

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NATERA, INC.,

Plaintiff,

v.

ARCHERDX, INC., ARCHERDX, LLC, and
INVITAE CORP.,

Defendants.

C.A. No. 20-125-GBW
(CONSOLIDATED)

Jack B. Blumenfeld, Derek J. Fahnestock, Anthony D. Raucci, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, Delaware; William G. Gaede, III, Jodi L. Benassi, MCDERMOTT WILL & EMERY LLP, San Francisco, California; Bhanu K. Sadasivan, Cecilia Choy, MCDERMOTT WILL & EMERY LLP, Menlo Park, California; Mandy H. Kim, MCDERMOTT WILL & EMERY LLP, Irvine, California; Sarah Chapin Columbia, MCDERMOTT WILL & EMERY LLP, Boston, Massachusetts

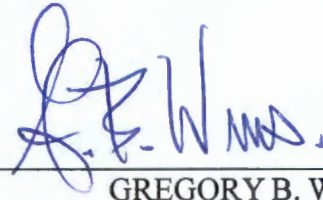
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Counsel for Defendants

OPINION

September 5, 2023
Wilmington, Delaware



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

On June 22, 2023, the Court held a one-day bench trial in this action on the issue of whether U.S. Patent Nos. 10,557,172 (“the ’172 patent”) and 10,731,220 (“the ’220 patent”) (collectively, the “Asserted cfDNA Patents”) are unenforceable due to prosecution laches. Presently before the Court are the parties’ post-trial briefing on this issue. D.I. 644; D.I. 650; D.I. 655.¹ In connection with the briefing, the parties submitted proposed findings of fact and conclusions of law. D.I. 642; D.I. 643.

Pursuant to Federal Rule of Civil Procedure 52(a), and after having considered the entire record in this case and the applicable law, the Court concludes that Defendants ArcherDX, Inc., ArcherDX, LLC, and Invitae Corporation (collectively, “Defendants”) have not shown by clear and convincing evidence that the Asserted cfDNA Patents are unenforceable due to prosecution laches.

The Court’s findings of fact and conclusions of law are set forth below.

I. FINDINGS OF FACT²

A. The Parties

1) Plaintiff Natera, Inc. (“Natera”) is a corporation organized and existing under the laws of Delaware, having a principal place of business at 201 Industrial Road, San Carlos, California 94070. D.I. 579, Ex. 1 (Joint Statement of Uncontested Facts) (“JSUF”) ¶ 1.

¹ All D.I. citations refer to C.A. No. 20-125-GBW unless otherwise noted.

² The Court’s Findings of Fact are cited as “FF, Section ___ ¶ ___.”

2) Defendant Invitae Corporation (“Invitae”) is a corporation organized and existing under the law of the state of Delaware, having a principal place of business at 1400 16th Street, San Francisco, California 94103. JSUF ¶ 3.

3) Defendant ArcherDX, LLC (“Archer”), formerly ArcherDX, Inc., is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 2477 55th Street, Suite 202, Boulder, Colorado 80301. JSUF ¶ 2. On October 2, 2020, ArcherDX, Inc. merged with Apollo Merger Sub A Inc., which then merged with Apollo Merger Sub B LLC to form Archer. JSUF ¶ 2.

4) Archer is a wholly-owned subsidiary of Invitae. JSUF ¶ 4.

5) The Court has subject matter jurisdiction and personal jurisdiction over all parties.

B. Procedural History

1) This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 1, *et seq.*, which Natera filed against ArcherDX, Inc. on January 27, 2020, for infringement of U.S. Patent No. 10,538,814 (“the ’814 patent”). D.I. 1. On April 15, 2020, Natera filed a First Amended Complaint, adding the ’172 patent, in addition to U.S. Patent Nos. 10,590,482 (“the ’482 patent”) and 10,597,708 (“the ’708 patent”). D.I. 17.

2) On August 6, 2020, Natera filed another patent infringement suit against ArcherDX, Inc. for infringement of the ’220 patent. *See* C.A. No. 20-1047-GBW, D.I. 1.

3) On September 25, 2020, Civil Action No. 20-1047-GBW was consolidated with Civil Action No. 20-125-GBW. D.I. 52. All filings were made in the lead case—Civil Action No. 20-125-GBW. D.I. 53.

4) On January 12, 2021, Natera filed a Second Amended Complaint to add Defendants Invitae and Archer in view of ArcherDX, Inc.'s merger with Invitae, which caused ArcherDX, Inc. to merge with various subsidiaries to form Archer. D.I. 116.

5) On October 27, 2021, Natera filed a Third Amended Complaint to include the corrected language of claim 1 of the '482 patent. D.I. 391.

6) On January 24, 2023, the Court heard oral argument on, *inter alia*, Natera's motion for summary judgment on no unenforceability of the Asserted cfDNA Patents due to prosecution laches (D.I. 429). D.I. 549. On February 6, 2023, the Court, *inter alia*, denied Natera's summary judgment motion on no prosecution laches. D.I. 550.

