM sales on which you did not award lost profits, what is the total amount of damages Natera has proven by a preponderance of the evidence that it is entitled to be paid as a reasonable royalty for past sales of Defendants' PCM?

Royalty Rate: _____ %

Amount for	Sales in the U	nited States:	\$ <u>0</u>

Amount for Sales Outside United States: \$ ()

18. What is the total amount of damages Natera has proven by a preponderance of the evidence that it is entitled to be paid as a reasonable royalty for Defendants' past sales of the accused products other than PCM?

Royalty Rate: _____/0%

Amount for Sales in the United States: \$ 5,430,181	
Amount for Sales Outside United States: \$ 4, 564, 963	

Continue to next page.

UNANIMOUS VERDICT

UPON REACHING A UNANIMOUS VERDICT ON EACH QUESTION ABOVE, EACH JUROR MUST SIGN BELOW.

We, the jury, unanimously agree to the answers to the above questions and return them under the instructions of this Court as our verdict in this case.

REDACTED

REDACTED

Dated: 5/15/23

Case 24-11362-MBK Doc 262-2 Filed 04/01/24 Entered 04/01/24 19:53:50 Desc Exhibit B Page 1 of 4

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NATERA, INC.,)	
Plaintiff,		
v. ARCHERDX, INC., ARCHERDX, LLC and)))	C.A. No. 20-125 (GBW) (CONSOLIDATED)
INVITAE CORP.,)	
Defendants.)	

[PROPOSED] JUDGMENT

Pursuant to the JURY VERDICT of May 15, 2023, (D.I. 609) and the Court's Order of September 5, 2023 (D.I. 663), JUDGMENT is hereby entered as follows:

IT IS ORDERED AND ADJUDGED that judgment be and hereby is entered in favor of Natera, Inc. ("Natera") and against Defendants ArcherDX, Inc., ArcherDX, LLC, and Invitae Corporation (collectively, "Defendants") with respect to Natera's claims for direct infringement of:

(i) claims 1, 6, and 8 of U.S. Patent No. 10,557,172 ("the '172 Patent")

(ii) claims 1 and 19 of U.S. Patent No. 10,597,708 ("the '708 Patent")

(iii) claims 1, 3, 4, 6, and 7 of U.S. Patent No. 10,731,220 ("the '220 Patent")

IT IS FURTHER ORDERED AND ADJUDGED that judgment be and hereby is entered in favor of Natera and against Defendants that the '172 Patent, the '708 Patent and the '220 Patent are not invalid;

IT IS FURTHER ORDERED AND ADJUDGED that judgment be and hereby is entered in favor of Natera and against Defendants that Defendants' use of the PCM product was not

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reasonably related to the development and submission of information to the U.S. Food and Drug Administration;

IT IS FURTHER ORDERED AND ADJUDGED that judgment be and hereby is entered in favor of Natera and against Defendants with respect to the '172 Patent and the '220 Patent that Defendants have failed to meet their burden of proving prosecution laches;

IT IS FURTHER ORDERED AND ADJUDGED that judgment be and hereby is entered in favor of Defendants against Natera that with respect to the '172 Patent, '220 Patent, and '708 Patent that Natera has failed to meet its burden of proving both induced and contributory infringement by Defendants;

IT IS FURTHER ORDERED AND ADJUDGED that judgment be and hereby is entered in favor of Natera and against Defendants for damages in the amount of \$9,356,886 for lost profits as a result of Defendants' infringing sales of PCM, in the amount of \$5,430,181 as reasonable royalty for Defendants' past sales in the United States of the accused products other than PCM, and in the amount of \$4,564,963 as reasonable royalty for Defendants' past sales outside the United States of the accused products other than PCM, subject to any additional damages, enhanced damages, interest, fees, and/or costs that properly may subsequently be sought and awarded by the Court;

IT IS FURTHER ORDERED AND ADJUDGED that this JUDGMENT shall have the effect of denying as moot all oral and written motions made by the parties during the trial pursuant to Federal Rule of Civil Procedure 50(a), subject to such motions being renewed as post-trial motions.