7) On April 21, 2023, the Court ordered Natera to narrow the number of claims and patents it can assert at trial. D.I. 573. Specifically, the Court ordered Natera to identify "no more than 10 asserted claims across no more than 3 asserted patents that it intends to assert at trial" to Defendants. D.I. 573.

8) At trial, Natera alleged infringement of the Asserted cfDNA Patents and the '708 patent. JSUF ¶ 6.

9) Natera accused the following products of infringing the Asserted cfDNA Patents: LiquidPlex, STRATAFIDE, and Personalized Cancer Monitoring ("PCM"), and all assays based on the above-listed products, including comprehensive kits. JSUF ¶ 11.

10) Natera accuses the following products of infringing the '708 patent: VariantPlex, FusionPlex, STRATAFIDE, and PCM, and all assays based on the above-listed products, including comprehensive kits. JSUF ¶ 12.

11) A five-day jury trial was held during the week of May 8, 2023. On May 15, 2023, the jury returned a verdict finding, *inter alia*, that Natera had proven by a preponderance of the

evidence that Defendants directly infringe claims 1, 6, and 8 of the '172 patent; claims 1, 3-4, and 6-7 of the '220 patent; and claims 1 and 19 of the '708 patent. D.I. 609 at 1.

12) In addition, the jury found that Natera had not proven by a preponderance of the evidence that Defendants indirectly infringe claims 1, 6, and 8 of the '172 patent; claims 1, 3-4, and 6-7 of the '220 patent; and claims 1 and 19 of the '708 patent. *Id.* at 3-4.

13) The jury also found that Defendants had not proven by clear and convincing evidence that claims 1, 6, and 8 of the '172 patent; claims 1, 3-4, and 6-7 of the '220 patent; and claims 1 and 19 of the '708 patent were invalid. *Id.* at 5-9. Specifically, the jury found that claims 1, 6, and 8 of the '172 patent and claims 1, 3-4, and 6-7 of the '220 patent are not invalid due to anticipation. *Id.* at 5. Claims 1 and 19 of the '708 patent are not invalid due to obviousness. *Id.* at 6. Claims 1, 6, and 8 of the '172 patent and claims 1, 3-4, and 6-7 of the '220 patent are not invalid due to lack of written description or for failure to claim what the inventors regarded as their invention. *Id.* at 7-8. Claims 1 and 19 of the '708 patent are not invalid due to indefiniteness. *Id.* at 8. Claims 1, 6, and 8 of the '172 patent and claims 1, 3-4, and 6-7 of the '220 patent are not invalid due to improper inventorship. *Id.* at 9.

14) Additionally, the jury found that Natera is entitled to \$9,356,886 for its lost profits as a result of Defendants' infringing sales of the PCM products and awarded a ten percent reasonable royalty rate for Defendants' past sales of the accused products other than PCM. *Id.* at 10. At the ten percent royalty rate, the jury awarded Natera \$5,430,181 for sales in the United States and \$4,564,963 for sales outside of the United States. *Id.*

15) On May 31, 2023, the Court scheduled a one-day bench trial on Defendants' prosecution laches defense. D.I. 618. The bench trial was held on June 22, 2023. "Tr. ____."

C. The Asserted cfDNA Patents and Their Prosecution

1) The '172 patent entitled, "Methods for Simultaneous Amplification of Target Loci," issued on February 11, 2020. JTX-3. U.S. Patent Application No. 16/399,103 ("the '103 Application"), which ultimately led to the '172 patent, was filed on April 30, 2019, and published on August 22, 2019. *Id.*

2) The assignee listed on the face of the '172 patent is Natera. *Id.*

3) Natera did not seek or receive any term adjustment or extension for the '172 patent. JTX-3.1; Tr. at 217:13-15.

4) The '220 patent entitled, "Methods for Simultaneous Amplification of Target Loci," issued on August 4, 2020. JTX-5. U.S. Patent Application No. 16/743,724 ("the '724 Application"), which ultimately led to the '220 patent, was filed on January 15, 2020, and published on May 7, 2020. *Id.*

5) The assignee listed on the face of the '220 patent is Natera. *Id.*

6) Natera did not seek or receive any term adjustment or extension for the '220 patent. JTX-5.1; Tr. at 217:13-15.

7) The Asserted cfDNA Patents recite, "methods for simultaneously amplifying multiple nucleic acid regions of interest in one reaction volume as well as methods for selecting a library of primers for use in such amplification methods. The invention also provides library of primers with desirable characteristics, such as minimal formation of amplified primer dimers or other non-target amplicons." JTX-3.1; JTX-5.1. At a high-level, the Asserted cfDNA Patents recite performing nested polymerase chain reactions ("PCR") on cell-free DNA to sequence the DNA. JTX-3; JTX-5.

8) The Asserted cfDNA Patents share a specification, which is approximately 125 pages long, and collectively includes forty-three claims. JTX-3; JTX-5.