This JUDGMENT is not a Final Judgment, and instead serves to trigger the time for filing post-trial motions on issues that were decided by the jury, as well as other post-trial matters, but

2

reserves Natera's motion for supplemental damages, interest and any ordered royalty to be filed following the Court's decision on the permanent injunction (see D.I. 614, D.I. 656).

Dated: September 19, 2023

Honorable Gregory B. Williams United States District Judge

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EXHIBIT C

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NATERA INC.,

Plaintiff,

v.

ARCHERDX, INC., ARCHERDX, LLC, and INVITAE CORPORATION,

C.A. No. 20-cv-125-GBW (Consolidated)

REDACTED PUBLIC VERSION

Defendants.

MEMORANDUM ORDER

Plaintiff Natera Inc. ("Natera") sued Defendants ArcherDx, Inc., ArcherDx, LLC., and Invitae Corporation (collectively, "Invitae") for patent infringement. Upon conclusion of the jury trial, the jury returned a verdict finding that Defendants' products Personalized Cancer Monitoring ("PCM"), Stratafide, and LiquidPlex infringe U.S. Patent Nos. 10,557,172 (the "172 patent") and U.S. Patent No. 10,731,220 (the "220 patent"). D.I. 609. The jury also found that Defendants' products PCM, Stratafide, VariantPlex, and FusionPlex infringe U.S. Patent No. 10,597,708 (the "708 patent"). *Id.* None of the asserted claims was found to be invalid by the jury, and the jury did not find that PCM was subject to the FDA safe harbor under 35 U.S.C. § 271(e)(1). *Id.* Thereafter, the Court held a one-day bench trial on prosecution laches, and ultimately found that Defendants failed to demonstrate that the patents were invalid for prosecution laches. D.I. 662. Natera now moves for an injunction against PCM. D.I. 621.

I. LEGAL STANDARD

Courts may "grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. A party seeking a permanent injunction must demonstrate (1) irreparable injury;

1

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(2) inadequacy of remedies available at law, such as monetary damages; (3) the balance of the hardships between plaintiff and defendant warrants granting a remedy; (4) the public interest is not harmed by an injunction. *eBay Inc. v. Mercexchange, L.L.C.*, 547 U.S. 388, 393 (2006). The "movant must prove that it meets all four equitable factors." *Nichia Corp. v. Everlight Americas, Inc.*, 855 F.3d 1328, 1341 (Fed. Cir. 2017). In particular, "[i]f a plaintiff fails to show 'that the public interest would not be disserved by a permanent injunction,' then the district court may not issue an injunction." *Amgen, Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed. Cir. 2017) (quoting *eBay*, 547 U.S. at 391).

II. DISCUSSION

Invitae has asserted that it is phasing out most of its use of the legacy PCM. D.I. 648 ¶ 11; D.I. 671. Invitae has indicated that will continue using the legacy PCM (1) in ongoing clinical trials and studies with AstraZeneca, Bristol Myers Squibb, and (2) in ongoing research studies (TRAK-ER, ARTEMIS, and MARIA) with hospitals, academics, and pharmaceutical companies; (3) by potentially updating data on old studies if necessary as part of peer-review (4); to re-run limited additional tests for quality control for regulators or customers; and (5) for 50 patients. D.I. 648 ¶¶ 20-35; D.I. 622 at 20. Natera does not seek to enjoin the use of the legacy PCM for the patients but seeks an injunction on all other uses, including any uses Invitae has not yet indicated it will undertake. D.I. 622 at 20.

A. The Court Declines to Enjoin the Use of Legacy PCM in Ongoing Clinical Trials, for Updating Old Studies Undergoing Peer Review, and for Limited Quality Control, Because an Injunction Would Impermissibly Harm the Public Interest.

Invitae argues at length that enjoining its ongoing uses of legacy PCM would harm the public. The Court agrees that enjoining the use of legacy PCM in ongoing clinical trials and studies, for updating old studies, and for limited quality control would harm the public interest. Thus, the Court denies Natera's motion for an injunction as to those uses.