9) Natera requested, and was granted, prioritized examination pursuant to 37 C.F.R. § 1.102(e) for the '103 Application and the '724 Application. JTX-3.1; JTX-5.1; Tr. at 214:22-24, 215:14-21. As a result, the '172 patent issued about 287 days after the '103 Application was filed, and the '220 patent issued about 202 days after the '724 Application was filed. JTX-3.1; JTX-5.1.

10) Defendants retained Nathan Kelley as an expert in the field of patent prosecution and procedure. Tr. at 103:10-15. Mr. Kelley testified that Natera was “able to get [its] [Asserted cfDNA Patents] very quickly,” in “less than a year, which is very fast.” Tr. at 131:15-23.

11) The Asserted cfDNA Patents were filed post-GATT. JTX-3; JTX-5. Accordingly, the term of the Asserted cfDNA Patents are 20 years from the filing date of the earliest U.S. or international application to which priority is claimed. *See* Manual of Patent Examining Procedure (“MPEP”) § 2701.

12) Natera did not submit any nonpublication requests during the prosecution of the Asserted cfDNA Patents or for any family applications. Tr. at 231:19-21, 232:6-8.

13) Natera did not delay publication or issuance of any application or patent during the prosecution of the Asserted cfDNA Patents or for any family applications. Tr. at 232:1-5.

14) Natera has disclosed all members of the Asserted cfDNA Patents, including all abandoned applications, to the public. Tr. at 158:25-159:3.

15) Natera did not make any attempt to keep its invention disclosures secret from the public. Tr. 231:22-25.

16) The Asserted cfDNA Patents claim priority to U.S. Patent Application No. 13/300,235 (“the ’235 Application”), which was filed on November 18, 2011. JTX-3.1; JTX-5.1; JTX-84.

17) The ’235 Application is entitled “Methods for Non-Invasive Prenatal Ploidy Calling” and “provides methods for determining the ploidy status of a chromosome in a gestating fetus from genotypic data measured from a mixed sample of DNA comprising DNA from both the mother of the fetus and from the fetus, and optionally from genotypic data from the mother and father.” JTX-84.1.

18) The ’235 Application published and was available in the public domain on October 25, 2012. JTX-84.1; Tr. at 142:20-25, 143:9-13, 231:8-18. As such, the disclosure of the inventions claimed in the Asserted cfDNA Patents was available to the public by, at the latest, October 25, 2012. *Id.*

19) From the filing date of the ’235 Application to the issuance date of the Asserted cfDNA Patents—approximately a seven to eight year time period—“Natera prosecuted 13 additional applications in the same family, 6 of which issued as patents claiming various other aspects of the inventions disclosed in these related applications.” D.I. 499 at 2.

20) Natera prosecuted several patent applications in the same family as the Asserted cfDNA Patents. Below are examples of patent applications that are incorporated by reference in the Asserted cfDNA Patents. JTX-3; JTX-5.

- a. U.S. Patent Application No. 13/335,043 (“the ’043 Application”) was filed on December 22, 2011. DTX-66. The ’043 Application is entitled “Methods for Non- Invasive Prenatal Paternity Testing.” *Id.*
- b. U.S. Patent Application No. 13/780,022 (“the ’022 Application”) was filed on February 28, 2013. DTX-69. The ’022 Application is entitled “Informatics Enhanced Analysis of Fetal Samples Subject to Maternal Contamination.” *Id.*

- c. U.S. Patent Application No. 14/225,356 (“the ’356 Application”) was filed on March 25, 2014. DTX-70. The ’356 Application is entitled “Methods for Preimplantation Genetic Diagnosis By Sequencing.” DTX-70.

21) When asked “can you state when Natera began work on prosecuting the asserted patents?” Matthew Rabinowitz, co-founder and executive chairman of Natera, responded as follows:

Well, you have got to be more specific in what you mean by “work” because the IP that went into the patents started very early on. I mean, I would say before 2010. And the provisional patents that are relevant here have a very early filing date, I believe around 2011; so the technology was developed by Natera for a long time. The particular patents that are at issue [the Asserted cfDNA Patents], I believe we were working on those particular patents from around -- you know, it must have been about a year before they were issued; so I would say around 2019 time frame is when that, you know, particular work on these particular patents started.

Tr. at 79:18-80:7.

22) When asked why Natera prosecuted the Asserted cfDNA Patents, Dr. Rabinowitz testified:

Natera develops a lot of technology. We had described that technology in a lot of detail, and then we were applying that technology in a market of oncology. And we started to see that that technology was being infringed upon and needed to be protected; so when other people are threatening our position in the market and we have a unique technology capability that we spend a lot of time and effort developing, that is when we -- that is when we want to protect our technology by prosecuting patents.