2

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1. Ongoing Clinical Trials

Third-party companies are relying on the legacy PCM to conduct cancer research. Once a study design has been locked in, it is "very difficult to change that test, if not, nearly impossible." D.I. 647, Ex. A, Bench Trial Tr. 175:15-176:17 (Stefanelli). Changing the PCM would result in a confounding variable and may result in the stop of research in progress. Id. Natera argues that the changing the PCM is possible, since Invitae is using the PCM on stored samples. D.I. 657 at 8 (quoting D.I. 648 ¶ 20). However, Natera only cites evidence that the PCM is being used exclusively on stored samples for one of the three ongoing clinical studies, and the Court has no indication that all samples have been stored for all three clinical studies. Id. In any event, forcing third parties to re-run PCM for thousands of stored samples could significantly obstruct ongoing cancer research. See D.I. 647, Ex. A, Bench Trial Tr. 175:15-176:17 (Stefanelli). Impeding ongoing cancer research would significantly harm the public interest. See Alcon, Inc. v. Teva Pharms. USA, Inc., Civ. No. 06-234-SLR, 2010 WL 3081327, at *3 (D. Del. Aug. 5, 2010) (denying a permanent injunction because an injunction would "deprive the public of the benefit of [a drug manufacturer's] developmental efforts."). Accordingly, the Court denies Natera's motion for an injunction on the use of legacy PCM in ongoing clinical trials and studies.

2. Updating Old Studies in Already Completed Research

Some researchers who have already used the legacy PCM may seek to publish their research. D.I. 648 \P 32. As part of peer-review, publishers may request the researchers to conduct additional PCM tests. *Id.* \P 33. Changing the PCM used for these new tests would introduce a confounding variable, and thus potentially prevent the publishing of the studies. *Id.* Natera does not specifically address this potential use. *See* D.I. 657 at 8-9. The Court accordingly finds that enjoining this use would significantly harm the public's interest in speedy and accurate research.

3

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See Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc., 967 F.3d 1353, 1379-80 (Fed. Cir. 2020) (affirming a carve-out from a permanent injunction for in-progress research). Thus, the Court denies Natera's motion for an injunction on the use of legacy PCM in already-completed research.

3. Limited Quality Control Uses

Regulators or customers may request that Invitae verify the accuracy of an alreadyperformed test using the legacy PCM. D.I. 648 ¶ 34. Natera does not discuss or specifically object to these limited quality control uses. See D.I. 657 at 8-9. The public has an interest in ensuring that already-performed tests were accurate—if Invitae could not tell past patients if a test was accurate, patient care would be harmed. Meanwhile, Invitae has represented that these uses will be limited, dampening any public interest in enforcing an injunction against them. Ensuring an already performed test was accurate is not the sort of market activity that Natera would be able to capture. *Cf.* Section II.B.iv, *infra* (discussing sales Natera could capture). Any injunction must be reasonable and fit the principles of equity. 35 U.S.C. § 283. The Court finds the public interest in permitting accurate quality control weighs against an injunction. Thus, the Court denies Natera's motion for a permanent injunction on the use of legacy PCM to perform limited quality control on already-performed tests.

B. The Court Enjoins the Use of Legacy PCM in Research Studies and All Other Non-Exempted Uses.

Invitae has indicated that it intends to phase out the use of its legacy PCM in ongoing research studies (TRAK-ER, ARTEMIS, and MARIA). D.I. 648 ¶¶ 20-22, 31; D.I. 671. Invitae has represented that it has designed a non-legacy PCM that is able to substitute into research studies, and other uses in the future. D.I. 648 ¶¶ 11-16; D.I. 671. However, a promise to transition to a non-infringing alternative does not necessarily justify denying an injunction. See Callaway Golf Co., v Acushnet Co., 585 F. Supp. 2d 600, 622 (D. Del. 2008), rev'd on other grounds, 576