Tr. 80:17-81:6. Dr. Rabinowitz also testified:

[T]here’s a lot of stuff going on all the time. You know, Natera’s been coming from behind and defining the leading edge of genetic testing in women’s health and becoming the leader in women’s health genetic testing. And then we’ve been doing a lot of technology development in oncology and organ transplantation. You know, there’s a ton of stuff that we just don’t get to. And I think that’s relevant in both the technology development arena as well as in the legal arena. And so, a lot of things that you might say, it makes no sense for Natera to not have gotten to those things, the simple reality is, we are just too busy all the time. You know, we’re drinking from a firehose and we’re becoming the leaders in three separate markers – three separate markets. And so there’s a lot of stuff that we just can’t get to even though it would be very important. I can sort of augment what I said earlier, with that general description, that there’s just a lot to cover in a lot of the time.

Tr. at 76:13-77:7.

23) Between February 27, 2019 and January 15, 2020, Natera filed twenty-six patent applications in the same family as the Asserted cfDNA Patents that are directed to both cell-free DNA and nested PCR. Tr. at 131:9-14, 131:24-132:6, 138:25-139:11.

24) Defendants retained Robert Stoll as an expert in the field of patent prosecution and procedures. Tr. at 209:4-13. During the bench trial, when asked, “in your analysis of the file histories of the ’172 and the ’220 patent family, did you see any evidence of repetitive requests for the maximum extension of time to respond to office actions?” Mr. Stoll responded “[n]o.” Tr. at 229:12-16.

25) When asked, “[i]n your analysis of the file histories of the ’172 and the ’220 patent family, did you see any evidence of repeated failure to file applications without missing parts or other improper formalities to extend to prosecution?” Mr. Stoll responded “[n]o.” Tr. at 229:17-21.

26) When asked, “[i]n your analysis of the file histories of the ’172 and the ’220 patent family, did Natera withhold any allowed claims from issuance?” Mr. Stoll responded “[n]o.” Tr. at 229:22-25.

27) Natera did not (1) deliberately make repetitive requests for the maximum extensions of time to respond to office actions when prosecuting the Asserted cfDNA Patents or related applications, Tr. at 156:15-19, 229:12-16; (2) repeatedly fail to file applications without improper formalities, such as missing parts, to extend prosecution of its patents, Tr. at 157:12-16, 229:17-21; or (3) deliberately refile continuation applications for claims that had already been adjudicated on the merits to unreasonably delay prosecution in order to delay the issuance of its patents, Tr. at 156:20-25, 230:1-5.

D. Natera's Awareness of Defendants' Products

1) On February 5, 2014, Bernhard Zimmermann, Natera's Chief Scientific Officer and an inventor on the Asserted cfDNA Patents, wrote to Joshua Babiarz, a senior scientist at Natera and also an inventor on the Asserted cfDNA Patents, stating that Dr. Babiarz should attend Advances in Genome Biology and Technology's ("AGBT") presentation on "Targeted Next Generation Sequencing for Oncology Research." DTX-140. AGBT's presentation was on Defendants' anchored multiplex PCR ("AMP") technology. *Id.*; Tr. at 92:10-13. Specifically, Dr. Zimmermann wrote:

YES!!!
ask them what the IP behind it is (cause I think they violate ours!). Find out as much as possible on the method... Where does the anchored come from?

See DTX-140.

2) On April 1, 2014, Dr. Babiarz forwarded links to a presentation on Defendants' AMP technology to the email address "rnd." DTX-141. Dr. Babiarz wrote:

Hi all,

Here are links to the presentations by Enzymatics on their Archer Dx technology. It uses a one-sided nested PCR to look at recurrent fusions from mRNA.

Let me know if you want to hear about my notes on the talks.

Josh

Id.

3) When John Fesko, Natera's Chief Business Officer, was asked, "[w]hen is the earliest you feel comfortable saying that Natera as a company knew Archer was a competitor?," he testified, "I don't know what others thought, but I do know that 2017 to 2018 was the time when people were talking about Archer, at least in the meetings I was in." Tr. at 59:11-15.

E. Defendants' Investments During the Alleged Delay Period

1) Defendants first sold the following products in the United States at or around the following dates:

- a. LiquidPlex in August or September 2016;
- b. Stratafide in August 2019; and
- c. PCM in January 2020.

See Tr. at 168:11-16; 190:11-18.

2) From July 2015 to 2020, Defendants grew from 50 employees to 400 employees, “which is almost an eight-fold increase.” Tr. at 169:7-15. Jill Stefanelli, an employee of Defendants between July 2015 to October 2021 who held several positions including executive director and vice president, stated that, during that time period, the following teams at Archer/Invitae were growing in size: regulatory, quality, commercial, sales marketing, and research and development (“R&D”) teams. Tr. at 166:24-170:4, 172:8-173:15.

3) From 2015 to 2017, Defendants’ “total operating expenses were approximately 20 million with almost half of that being the R&D itself.” Tr. at 172:8-16; DTX-759. From 2018 to 2020, Archer invested about \$8.2 million, \$34.2 million, and \$75.7 million in R&D, respectively. DTX-759; Tr. at 172:24-173:15.

4) From 2017 to 2019, Defendants entered into five “design locks” for its AMP technology with five separate pharmaceutical companies, one of which was AstraZeneca. Tr. 175:6-25.

5) Defendants’ 30(b)(6) witness, Joshua Stahl, who was the Chief Operating Officer and Chief Scientific Officer of Archer and is currently the President of Oncology at Defendant Invitae, was designated to testify about Defendants’ “knowledge of facts relating to whether Natera

delayed unduly in the prosecution of the asserted patents and any prejudice to you.” Tr. at 197:3-14.

6) When Mr. Stahl was asked, “[w]ould Archer have changed its course of action in terms of its R&D, product development, commercialization, if it had known that Natera would be asserting its patent against Archer?,” he testified “I don’t think it would have changed anything.” Tr. at 202:25-203:9.

7) Mr. Stahl also testified that, “as a result of this litigation, we have not changed our course at all. We’ve proceeded as if it wasn’t present. We continue to develop products. We’ll continue to commercialize them, and we don’t really slow down.” Tr. at 202:12-19.

II. PROSECUTION LACHES

A. Legal Standard

Prosecution laches is an equitable affirmative defense to patent infringement. *Personalized Media Commc’ns, LLC v. Apple Inc.*, 57 F.4th 1346, 1354 (Fed. Cir. 2023) (“Personalized Media”); *Hyatt v. Hirshfeld*, 998 F.3d 1347, 1359-60 (Fed. Cir. 2021). The doctrine of prosecution laches “may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances.” *Cancer Rsch. Tech. Ltd. v. Barr Lab’ys Inc.*, 625 F.3d 724, 728 (Fed. Cir. 2010) (citation and quotation marks omitted); *see also Hyatt*, 998 F.3d at 1359-60. Prosecution laches requires proving two elements: “(1) the patentee’s delay in prosecution must be unreasonable and inexcusable under the totality of circumstances and (2) the accused infringer must have suffered prejudice attributable to the delay.” *Personalized Media*, 57 F.4th at 1354 (citing *Hyatt*, 998 F.3d at 1362). To establish the prejudice necessitated in the second element, an accused infringer must show evidence of “intervening rights,” i.e., “that either the

accused infringer or others invested in, worked on, or used the claimed technology during the period of delay.” *Hyatt*, 998 F.3d at 1369 (quoting *Cancer Rsch.*, 625 F.3d at 729). While there are no “firm guidelines” to determine when prosecution laches should apply, *see Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005), courts should weigh the totality of the circumstances as a matter of equity to determine the reasonableness of prosecution, *see id.* at 1386. Ultimately, the doctrine “should be used sparingly lest statutory provisions be unjustifiably vitiated. The doctrine should be applied only in egregious cases of misuse of the statutory patent system.” *Id.* at 1385.

When prosecution laches is raised as a complete defense to patent infringement, courts have applied the clear and convincing standard. *See, e.g., Shire Orphan Therapies LLC v. Fresenius Kabi USA, LLC*, C.A. No. 15-1102-GMS, 2018 WL 2684097, at *24 (D. Del. June 5, 2018); *Seagen Inc. v. Daiichi Sankyo Co., Ltd.*, C.A. No. 20-337-JRG, 2022 WL 2789901, at *4 (E.D. Tex. July 15, 2022).³

³ In *Seagen*, the Court provided the following helpful analysis explaining why courts apply “the clear and convincing evidence standard when the enforceability of an issued patent is challenged for prosecution laches,” 2022 WL 2789901, at *4 (citations omitted):

[Applying the clear and convincing standard when the enforceability of an issued patent is challenged for prosecution laches] is consistent with the presumption of validity, and with the application of the clear and convincing evidence standard to other invalidity and unenforceability defenses. *See* 35 U.S.C. § 282(a) (presumption of validity), § 282(b)(1) (unenforceability is a defense to patent infringement); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1358-59 (Fed. Cir. 1984) (the burden under § 282 “is constant and never changes and is to convince the court of invalidity by clear evidence”), *abrogated on other grounds, Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290-91 (Fed. Cir. 2011) (abrogating the “sliding scale” approach to inequitable conduct but nonetheless maintaining the clear and convincing evidence standard); *see also Radio Corp. of Am. v. Radio Eng’g Labs.*, 293 U.S. 1, 8 (1934) (Cardozo, J.) (“[O]ne otherwise an infringer who assails the validity of a patent fair upon its face bears a heavy burden of persuasion, and fails unless his evidence has more than a dubious preponderance.”); *contra Hyatt*, 998 F.3d at 1370-71 (applying a preponderance of the evidence standard in

B. Discussion

a. Natera did not engage in an unreasonable or inexcusable delay in prosecution of the Asserted cfDNA Patents

Defendants argue that there are three primary reasons why Natera's delay in prosecuting the Asserted cfDNA Patents was unreasonable: (1) Natera waited nearly a decade before presenting its claims in the Asserted cfDNA Patents; (2) Natera's delay in prosecuting the Asserted cfDNA Patents was unreasonable "given Natera's longstanding knowledge of the details of Archer's products and Natera's own alleged market strategy;" and (3) Natera failed to provide any explanation as to its delay in prosecuting the Asserted cfDNA Patents. D.I. 644 at 6-13; D.I. 655 at 3-9.