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F.3d 1331 (Fed. Cir. 2009) ("Defendant suggests allowing it to infringe until. . . it plans to launch a new version of the [infringing product]. The court is not in the business of making defendants' infringements easier to unravel."); *E.I. DuPont de Nemours and Co. v. Unifrax I LLC*, No. 14-1250-RGA, 2017 WL 4004419, at *4-6 (D. Del. Sept. 12, 2017) ("[A] bare promise by a party in the course of litigation to discontinue past or ongoing misconduct does not justify denial of injunctive relief."). Thus, the Court applies the full *eBay* equitable analysis. In applying the equitable factors, the Court finds that all four factors favor granting an injunction in Natera's favor.

i. Irreparable Injury

First, Natera would suffer irreparable injury if the legacy PCM is not enjoined. The PCM market is nascent, and there are significant first-mover advantages. D.I. 648 ¶ 111, 114. Invitae has represented that it is possible to substitute an alternative PCM into the ongoing research studies and has not provided a reason that this substitution cannot be with Natera's competitive product rather than Invitae's new PCM. See D.I. 648 ¶ 11-16; D.I. 646 at 6-8. That Natera and Invitae are competitors and Natera has lost market share strongly suggests irreparable harm. Broadcom Corp. v. Emulex Corp., 732 F.3d 1325, 1338 (Fed. Cir. 2013). This is especially true where Natera has not licensed competitors to sell tests. Presidio Components, Inc. v. Am. Tech. Ceramics Corp., 702 F. 3d 1351, 1363-64 (Fed. Cir. 2012); D.I. 622, Ex. 4, Trial Tr. 630:11-14. Invitae's infringing competitive product threatens to erode prices, by increasing the number of competitors and limiting the ability of Natera to charge a profit-maximizing monopoly price. D.I. 627 ¶ 14-15. That there are other competitors in the broader cancer-testing market "does not negate irreparable harm," especially since the specific market (personalized cancer monitoring) was a two-company market until recently. Robert Bosch LLC v. Pylon Mfg. Corp., 659 F.3d 1142, 1151 (Fed. Cir. 2011); D.I. 629. The new non-infringing PCM also does not alter this analysis. There is no

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evidence in the record that the new non-infringing PCM is a perfect substitute for Natera's product. See generally D.I. 648. Therefore, there is still a significant risk of price erosion and loss of market share from the legacy PCM, if its use were not enjoined.

Natera also would continue to suffer reputational harm. Natera suffered reputational harm and lost customer goodwill from losing the TracerX study and other projects to Defendants' legacy PCM. D.I. 622, Ex. 3, Trial Tr. 592:3-9 (losing TracerX study "was quite public" and after being published on the cover of Nature "when people found out cancer research in UK and professor [Swanton] were going with different technology everybody started asking questions why that happened is there something wrong with Natera."); D.I. 623 Ex. 1 ("Malani Rpt.") ¶¶ 175-176. Invitae argues that Natera's loss of goodwill was compensated by the jury, but "a finding of lost profits demonstrates that a plaintiff was deprived of market share and business opportunities *in addition* to lost profits." *freal Foods, LLC v. Hamilton Beach Brands, Inc.*, No. CV 16-41-CFC, 2020 WL 4015481, at *4 (D. Del. July 16, 2020) (emphasis added). Invitae also argues that Natera caused its own harm, since Dr. Swanton was unhappy with them. D.I. 646 at 11. However, Invitae's infringing alternative product switch. Natera suffered irreparable reputational damage from Invitae's infringement.

Invitae advances three more arguments that Natera has not suffered irreparable harm: (1) that Natera waited too long to file its claims; (2) that Natera is not using the patented technology itself; and (3) that Natera's patented technology does not drive purchasing decisions because Invitae was able to create a non-infringing alternative with comparable accuracy. D.I. 646 at 8-14. Each of these arguments fails.