The Court must examine, under the totality of the circumstances, Natera's prosecution conduct, "including the prosecution history of all of a series of related patents and overall delay in issuing claims[.]" *Symbol*, 422 F.3d at 1386; *see also Hyatt*, 998 F.3d at 1362. Natera's conduct is different from the conduct in the handful of cases that have found prosecution laches. In fact, the Federal Circuit addressed prosecution laches earlier this year. *Personalized Media*, 57 F.4th at 1346. In *Personalized Media*, the Federal Circuit affirmed the district court's finding that the asserted patent was unenforceable due to prosecution laches. *Id.* at 1358. The following facts were relevant to the Federal Circuit's—and district court's—analysis: (1) the patentee had filed

a *de novo* civil action to obtain a patent under § 145). The Federal Circuit has also confirmed that the PTO may issue laches rejections during prosecution. *In re Bogese*, 303 F.3d 1362, 1367-68 (Fed. Cir. 2002). Where the PTO has not, it is presumed to have acted correctly. Consistent with these principles, and its prior practice, the Court applies the clear and convincing evidence standard to prosecution laches when raised as a complete defense to patent infringement.

Id. The Court agrees with the analysis in *Seagen*.

hundreds of GATT-Bubble applications,⁴ (2) “[the patentee’s] applications derive from two earlier applications[;]” (3) [the patentee’s] applications were long and complex, “containing over 500 pages of text and over 22 pages of figures[;]” (4) “the patentee filed each of its applications with a single claim, then subsequently amended the claims, sometimes to recite identical language across different applications[;]” (5) the patentee greatly increased the total number of claims in the range of 6,000 to 20,000 claims; and (5) “[the patentee] waited eight to fourteen years to file its patent applications and at least sixteen years to present the asserted claims for examination.” *Id.* at 1350-51. The district court found, and the Federal Circuit affirmed, that the patentee “employed an inequitable scheme to extend its patent rights” out to thirty to fifty years. *Id.* at 1350, 1356.

Natera’s conduct does not amount to the egregious misconduct described in *Personalized Media*. See FF, Section C ¶¶ 1-27, Section D ¶¶ 1-3. For example, Natera did not file hundreds of GATT-Bubble applications. The Asserted cfDNA Patents are post-GATT patents and, thus, have a fixed 20-year patent term from the filing of the earliest priority application. FF, Section C ¶ 11. Natera did not seek or receive any term adjustment or extension for the Asserted cfDNA Patents. FF, Section C ¶¶ 3, 6. The Asserted cfDNA Patents share a specification, which is approximately 125 pages long, and there are a total of forty-three claims. FF, Section C ¶ 8.

⁴ The Federal Circuit explained in a footnote:

During negotiations of the Agreement on Trade-Related Aspects of Intellectual Property (“TRIPS Agreement”) at the Uruguay Round of the General Agreement on Tariff and Trade (“GATT”), the U.S. agreed to change the term of U.S. patents from 17 years following the date of issuance to 20 years following the patent’s priority date. *Hyatt*, 998 F.3d at 1352. In the months leading up to the law change, the U.S. Patent and Trademark Office (“PTO”) saw an enormous influx of so-called “GATT Bubble” applications as applicants sought to take advantage of the existing law providing a patent term keyed from issuance. *Id.* at 1352-53.

Personalized Media, 57 F.4th at 1350 n.2.

The facts in this case are more akin to the facts in *Seagen*, where the district court, after a bench trial, found that the moving party had failed to meet its burden of clear and convincing evidence to show that the asserted patent should be unenforceable under prosecution laches. Similar to *Seagen*, Natera “did not bulk-file hundreds of patent applications with hundreds of thousands of claims to ‘unduly increase[] the administrative burden on the PTO’ in an effort to artificially inflate the life of its patents.” 2022 WL 2789901, at *6 (citing *Hyatt*, 998 F.3d at 1370; *Personalized Media*, 552 F. Supp. 3d at 687); FF, Section C ¶¶ 1-27. The Asserted cfDNA Patents are “not a submarine patent that has ‘been in the patent office for an extended period of time—intentionally or otherwise.’” *Seagen*, 2022 WL 2789901, at *6 (quoting *Personalized Media*, 552 F. Supp. 3d at 671 (internal quotations omitted)); FF, Section C ¶¶ 1-27. To the contrary, Natera “sought, and was granted, expedited prosecution for the [Asserted cfDNA Patents], which resulted in issuance just” less than a year after Natera filed its applications. *Seagen*, 2022 WL 2789901, at *6; FF, Section C ¶ 9. Furthermore, the prosecution history of the Asserted cfDNA Patents family indicates that Natera was diligently prosecuting its patent applications from 2011 to the issuance of the Asserted cfDNA Patents, and there are no “‘unexplained gap[s]’ in the prosecution history of the” Asserted cfDNA Patents. *Seagen*, 2022 WL 2789901, at *6 (citations omitted); FF, Section C ¶¶ 1-27.