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First, delay in filing, or in seeking a preliminary injunction, need not be considered when evaluating whether to grant a permanent injunction. 800 Adept, Inc. v. Murex Securities, Ltd., 505 F. Supp. 2d 1327, 1335-37 (M.D. Fla. 2007) (holding that even a delay significant enough to prevent pre-judgment interest does not weigh against an irreparable injury); see Mytee Prod., Inc. v. Harris Rsch., Inc., 439 F. App'x 882, 888 (Fed. Cir. 2011) ("While we have held that delay in seeking an injunction is a factor to be considered in determining whether to issue a preliminary injunction, we have never held that failure to seek a preliminary injunction [and its consequent delay] must be considered as a factor weighing against a court's issuance of a permanent injunction.").

Second, that Natera does not practice the invention does not disprove irreparable injury. "Although a patentee's failure to practice an invention does not necessarily defeat the patentee's claim of irreparable harm, the lack of commercial activity by the patentee is a significant factor in the calculus." *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1556 (Fed. Cir. 1995). Here, the patentee does have commercial activity, and the two companies are direct competitors. *See* D.I. 622, Ex. 2, Trial Tr. 240:10-12. This case is thus unlike the genre of cases dealing with non-practicing entities, since there is a clear record of commercial and irreparable harm to Natera's business model. *See Presidio*, 702 F.3d at 1363 ("Even without practicing the claimed invention, the patentee can suffer irreparable injury.").

Third, Invitae's allegations that it was able to design a non-infringing design-around do not weigh against a finding of irreparable harm. Invitae argues that, because it was able to designaround the patented technology with accurate tests, Natera failed to show a "nexus" between the technology and purchasing decisions. D.I. 646 at 13-14. However, the Court has not analyzed whether Invitae's new technology is non-infringing, nor if it is equally accurate. Also, all Natera

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needs to do is show that there is "some connection between the harm alleged and the infringing acts." *Apple Inc. v. Samsung Electronics*, 809 F.3d 633, 640 (Fed. Cir. 2015). Natera has demonstrated that its patented technology aided accuracy of tests, and Invitae's own expert conceded that the implementation of the patented technology was "extremely valuable" in PCM. *ArcherDX v. Qiagen LLC*, No. 18-1019-MN, D.I. 537, Ex. 66, at 4 (D. Del.).

"Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm." *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012). Thus, the Court finds that Natera is suffering irreparable harm, which favors an injunction.

ii. Inadequacy of Remedies Available at Law

The second factor, inadequacy of remedies available at law, is nearly indistinguishable from irreparable injury. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1155 (Fed. Cir. 2011) ("With respect to the adequacy of money damages, Bosch argues that it will continue to suffer irreparable harm"); *Apple*, 809 F.3d at 644-45 (holding that error on irreparable harm leads necessarily to error on inadequacy of remedies). Invitae's only new argument on inadequacy of remedies is that a "sunset royalty" would appropriately compensate Natera. *See* D.I. 646 at 18. However, sunset royalties are "inadequate to compensate Plaintiff . . . forced to compete against a rival gaining market share with Plaintiff's technology." *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, No. CV 14-1250-RGA, 2017 WL 4004419, at *4-6 (D. Del. Sept. 12, 2017). A sunset royalty would maintain first-mover advantage and aggravates the risk of price erosion discussed above. *See id*; Malani Rpt. ¶ 122-25. The Court has already found "loss of market share, brand recognition, and customer goodwill," factors which demonstrate inadequacy of monetary damages, "particularly when the infringing acts significantly change the relevant market." *i4i Ltd*.

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P'ship v. Microsoft, Corp., 598 F.3d 831, 862 (Fed. Cir. 2010). Accordingly, the Court finds that the remedies available at law are unable to adequately compensate Natera.

iii. Balance of Hardships

The balance of hardships favors granting an injunction. All of Invitae's arguments on the balance of hardships relate to the clinical trials and studies, which the Court has already decided not to enjoin. D.I. 646 at 14-16. Invitae began the research studies after the filing of the lawsuit in January 2020. See D.I. 658 Ex. 72, Ex. 73, Ex. 74. Similarly, any other enjoined use would be initiated after the trial began. When the harms an infringer faces are "almost entirely preventable" and triggered by a "calculated risk to launch its product pre-judgment," the balance of hardships strongly tilts in favor of the patentee. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006); *see also Windsurfing Intern'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n. 12 (Fed. Cir. 1986) (One "who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected."). Thus, this factor favors granting an injunction.

Moreover, revenues from PCM are a small fraction of Invitae's total business. D.I. 627 ¶ 11, D.I. 624, Ex. 22, 12. In contrast, it is the primary driver of long-term growth for Natera. D.I. 624, Ex. 23, 1. Comparing the "parties' sizes, products, and revenue sources," the Court finds that these traditional factors also indicate that the balance of hardships tilts in favor of granting an injunction. *i4i Ltd. P'ship*, 598 F.3d at 862-63 (when the infringing product "relates to only a small fraction" of a defendant's revenue, the balance of hardships tilts towards plaintiff.).

Further, the representation from Invitae that it is phasing out the use of the legacy PCM weighs in favor of an injunction on any future not yet contemplated uses, as well as on the research

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studies. D.I. 648 ¶ 11; D.I. 671. Invitae has itself indicated that it has an option other than continuing to infringe, so any hardship it suffers is limited. D.I. 671.

iv. Public Interest

For the non-excepted uses, the public interest weighs in favor of an injunction. Invitae argues that the public interest for the research studies favors an injunction because "[i]f the Court orders Invitae to immediately stop using the legacy PCM-before Invitae is able to transition the studies to the updated PCM-the Court would necessarily also halt the TRAK-ER study and the other ongoing trials and studies." D.I. 646 at 17. However, Invitae has not provided any reason why the updated PCM can replace the legacy PCM in the studies, but Natera's competitive product cannot. See D.I. 646 at 16-18. Naterae's competitive product, Signatera, appears to be equally accurate, covers all the same diseases, and has sufficient capacity to meet the market's needs. See D.I. 623, Ex. 4, Trial tr. 624:18-20 (equally accurate); D.I. 624, Ex. 24, 25, 26, 27 (same diseases), D.I. 622 at 18 (capacity). In circumstances where "the public can obtain the products from [Plaintiff]" the public interest does not disfavor an injunction. Celsis, 922 F.3d at 932. Instead, given the "importance of the patent system in encouraging innovation" and "the encouragement of investment-based risk," the public interest for the remaining uses favors an injunction. Apple, 809 F.3d at 647; Sanofi-Synthelabo, 470 F.3d at 1383. Thus, the Court finds that the public interest factor favors an injunction on the research studies, and on any use not specifically exempted.

Because all four factors support granting an injunction for the remaining uses, the Court GRANTS-IN-PART Natera's motion for a permanent injunction.

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Therefore, at Wilmington this 21st day of November 2023, **IT IS HEREBY ORDERED** that Plaintiff Natera Inc.'s ("Natera") Motion for Permanent Injunction (D.I. 621) against Defendants ArcherDx, Inc., ArcherDx, LLC., and Invitae Corporation (collectively, "Invitae"), is

GRANTED-IN-PART.

Defendants and each of their officers, servants, employees, attorneys, and any other persons who are in active concert or participation with them, are hereby permanently enjoined from infringing in any ways Claims 1, 6, and 8 of U.S. Patent No. 10,557,172; claims 1, 3, 4, 6, and 7 of U.S. Patent No. 10,731,220; and claims 1 and 19 of U.S. Patent No. 10,597,708, by using PCM or any product or service not more than colorably different from PCM, through and including the respective expiration date of each patent, including any USPTO extensions granted thereon, with the following exceptions:

- A. Using PCM in currently ongoing clinical trials and studies with AstraZeneca, Bristol Myers Squibb, and
- B. Using PCM to update data in old studies if necessary as part of peer-review;
- C. Using PCM to re-run limited additional tests for quality control for regulators or customers;

D. Using PCM for the few patients using PCM as of the effective date of this injunction.

Defendants shall file with the Court under seal and serve on all parties a notice identifying all additional uses of PCM performed under this injunction. Plaintiff shall have the right to challenge these identifications. The Court retains jurisdiction to enforce the judgment and permanent injunction pertaining to this action.

GREGORY B. WILLIAMS UNITED STATES DISTRICT JUDGE