Defendants take issue with Natera’s “decade-long delay” in presenting the claims of the Asserted cfDNA Patents. D.I. 644 at 6. “Duration of prosecution[,] however, does not provide a bright-line rule as to the reasonableness of prosecution[.]” *Cordance Corp. v. Amazon.com*, 631 F. Supp. 2d 484, 491 (D. Del. 2009); *see also Seagen*, 2022 WL 2789901, at *7 (“However, prosecution laches is not simply a time-counting exercise.”). Courts have declined to find prosecution laches for patents that were presented about a decade after the earlier application was

filed. *See, e.g., Cordance*, 631 F. Supp. 2d at 489-90 (eight years); *Stambler v. RSA Security, Inc.*, 243 F. Supp. 2d 74, 76 (D. Del. 2003) (seven years); *Medtronic, Inc. v. Boston Sci. Corp.*, 777 F. Supp. 2d 750, 782-83 (D. Del. 2011) (fourteen years); *Novozymes A/S v. Genencor Int'l, Inc.*, 446 F. Supp. 2d 297, 333-34 (D. Del. 2006) (ten years); *Intuitive Surgical, Inc. v. Computer Motion, Inc.*, C.A. No. 01-203-SLR, 2002 WL 31833867, at *6 (D. Del. 2002) (nine years); *Shire*, 2018 WL 2684097, at *22 (eight years). There is no evidence in the record that Natera has tried to hide its disclosure or prosecution of the Asserted cfDNA Patents or its family. Indeed, Natera even sought expedited prosecution of the Asserted cfDNA Patents, which resulted in the issuance of these patents in less than a year. FF, Section C ¶¶ 9-15, 24-27. The jury found that the inventions claimed in the Asserted cfDNA Patents were disclosed in the '235 Application, which published on October 25, 2012.⁵ FF, Section B ¶ 13. In other words, the inventions claimed in the Asserted cfDNA Patents were in the public domain as early as October 25, 2012. FF, Section C ¶ 18. Additionally, there is no indication in the record before the Court that Natera sat on its hands. FF, Section C ¶¶ 1-27. Rather, Natera diligently prosecuted each of the patent applications in the Asserted cfDNA Patents family during the period Defendants contend constitutes an undue delay. Natera did not repeatedly request the maximum extension of time to respond to office actions, repeatedly fail to file applications without improper formalities to extend prosecution, or deliberately refile continuation applications for claims that had already been adjudicated on the merits to unreasonably delay prosecution in order to delay issuance of the Asserted cfDNA Patents. FF, Section C ¶¶ 9-15, 24-27. Moreover, the Court notes that Natera's Asserted cfDNA Patents were filed after June 1995 and, therefore, Natera was not extending its patents term by delaying

⁵ Where there are overlapping factual issues that relate to a claim tried to a jury and a claim to be resolved by the court, the court must defer to the jury's finding on any overlapping factual issues. *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 510 (1959).

the filing of the claims in the Asserted cfDNA Patents—i.e., the Asserted cfDNA Patents are not “submarine” patents. *Cf. Seagen*, 2022 WL 2789901, at *7 (“Use of the patent prosecution process to extend the patent term is an important commonality amongst cases finding prosecution laches.”); FF, Section C ¶¶ 1, 4, 11.

At the crux of Defendants’ arguments is their dissatisfaction with Natera’s lawful filing of multiple continuation applications. But “[t]he filing of multiple continuing applications is not *per se* unreasonable.” *Shire*, 2018 WL 2684097, at *22 (citing *Novozymes A/S*, 446 F. Supp. 2d at 333-34). “There are legitimate grounds for refiling a patent application which should not normally be grounds for a holding of laches, and the doctrine should be used sparingly lest statutory provisions be unjustifiably vitiated.” *Symbol*, 422 F.3d at 1385. “Commonly, and justifiably, one might refile an application to add subject matter in order to attempt to support broader claims as the development of the invention progresses . . . One may also refile an application even in the absence of any of these reasons, provided that such refiling is not unduly successive or repetitive.” *Id.* None of Natera’s conduct amount to an “unreasonable and unexplained delay in prosecution that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances.” *See Cancer Rsch.*, 625 F.3d at 728-29 (citation and quotation marks omitted).

The Court also disagrees with Defendants’ remaining arguments—i.e., that Natera’s delay was all the more unreasonable given its awareness of Defendants’ product designs since 2014 and Natera’s delay is unexplained. D.I. 644 at 8-13; D.I. 655 at 4-9. With respect to the timing and filing of the Asserted cfDNA Patents, Dr. Rabinowitz testified that in Natera’s early growth stages, “a lot of stuff” was “going on all the time” and Natera was “drinking from a firehose.” FF, Section C ¶ 22. As a result, “there’s a lot of stuff that [Natera] can’t get to,” like prosecuting certain patents, “even though it would be very important.” FF, Section C ¶ 22. Dr. Rabinowitz states that

Natera prosecutes patents “when other people are threatening [Natera’s] position in the market.” FF, Section C ¶ 22. Mr. Fesko, Natera’s Chief Business Officer, credibly stated that it was around the 2017-to-2018-time frame when individuals at Natera were talking about Archer. FF, Section D ¶ 3. Natera filed the ’172 patent, which is one of the Asserted cfDNA Patents, on April 20, 2019. FF, Section C ¶ 1. The Court finds that Natera provided reasonable business considerations as to why Natera prosecuted the Asserted cfDNA Patents when it did. *See Cordance*, 631 F. Supp. 2d at 492 (considering a companies’ financial resources and size when determining whether the alleged delay in prosecuting the asserted patent was reasonable); FF, Section D ¶¶ 1-3, Section C ¶ 22.

Accordingly, based on the record before the Court and under the totality of the circumstances, Natera’s prosecution of the Asserted cfDNA Patents does not amount to unreasonable and unexplained delay that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances so as to warrant a finding of prosecution laches.

b. Defendants have failed to show intervening rights or prejudice

Defendants argue that, during the alleged delay period, Defendants “locked itself into its assay format, invested millions to engage in new R&D efforts, expand its product line, hire new employees, and establish new business relationships.” D.I. 644 at 13; *see also* D.I. 655 at 9-10. Defendants contend that, but for Natera “conceal[ing] for nearly a decade its intention to seek claims directed to Archer’s process, Archer could have taken steps to avoid the threat from Natera.” D.I. 644 at 3.

“To establish prejudice, [Defendants] must show that the alleged delay in prosecution ‘adversely affected’ the party with *intervening rights*.” *Shire*, 2018 WL 2684097, at *23 (quoting *Cancer Rsch.*, 625 F.3d at 729-32) (emphasis in original). “To show that a party was ‘adversely

affected,’ it must show that the holder of intervening rights would have either done something differently or experienced a change in economic position as a result of the alleged delay in issuance of the patent-in-suit.” *Id.* (quoting *Cancer Rsch.*, 625 F.3d at 731).

Defendants have failed to establish that they “invested in, worked on, or used *the claimed technology* during the period of delay.” *Hyatt*, 998 F.3d at 1362 (emphasis added). Defendants fail to explain how their investments, in particular their R&D expenditures, are tied to their relevant products, i.e., LiquidPlex, STRATAFIDE, and PCM products, or the claimed technology. FF, Section B ¶ 9, Section E ¶¶ 1-7. Also, as correctly noted by Natera, “by August 2019, the [’]172 [p]atent claims had been published and the complaint was filed by January 2020. Thus, there can be no delay from August 2019 onwards and any expense incurred by Defendants from August 2019 onwards . . . cannot be attributed to any alleged delay by Natera.” D.I. 650 at 17-18 (citing *Personalized Media*, 57 F.4th at 1354 (prejudice must be “attributable to the delay”)) (citations omitted); FF, Section C ¶ 1.

Furthermore, Defendants have failed to show prejudice. Specifically, Defendants have failed to show that they would have either done something differently or experienced a change in economic position as a result of the alleged delay. FF, Section E ¶¶ 1-7. Defendants’ 30(b)(6) witness, Joshua Stahl, testified that Defendants would not have changed anything if they had known about the Asserted cfDNA Patents earlier. FF, Section E ¶ 6. Mr. Stahl also testified that Defendants have not changed course as a result of the litigation. FF, Section E ¶ 7. Thus, Defendants have failed to prove that the alleged delay adversely impacted or prejudiced them.

III. CONCLUSION

For the foregoing reasons, the Court finds that Defendants have failed to meet their burden of clear and convincing evidence to show that the Asserted cfDNA Patents are unenforceable under

the equitable theory of prosecution laches. The Court will issue an Order consistent with this Memorandum Opinion.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATERA, INC.,

Plaintiff,

v.

ARCHERDX, INC., ARCHERDX, LLC, and
INVITAE CORP.,

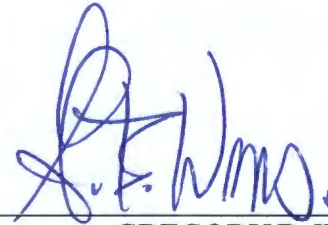
Defendants.

C.A. No. 20-125-GBW
(CONSOLIDATED)

ORDER

At Wilmington on this 5th day of September, 2023:

For the reasons set forth in the Memorandum Opinion issued this day, **IT IS HEREBY ORDERED** that, with respect to U.S. Patent Nos. 10,557,172 (“the ’172 patent”) and 10,731,220 (“the ’220 patent”), Defendants have failed to meet their burden of proving prosecution laches. **IT IS ALSO HEREBY ORDERED** that the parties shall submit, by no later than September 15, 2023, a proposed form of judgment consistent with the Opinion issued this day.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE