

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

ARCHERDX, LLC and THE GENERAL
HOSPITAL CORPORATION d/b/a
MASSACHUSETTS GENERAL HOSPITAL,

Plaintiffs,

v.

QIAGEN SCIENCES, LLC, QIAGEN LLC
f/k/a QIAGEN, INC., QIAGEN BEVERLY,
LLC f/k/a QIAGEN BEVERLY, INC.,
QIAGEN GAITHERSBURG, LLC f/k/a
QIAGEN GAITHERSBURG, INC., QIAGEN
GMBH, QIAGEN N.V. and JONATHAN
ARNOLD,

Defendants.

C.A. No. 18-1019-MN

PUBLIC VERSION

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR
INJUNCTION, ONGOING ROYALTY, SUPPLEMENTAL DAMAGES,
PRE- AND POST-JUDGMENT INTEREST, AND ENHANCED DAMAGES**

OF COUNSEL:

David Bilsker
Andrew Naravage
QUINN EMANUEL URQUHART & SULLIVAN LLP
50 California Street, 22nd Floor
San Francisco, CA 94111
Tel: (415) 875-6600

Anne Toker
James E. Baker
Anastasia M. Fernands
QUINN EMANUEL URQUHART & SULLIVAN LLP
51 Madison Ave., 22nd Floor
New York, NY 10010
Tel: (212) 849-7000

Jeffrey C. Wu
QUINN EMANUEL URQUHART & SULLIVAN LLP
60 E South Temple, Suite 500
Salt Lake City, UT 84111
Tel: (801) 515 7300

David E. Moore (#3983)
Bindu A. Palapura (#5370)
Stephanie E. O'Byrne (#4446)
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com
sobyne@potteranderson.com

*Attorneys for Defendants Qiagen Sciences,
LLC, Qiagen LLC f/k/a Qiagen, Inc.,
Qiagen Beverly LLC, f/k/a Qiagen Beverly,
Inc., Qiagen Gaithersburg LLC, f/k/a
Qiagen Gaithersburg, Inc., Qiagen GmbH,
Qiagen N.V. and Jonathan Arnold*

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TABLE OF ABBREVIATIONS

Document	Abbreviation
Declaration of Jonathan Arnold dated December 1, 2021	Arnold Decl.
Declaration of Anastasia Fernands in Support of Defendants' Opposition to Plaintiffs' Motion for injunction, Ongoing Royalty, Supplemental Damages, Pre- and Post-Judgment Interest, and Enhanced Damages dated December 1, 2021	Fernands Decl.
Declaration of Christopher A. Martinez with Respect to Ongoing Royalties and Prejudgment Interest dated December 1, 2021	Martinez Decl.
Declaration of Michael L. Metzker in Support of Defendants' Opposition to Plaintiffs' Motion for Injunction dated December 1, 2021	Metzker Decl.
Expert Report of Maria Fe Paz, M.D., Ph.D., M.B.A., dated October 7, 2020, attached as Exhibit 1 to Exhibit A to D.I. 496	Paz
Declaration of Maria Fe Paz, M.D., Ph.D., M.B.A., dated October 28, 2021, attached as Exhibit A to D.I. 496	Paz Decl.
Declaration of Raymond S. Sims Regarding Damages Through Date of Verdict, Prejudgment interest, Post-Judgment Interest, and Ongoing Royalties, dated November 1, 2021, attached as Exhibit E to D.I. 496	Sims Decl.
Declaration of Jill Stefanelli, Ph.D., dated November 16, 2020, attached as Exhibit C to D.I. 496	Stefanelli Nov. Decl.
Declaration of Jill Stefanelli, Ph.D., dated October 6, 2020, attached as Exhibit 1 to the Fernands Declaration submitted herewith	Stefanelli Oct. Decl.

I. SUMMARY OF ARGUMENTS

Independent third-party scientists have determined that QIAGEN's products are superior to Archer's in several respects and have published their test results in a peer-reviewed journal. The companion diagnostic ("CDx") field where QIAGEN's superior products may be used is emerging and several big players like Illumina and Foundation Medicine (owned by Roche, hereinafter "FM") have approved products and generally dominate the field. Nonetheless, Plaintiffs seek to prevent the public from having access to QIAGEN's superior products linked to cancer therapies for CDx applications. The four traditional *eBay* factors do not support this action.

- Plaintiffs cannot show irreparable harm: they have shown no past harm and cannot show future harm because, even without QIAGEN offering its products for CDx applications, other established players dominate the CDx market and will likely make any sales that QIAGEN is unable to make.

- There is an adequate remedy at law: any revenue that QIAGEN makes for CDx applications can be quantified and Archer has already done so.

- The balance of hardships weighs in QIAGEN's favor: QIAGEN spent years developing its products before the asserted patents issued. Further, Archer's parent, Invitae, is a large multibillion-dollar company with many products.

- The public interest weighs heavily against an injunction: the public benefits from having QIAGEN's superior products and expertise available for CDx applications in the cancer treatment field and could only be harmed if QIAGEN's products are enjoined from that application.

Plaintiffs' request for enhanced damages and an increased royalty amount is also not well founded. This was a close case where QIAGEN won on a significant number of issues. Further,

QIAGEN independently developed its product years before the patents issued. QIAGEN's products are fundamentally different than Plaintiffs', utilizing a single enrichment step rather than the two that Plaintiffs patented and employed in their commercial products. When QIAGEN was sued on the day(s) the patents issued, no one ever believed it was using any of the patented technology. Moreover, going forward, there is no basis for increasing the royalty that Plaintiffs argued for at trial and that the jury awarded.

II. THE COURT SHOULD DENY PLAINTIFFS' REQUEST FOR PERMANENT INJUNCTION

Plaintiffs seek a permanent injunction preventing QIAGEN from offering the accused products for CDx use. D.I. 496 at 2. QIAGEN has been selling these products, which are superior to the products Archer offers both in terms of sensitivity and analysis, since at least 2016. *See generally* Metzker Decl. Plaintiffs cannot meet any of the relevant factors.

A. Applicable Law

The Court is familiar with the 4-factor test established in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). To obtain a permanent injunction, a patentee must also establish that a "sufficiently strong causal nexus" relates any alleged irreparable harm to the alleged infringement. *Apple, Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012) ("*Apple II*"). A decision whether to grant a permanent injunction must be based on a case-by-case assessment of these traditional equitable factors. *Belden Techs. Inc. v. Superior Essex Commc'ns LP*, 802 F. Supp. 2d 555, 574 (D. Del. 2011).

B. Plaintiffs Have Identified No Actionable Harm

1. Archer¹ Cannot Show Irreparable Harm in This Multi-Player Market

¹ Because Plaintiffs' arguments for a permanent injunction focus on alleged harm to Archer, QIAGEN refers to arguments by "Archer" in this section.

Archer's arguments that it will be irreparably harmed because there is direct competition between QIAGEN and Archer are purely speculative. D.I. 496 at 4-7. The evidence shows that there are many competitors in the CDx space that compete with both Archer and QIAGEN for the type of product that each supplies. Tr. at 1032:5-1033:1 (Arnold); Arnold Decl. ¶ 3; DX-327.145. Among others, Illumina, FM, and Thermo Fisher have products that compete with those QIAGEN and Archer offer. Tr. at 1032:5-1033:1 (Arnold); Arnold Decl. ¶ 6-10; DX-327.145. In fact, Archer's own June 5, 2020 Form S-1 filing lists each of these companies, but not QIAGEN, among the numerous competitors in "clinical diagnostics" or "biopharmaceutical services, clinical trials and companion diagnostics projects." DX-327.145. Each of these large corporations have significant experience obtaining CDx approval. Arnold Decl., ¶ 6-10, Exs. 1-2, 4-7. In fact, FM is the dominant player in obtaining such approval. *Id.* ¶ 9; Tr. at 1032:13-21 (Arnold). Courts frequently find a lack of irreparable harm when, as here, there are multiple market competitors. *See, e.g., Belden Techs.*, 802 F. Supp. 2d at 577-78 (finding "the fact that the parties are not the only competitors in the market" weighed against irreparable harm); *LG Elecs. U.S.A. v. Whirlpool Corp.*, 798 F. Supp. 2d 541, 563 (D. Del. 2011) (denying injunction where there was, *inter alia*, a lack of specific evidence tying lost sales to infringement in a multi-competitor market); *IGT v. Bally Gaming Int'l Inc.*, 675 F. Supp. 2d 487, 489-90 (D. Del. 2009) ("This is not a clear case of a two-supplier (two-product) market wherein a sale to defendants represents, necessarily, the loss of a sale to plaintiff."); *accord Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554, 559 (D. Del. 2008) ("ACS").

Archer relies on *Bosch* (D.I. 496 at 5), which is consistent with this established law. *Bosch* states that, "***without additional facts showing that the presence of additional competitors renders the infringer's harm reparable***, the absence of a two-supplier market does not weigh

against a finding of irreparable harm.” 659 F.3d at 1151 (emphasis added). The “additional facts” here show that, not only is this a multi-player market, but QIAGEN’s accused products are not a significant competitive threat to Archer within it.

Archer’s conclusory claims that QIAGEN is its principal competitor or “only genuine threat” in the CDx market (D.I. 496 at 5) are belied by its failure to even include QIAGEN among the competitors for these projects in its SEC filing (DX-327.145), and its public interest argument that “numerous other companies offer diagnostics for CDx deals.” D.I. 496 at 14.

Archer also contends that its CDx business has “completely slowed” since late 2019 when QIAGEN began marketing the accused products for CDx opportunities. *Id.* at 4-5. Yet Archer cannot identify a single CDx opportunity that it lost to the accused products despite more than adequate time having passed for QIAGEN to have entered CDx deals. Although Archer’s Dr. Stefanelli asserts that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Archer’s experience is consistent with Jonathan Arnold’s testimony that negotiations for CDx deals average from six months to a year. Tr. at 1033:2-10 (Arnold). Two years have now passed since QIAGEN began marketing the accused products for CDx opportunities, yet QIAGEN has not won a single deal from Archer with the accused products, demonstrating that if Archer’s CDx deals have “completely slowed,” it is not due to competition with QIAGEN’s accused products. In that same two year period, at least Illumina, Thermo Fisher, FM, and Guardant have announced CDx deals based on NGS technology. Arnold Decl. ¶¶ 6-10, Exs. 1-2, 4-7.

Archer’s additional arguments about “direct competition” further support that QIAGEN

should not be enjoined from seeking CDx opportunities. Archer admits that QIAGEN has numerous advantages over Archer that [REDACTED] and worldwide commercial resources. D.I. 496 at 6-7; Paz ¶ 53. Far from showing irreparable harm, these advantages defeat any of the required nexus between perceived harm and the alleged infringement. *Apple II*, 695 F.3d at 1375 (for causal nexus, patentee must “show that the infringing feature drives consumer demand for the accused product.”); *see also Apple Inc. v. Samsung Elecs, Co.*, 735 F.3d 1352, 1363-64 (Fed. Cir. 2013) (“Apple III”) (“[T]he purpose of the causal nexus requirement is to show that the patentee is irreparably harmed *by the infringement*.”).

2. There Is No Evidence of Any Lost Market Share

(a) No Evidence of Market Share

There is no evidence that Archer has lost any market share to QIAGEN, particularly not based on the sale of any accused products. To begin, Archer has introduced no evidence of market share, which alone negates its arguments. Further, although Archer has not presented its sales in terms of market share, [REDACTED] Fernands Decl. Ex. 2 (Sims Suppl. Report) at 10; *cf. Belden Techs.*, 802 F. Supp. 2d at 577 (no irreparable harm where evidence concerning market share showed “insubstantial change compared to cases where irreparable harm was found showing this kind of data”). Moreover, Archer has not identified any specific customer that it has lost, or stands to lose, directly as a result of QIAGEN’s continued promotion of the accused products for CDx opportunities. *See ACS*, 579 F. Supp. 2d at 560 (no irreparable harm where, *inter alia*, patentee failed to identify specific customers that it lost or stood to lose); *LG Elecs.*, 798 F. Supp. 2d at 563 (patentee failed to identify “specific customers it has lost, or stands to lose, directly as a result” of continued sales of the infringing products). In short, lacking any evidence of lost

market share or even potential lost market share, Archer cannot show harm on these grounds.

Archer also argues that its lost market share “is exacerbated by the emerging and dynamic nature of the market.” D.I. 496 at 8. As already addressed, Archer has no evidence of any lost market share to be “exacerbated.” Further, even if Archer had any such evidence, Dr. Paz’s conclusory opinion that the market is at an “inflection point” does not support Archer’s request for a permanent injunction. *Id.* Dr. Paz opines that the “market is evolving rapidly as new technologies are developed and approved,” but provides no details concerning what those new technologies are and how, if at all, they are likely to affect the relevant market. D.I. 496, Ex. A, ¶ 6. Illumina and FM, among others, offer competing products, and Illumina’s products are recognized as superior to Archer’s product. (Tr. 1032:5-12 (Arnold); DX-327.145; Tr. 385:8-18; Arnold Decl. ¶ 7, Ex. 3). Under the circumstances, if there is going to be a market shift, it would likely shift toward FM and Illumina, not QIAGEN. In this multi-competitor market in which QIAGEN has yet to enter a single deal involving the accused products, unsupported statements that the market is at an “inflection point” do not support a finding of irreparable harm. *See Praxair, Inc. v. ATMI, Inc.*, 479 F. Supp. 2d 440, 443-44 (D. Del. 2007) (denying motion for permanent injunction where plaintiff “[had] not provided or described any specific sales or market data to assist the court, nor [had] it identified precisely what market share, revenues, and customers” plaintiff lost).

(b) No Evidence that Archer Lost Any Relevant CDx Opportunity

Archer has identified only one CDx opportunity it lost to QIAGEN—a partnership between Janssen and QIAGEN involving an unaccused QIAGEN PCR product that Archer called a “very old car.” Tr. 397:18-398:4 (Stefanelli). Archer now contends that this lost opportunity was QIAGEN enticing a partner away from Archer using the “tactic” of starting a partnership using the PCR technology then transitioning them over to NGS technology. D.I. 496

at 7. Archer cites no evidence that any customer, including Janssen, has entered any CDx deal for QIAGEN's PCR technology with the expectation of transitioning to the accused technology. Further, Archer's speculation concerning this anticipated harm ignores the fact that, in this highly regulated industry, any new product would have to undergo separate regulatory approval. That is, a company providing the PCR product would have no advantage over any other company for a later NGS product. Arnold Decl. ¶ 14.

(c) No Evidence that Archer's Lack of New CDx Deals Is Attributable to QIAGEN

Archer argues that "[j]ust over a year after QIAGEN's launch into this market" Archer has no new partnerships. D.I. 496 at 8. To begin, it has now been two years since QIAGEN began marketing the accused products for CDx opportunities. Thus, even using Archer's longest time estimate, sufficient time has passed for a party to move from initial contact to executed CDx deal. Yet QIAGEN still has not entered any CDx partnerships involving the accused technology (Tr. 1031:20-1032:4 (Arnold)), making clear that whatever the reason for Archer's lack of new partnerships, it is not QIAGEN's accused products.

Archer ignores that the likely explanation for its lack of success in obtaining further CDx deals is that potential customers are waiting for some evidence that Archer is a viable partner. For example, although Archer entered its own right of reference agreement with Illumina in May of 2016 and entered a CDx collaboration with Celgene in November of 2017 (D.I. 496, Ex. A to Ex. C), Archer has not yet received approval for any CDx product. Tr. at 392:13-15 (Stefanelli). In addition, potential FDA approval of Archer's Stratafide product is no longer expected by the previously projected date of March 31, 2022. Tr. at 393:2-11 (Stefanelli). Further, one of Archer's competitors, Natera, has initiated litigation accusing Archer's AMP technology of infringing Natera's patents, and Invitae has disclosed in SEC filings that Archer might be

required to redesign its technology as a result. *See* Fernands Decl. Ex. 4 at 31, 70-71. The evidence does not show a loss of market share, but shows that Archer has lost no CDx sales to QIAGEN's accused products and that Archer maintained its CDx revenue from 2019 to 2020.

3. No Evidence of Loss of Goodwill or Reputational Harm

No facts support a conclusion that QIAGEN's infringement has led to irreparable harm by damaging Archer's reputation for innovation. It is undisputed that QIAGEN is and has been for many years a leader in providing tools to the biotechnology industry. *See* Tr. 793:16-795:20, 796:14-20, 797:6-15 (Viola); Paz ¶ 53. To the extent that QIAGEN is using the patented technology in its superior products, that would not harm Archer's reputation. *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, No. C 09-5235 MMC, 2015 WL 604582, at *5 (N.D. Cal. Feb. 12, 2015) (rejecting patentee's argument of reputational damage because it "submitted no evidence suggesting Fairchild's products are in any manner considered inferior to [patentee's] products, or that Fairchild's inclusion of either patented feature has otherwise diminished [patentee's] reputation"). Thus, this situation is not akin to *Douglas Dynamics, LLC v. Buyers Products Co.*, 717 F.3d 1336 (Fed. Cir. 2013). D.I. 496 at 9. In *Douglas Dynamics*, the patentee offered the "Mercedes Benz S550" of snow plows, while the infringer's snowplow was akin to a "Ford Taurus." 717 F.3d at 1344. There, the Federal Circuit noted that the patentee's "reputation as an innovator [would] certainly be damaged if customers found the same 'innovations' appearing in competitors' snowplows, particularly products considered less prestigious and innovative." *Id.* at 1344-45.

Archer does not attempt to argue that QIAGEN's CDx products are "considered less prestigious and innovative." Rather, Archer acknowledges QIAGEN's superior reputation and name recognition. *See* Paz ¶¶ 53, 55. There is no reason to believe, and no evidence to support, that potential CDx partners who spend months considering potential partnerships would be

confused about either product source or Archer's enforcement of its intellectual property rights.

Finally, Archer can draw no link between customer questions concerning the relationship between Archer and QIAGEN or Archer's patent rights and any harm to Archer's reputation. D.I. 496 at 9. The questions Archer identified do not indicate any consumer confusion, and Archer has not explained how any such questions have allegedly harmed its reputation, particularly considering QIAGEN's superior product and reputation. *Id.*

4. Plaintiffs' Timing Weighs Against Irreparable Harm

Plaintiffs displayed no urgency in seeking to address the harm they now assert is irreparable. Plaintiffs claim to have known of infringement of their pending patent rights (Tr. 309:14-23 (Myers); Tr. 192:19-193:16 (Iafra)), yet they delayed in obtaining their patents, never filing a petition to make special to speed issuance. *See* 37 C.F.R. § 1.102 (knowledge of infringement is a basis for expedited examination). Plaintiffs did not seek a preliminary injunction when they sought to amend the Complaint once the '597 patent issued on October 22, 2019 (D.I. 114), despite that QIAGEN had announced its CDx agreement with Illumina just two weeks earlier, on October 7, 2019. *See* Fernands Decl., Ex. 1, ¶ 2. Plaintiffs' delay and failure to seek a preliminary injunction give further indication that they have not been irreparably harmed by QIAGEN's presence in the CDx space. *PGBA, LLC v. United States*, 389 F.3d 1219, 1229 (Fed. Cir. 2004) (not seeking a preliminary injunction weighed against a grant of injunctive relief).

5. No Causal Nexus Between Infringement and Alleged Harm

Archer has not established a causal nexus between any alleged harm and QIAGEN's accused products. *See Apple II*, 695 F.3d at 1374 (requiring a "sufficiently strong causal nexus" between any alleged irreparable harm and the alleged infringement). At most, Archer offers reasons why QIAGEN's marketing employees believe customers buy QIAGEN products. D.I.

496 at 11. Archer offers no evidence from any potential CDx partner that the features that Archer contends infringe its patents would drive demand to use QIAGEN's products in CDx partnerships. *See Apple III*, 735 F.3d at 1363-64 (discounting the idea that another's opinion of what consumers desire proves the consumer's actual reason for purchasing the product); *Citrix Sys., Inc. v. Workspot, Inc.*, C.A. No. 18-588-LPS, 2019 WL 3858602,*5 (D. Del. Aug. 16, 2019) (rejecting evidence that was merely another's perception of what customers found important).

In its efforts to establish irreparable harm from alleged infringement, Archer succeeds in explaining why a potential CDx partner would choose QIAGEN for reasons that have nothing to do with the accused technology. QIAGEN has entered more than 30 global CDx partnerships, nine of which are in the United States, having nothing to do with the accused products. D.I. 496 at 12. In other words, QIAGEN has a proven track record navigating the CDx regulatory landscape (D.I. 496 at 6), while Archer has none (Tr. at 392:13-15 (Stefanelli)).

Testimony from customers outside of the CDx partnership context also demonstrates that customers choose QIAGEN for reasons unrelated to the accused technology. Dr. Corless of OHSU identified QIAGEN's ability to customize, cost per sample, and informatics (software to analyze the data) as reasons why OHSU chose QIAGEN's products. Tr. 409:24-410:20, 416:19-417:13 (Corless). In fact, Dr. Corless testified that they were not even willing to consider Archer DNA panels because of Archer's unwillingness to do the necessary customization. Tr. 411:6-11 (Corless). Further, one aspect of the products OHSU evaluated was sensitivity (Tr. 413:18-414:2 (Corless)), and QIAGEN's sensitivity is superior to Archer's. *See Metzker Decl.* ¶¶ 8-18.

Regardless of the extent to which Archer might be harmed by QIAGEN's participation in the CDx market—and as discussed above, Archer has not met its burden on this issue—without a

showing that the harm flows from QIAGEN's alleged infringement, the irreparable harm factor weighs against entry of an injunction. *See Apple II*, 695 F.3d at 1377.

C. Monetary Damages Would Be Adequate to Compensate Plaintiffs

Archer asserts that the difficulty of quantifying “lost market share, brand recognition, and customer goodwill,” and estimating money damages indicates that remedies at law are inadequate. D.I. 496 at 10. For all of the reasons discussed above, Archer has shown neither lost market share nor any loss of brand recognition or customer goodwill. Accordingly, whether quantifying those types of harms is “difficult” is irrelevant to Archer's request for an injunction.

The portions of Dr. Paz's report Archer relies on (D.I. 496 at 10) also do not support that damages are unquantifiable. In fact, Dr. Paz's discussion of “financial damages,” including milestone payments and revenue from sales to hospitals, provides quantified damages from lost CDx sales. *Id.* In addition, in an October 6, 2020 declaration, Dr. Stefanelli, quantified the expected loss from lost CDx opportunities. Fernands Decl., Ex. 1, ¶ 10. These types of damages would be readily quantifiable, were they to occur. Fernands Decl. Ex. 3, ¶¶ 272-76.

Dr. Paz's conclusory assertions about reputational harm also do not support Archer's claim regarding unquantifiable damages. Dr. Paz asserts that “every CDx partnership that Archer loses means that it will be that much harder for Archer to secure the next partnership.” D.I. 496 at 10 (citing Paz ¶ 60). But at her deposition, Dr. Paz testified that she did not know whether it would be publicly known which companies had competed for, and therefore lost, specific CDx partnerships. She could also not answer a single question identifying in whose opinion a losing company reputation might be harmed under the circumstances. Fernands Decl. Ex. 7 (Paz Dep.) at 208:11-216:10. Factor 2 of the *eBay* test weighs against an injunction.

D. The Balance of Hardships Weighs in QIAGEN's Favor

Archer asserts that the balance of hardships weighs in its favor because it will purportedly

suffer irreparable harm, including through lost market share and reputational harm. D.I. 496 at 12. For all of the reasons discussed above, Archer has shown neither lost market share nor reputational harm, thus these factors do not tip the balance in Archer's favor.

Archer argues that QIAGEN cannot be heard to complain of hardship because QIAGEN built the relevant business on infringement. D.I. 496 at 13. As discussed in detail below, QIAGEN developed and launched the accused products many years before either of the asserted patents issued. Tr. 687:19-688:12, 689:11-13 (Lader); Tr. 776:3-777:5 (Wang); PX-207. Further, Archer delayed in obtaining its patents, never filing a petition to make special (*see* 37 C.F.R. § 1.102) to speed the issuance of its patents even though it claimed in knew there was infringement. *See* Tr. 309:14-23 (Myers); Tr. 192:19-193:16 (Iafrate). This is not a case where a party built its business on infringement such that hardship to that party should be discounted. *See Conceptus, Inc. v. Hologic, Inc.*, No. C 09-02280 WHA, 2012 WL 44064, at *3 (N.D. Cal. Jan. 9, 2012) (denying motion for permanent injunction, noting the balance of the hardships weighed against it because the infringing product was “not a copycat product” and “was independently developed and provide[d] important advantages over” the patentee's product).

Archer also attempts to minimize the harm to QIAGEN by asserting that the infringing products “make up a miniscule portion of QIAGEN's **overall business**.” D.I. 496 at 12. However, Archer makes no attempt to balance the harm to QIAGEN's “overall” business with the harm to Invitae's overall business. *Id.* Archer likewise offers no evidence of the “relative importance” (*see id.*) of the patented technology in the context of Invitae's business. The balance of the hardships weighs in QIAGEN's favor.

E. The Public Interest Weighs Strongly Against Injunction

In litigation concerning medical products, “[t]he public has two primary interests . . . protection of intellectual-property rights and access to necessary and effective medical care.”

Baxalta Inc. v. Genentech, Inc., C.A. No. 17-509-TBD, 2018 WL 3742610, at *12 (D. Del. Aug. 7, 2018). “[F]or good reason, courts have refused to permanently enjoin activities [where doing so] would injure the public health.” *Cordis Corp. v. Bos. Sci. Corp.*, 99 F. App’x 928, 935 (Fed. Cir. 2004). The strong public interest weighs against an injunction on medical products when the accused product and the patentee’s product differ in “meaningful ways.” *See Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp.*, C.A. No. 19-149-MN, 2019 WL 2521305, at *26 (D. Del. June 6, 2019); *Baxalta*, 2018 WL 3742610, at *12. Here, QIAGEN has superior products, superior ability to customize, and greater ability to obtain regulatory approval for life-saving diagnostics.

1. Superiority of QIAGEN’s Product

QIAGEN’s products are technically superior to Archer’s. *See generally* Metzker Decl. For example, a peer-reviewed, published study by third parties that carried out a head-to-head comparison of two QIAGEN accused products to one of Archer’s products demonstrated the superiority of QIAGEN’s accused products. *Id.* ¶¶ 3-4. This study showed that the QIAGEN accused products are superior to the Archer products in multiple respects, including the production of substantially higher data output and data quality, while providing more uniform read coverage across multiple target regions. *Id.* ¶¶ 3-4. The QIAGEN products evaluated use the same chemistry and workflow as the other QIAGEN accused products. *Id.* ¶ 5. The Archer product evaluated uses the standard Archer chemistry and workflow, like Archer’s other products. *Id.* ¶ 6. The study showed that both QIAGEN accused products outperformed the Archer product in all three performance metrics tested: (1) higher on-target rate; (2) higher mean depth of unique coverage; and (3) higher sequencing uniformity. *See id.* ¶¶ 3-37.

In addition, QIAGEN has carried out head-to-head evaluations of QIAGEN and Archer RNA fusion products that demonstrate the superiority of the QIAGEN accused RNA fusion

products over Archer's RNA fusion products. *See id.* ¶¶ 38-43. QIAGEN's accused products offer further advantages over Archer's products because QIAGEN's products use liquid reagent formulations, while Archer's products use lyophilized reagent formulations. *See id.* ¶¶ 44-45. The advantages of liquid over lyophilized formulations include that liquid forms of reagents are suitable for automated library preparation methods, while lyophilized forms are not. *See id.* ¶ 45. Further, QIAGEN's additional product advantages over Archer include QIAGEN's ability and willingness to work with customers to customize. Tr. 409:24-410:20 (Corless).

2. Ability to Obtain CDx Approval

QIAGEN, unlike Archer, has a track record of being able to get CDx approval. Archer seeks to downplay this fact by contending that no drugs will be “removed” from the market as a result of the requested injunction. D.I. 496 at 13-14. Archer ignores that enjoining QIAGEN would jeopardize the introduction of potentially life-saving drugs to the market if CDx approvals are not obtained. As acknowledged by Plaintiffs’ expert:

[T]he purpose of a CDx is to ensure that the right patients are getting the right treatment. For example, for cancer treatment, “precision medicine . . . aims to match therapeutics products [*i.e.* drugs] to those patients (and only those patients) who will positively respond to that therapeutic product, to maximize benefits and minimize risks from the therapeutic product received.”

Paz ¶ 20. If the FDA determines that a CDx is “essential to the safe and effective use” of a new drug, then the FDA generally will not approve the drug unless the CDx is approved or cleared for the indication. *Id.* ¶ 21. Thus, a company’s ability to obtain FDA approval for a CDx is critical to the introduction of life-saving drugs to the market and as between QIAGEN and Archer, QIAGEN has the proven track record of putting those therapies in patients’ and providers’ hands.

[REDACTED] D.I. 496 at 6-7. QIAGEN already has
 nine approved CDxs in the United States (all with non-infringing products). *Id.* Unlike

QIAGEN, Archer has no CDx track record—Archer has not yet received FDA approval for any CDx product. Tr. at 392:13-15 (Stefanelli).

In addition to a lack of regulatory success, Archer's ability to develop or launch its own CDx products has been further jeopardized by the Natera patent litigation that could affect all of Archer's products. Fernands Decl., Ex. 4 at 31, 70-71. Although many companies compete for CDx opportunities, enjoining QIAGEN would eliminate the opportunity to choose QIAGEN's product, which at least one study has shown is the best offered. Metzker Decl. ¶¶ 3-37.

3. Other Factors Relevant to Public Interest

Finally, Archer argues that barring QIAGEN will not limit the development of, or public access to, any lifesaving drug or diagnostic product because "numerous other companies offer diagnostics for CDx deals." D.I. 496 at 14. Archer cannot have it both ways. Either the accused technology has some advantage for CDx applications (in which case the public interest would be disserved if QIAGEN, with its superior expertise, were barred from offering that technology), or any of the "numerous other companies" that offer products for CDx deals can provide equivalent diagnostic advantages, thus negating all of Archer's claims of irreparable harm based on alleged competition from QIAGEN.

Where the products at issue would be used in connection with life-saving treatments, and where QIAGEN is in a much better position than Archer to be a successful partner in obtaining regulatory approval for a CDx, it would disserve the public interest to bar QIAGEN from offering the accused technology for CDx partnerships. This factor weighs heavily against Archer.

F. A Party Seeking Equity Must Do Equity

Unclean hands can weigh against the entry of an injunction. "The doctrine of unclean hands 'is a self-imposed ordinance that closes the doors of a court of equity to one tainted with inequity or bad faith relative to the matter in which he seeks relief, however improper

may have been the behavior of the defendant.”” *Princess Cruises, Inc. v. United States*, 397 F.3d 1358, 1369 (Fed. Cir. 2005) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945)). A trial court has broad discretion under this doctrine. *Id.*

Plaintiffs’ manipulation of the patent system should preclude them from obtaining an equitable remedy on their patents. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Plaintiffs included Archer employees and ’810 inventors Myers and Stahl as inventors on the ’597 patent (35 U.S.C. § 102(b)(1)(A)). JX-3. Tellingly, neither Myers nor Stahl could identify any contribution that they made to the inventions claimed in ’597 patent. Tr. 318:1-6 (Myers); 1020:14-1023:14 (Stahl). Nor did they point to any documentary evidence showing any tests or work they had done on the 597 invention.

G. Any Injunction Must be Clear and Narrowly Tailored

For all of the reasons discussed above, Archer has not satisfied the four-factor test required for a grant of injunctive relief. If the Court considers some scope of an injunction appropriate, it should be narrowly tailored and unambiguous in scope. *See Gemveto Jewelry Co. v. Jeff Cooper Inc.*, 800 F.2d 256, 259 (Fed. Cir. 1986) (“[I]njunctive relief should be narrowly tailored”); *Int’l Longshoremen’s Ass’n, Loc. 1291 v. Philadelphia Marine Trade Ass’n*, 389 U.S. 64, 76 (1967) (an injunction order must be clear and unambiguous concerning “what the court intends to require and what it meant to forbid”). Plaintiffs’ proposed language is neither. First, Plaintiffs seem to seek to enjoin non-infringing activities by including “making” products in the United States within the proposed scope of the requested injunction concerning its method patents. *See Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1313 (Fed. Cir. 2003)

(method claims are not infringed by sale or manufacture of product capable of performing the method). Second, Plaintiffs’ reference to “components” of the products is vague and undefined. Third, Plaintiffs’ language “products and services approved for clinical diagnosis by a regulatory authority” is ambiguous in both technical and geographic scope. Any injunction should be expressly limited to the types of CDx opportunities that form the basis of Archer’s arguments for injunction—CDx development partnerships in which QIAGEN would be the entity seeking U.S. FDA approval for a companion diagnostic product that uses the accused technology. Fourth, the request to enjoin products or services performing “single primer extension” and “sample indexing and amplification,” without any reference to the elements of the claims at issue, is vague and overly broad. D.I. 496 at 2.

H. An Evidentiary Hearing is Warranted

To the extent that the Court is considering granting an injunction on the weak record addressed above, QIAGEN respectfully submits that the Court should first hold an evidentiary hearing so that the Court can judge the credibility of witnesses, and so that QIAGEN can explore new evidence presented with the request for injunction. For example, Plaintiffs’ papers include a declaration of Dr. Maria Fe Paz, who previously submitted an expert report, but who did not testify at trial. D.I. 496, Ex. A. Plaintiffs’ papers also include a declaration of Invitae employee Vishal Sikri—an individual who was never identified in Plaintiffs’ discovery disclosures. D.I. 496, Ex. B. While QIAGEN has lodged rebuttal on the papers, under the circumstances, an evidentiary hearing on this new evidence would be appropriate.

III. THE COURT SHOULD DENY PLAINTIFFS’ REQUEST FOR ENHANCED ONGOING ROYALTIES

Plaintiffs ask this Court to use its equitable power under 35 U.S.C. § 283 to (1) impose an ongoing royalty and (2) conduct a new hypothetical negotiation to enhance that rate from the 7%

royalty rate the jury relied on to 10% for DNA products and 15.5% for RNA products. D.I. 496 at 14-18. Neither request is warranted. The Court should exercise its discretion not to set a royalty at least until after the conclusion of the appeal, when the parties' rights and obligations will be conclusively known.

If Plaintiffs' request to enhance royalties is considered at this juncture, it should be denied and the jury's rate imposed. There is no basis to deviate from the jury's determination of the result of a hypothetical negotiation (in which the patent is assumed valid and infringed) because there is no new economic situation different from the situation the jury considered. All Plaintiffs have identified is the infringement verdict—but that would be true in every case involving ongoing royalties.

A. The Court Should Defer an Ongoing Royalty Determination Until After Appeal

As a threshold matter, the Court should exercise its discretion and defer any decision on whether to award an ongoing royalty until after an appeal. *See Cordance Corp. v. Amazon.com, Inc.*, 730 F. Supp. 2d 333, 345-46 (D. Del. 2010) (exercising discretion to wait until the appeal concluded). Ample case law provides that although a court “could step in” and set a rate for ongoing royalties, there is no requirement to do so. *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1315 (Fed. Cir. 2007); *EMC Corp. v. Zerto, Inc.*, C.A. No. 12-956-GMS, 2016 WL 1291757, at *14 n.9 (D. Del. Mar. 31, 2016), *aff'd*, 691 F. App'x 623 (Fed. Cir. 2017); *Edwards Lifesciences AG v. CoreValve, Inc.*, C.A. No. 08-91-GMS, 2011 WL 446203, at *15 n.15 (D. Del. Feb. 7, 2011), *aff'd in relevant part, remanded in part*, 699 F.3d 1305 (Fed. Cir. 2012). Thus, this Court should defer ruling on the ongoing royalty rate until after the conclusion of

any appeals, at which point the parties' rights and obligations will be clear.²

B. If the Court Considers Ongoing Royalty, There Is No Basis for Plaintiffs' Request to Enhance

If the Court chooses not to defer consideration of an ongoing royalty, the Court should impose the rate determined by the jury and not an enhanced rate as Plaintiffs request. *See EMC Corp. v. Zerto, Inc.*, C.A. No. 12-956-GMS, 2017 WL 3434212, at *3-4 (D. Del. Aug. 10, 2017) (refusing injunction and applying ongoing royalties and rejecting enhanced rate, finding "a lack of significant post-verdict change in economic circumstances between the parties counsels against increasing the royalty rate above the jury's award."); *see also Vectura Ltd. v. GlaxoSmithKline LLC*, C.A. No. 16-638-RGA, 2019 WL 4346502, at *6 (D. Del. Sept. 12, 2019) (applying jury rate for ongoing royalty).

Courts routinely take additional evidence and argument in making the determination as to the ongoing rate because of its equitable nature. *See, e.g., Paice*, 504 F.3d at 1315. Many factors not before the jury must be considered in the equitable analysis. When the ongoing royalty is awarded in lieu of an injunction pending appeal, "the likelihood of success on appeal" is an important factor to be considered. *See Amado v. Microsoft Corp.*, 517 F.3d 1353, 1362 (Fed. Cir. 2008) (evaluating ongoing royalties where injunction stayed pending appeal).

Not only is the jury rate appropriate, but Plaintiffs have offered no reason to deviate from it. First, the jury has already undertaken the hypothetical negotiation to determine the reasonable royalty for these patent claims. The relevant economic factors and presumptions were baked into the jury's decision. Tr. at 1206:8-18, 1207:16-22, 1213:15-1217:25 (patents both valid and infringed for purposes of damages, including hypothetical negotiation). Critically, Plaintiffs

² If required, at that time, the Court could step in and set an orderly process for determination of the royalties.

have identified no economic factor that is different from what the jury considered. All they identify is the verdict. But that is true in all cases where a court is determining ongoing royalties.

With respect to the market in which a new hypothetical negotiation would take place, Plaintiffs have not specifically identified anything that would support deviating from the jury's hypothetical negotiation. Indeed, to the contrary, Plaintiffs submitted the declaration of Dr. Paz that declares that the CDx market is in flux. D.I. 496, Ex. A, ¶ 6 (Market is at "an inflection point" and "is evolving rapidly as new technologies are developed and approved."). A new hypothetical negotiation ought to analyze the market, not declare that it is "evolving rapidly." Indeed, for a market in flux as Dr. Paz argues, the rate might even go down. *XY, LLC v. Trans Ova Genetics, LC*, No. 13-cv-0876-WJM-NYW, 2016 WL 6664619, at *1-2 (D. Colo. Nov. 10, 2016) (limiting the ongoing royalty rate to approximately 66% of the jury awarded rate and rejecting any reading of Amado requiring district courts to set the ongoing royalty rate "no lower than the jury's past-infringement royalty"). But there is no way to know because Archer—who bears the burden—has failed to offer any specifics about the market or how that might effect a new hypothetical negotiation. This record, the closeness of the case, and the multitude of issues for appeal support leaving the rate as the jury determined if the Court is inclined to rule.

C. Plaintiffs' Economic Analysis For A New Hypothetical Negotiation Is Unsound

Plaintiffs also have provided no sound economic or market reason to deviate from the jury verdict. For the DNA products, Plaintiffs rely on the same evidence presented to the jury (MGH/Archer license) and bump it up to 10%. D.I. 496 at 16-17. Plaintiffs' expert states that

[REDACTED]

[REDACTED]

Sims Decl. ¶ 29. This is not a rational analysis. The damages evidence presented to the jury

assumed the patents were valid and infringed. Plaintiffs cannot get a do-over on their damages presentation because [REDACTED] But in an abundance of caution, QIAGEN hereby submits the expert declaration of Christopher Martinez to rebut Mr. Sims and to further explain why Plaintiffs' analysis is wrong. *See generally* Martinez Decl.

For the RNA products, Plaintiffs' calculation of a rate is unsound and inconsistent with the jury verdict. First, Plaintiffs purport to calculate an effective royalty rate from the lost profits damages. Then Plaintiffs take that lost profits effective rate and combines it with the jury's reasonable royalty to reach a midpoint of 15.5%. D.I. 496 at 17-18. Plaintiffs next take that number and purport to use it for all sales. *See* Martinez Decl. ¶ 19. A key flaw is that Plaintiffs' approach applies a lost profits factor to overseas sales—which the jury has determined are governed only by a reasonable royalty. It is improper to boost the rate for overseas sales based on a lost profits effective rate when those sales were never subject to lost profits analysis.

Another flaw is that is that Sims simply selected a midpoint between a lost profits number and the jury's reasonable royalty, without any explanation as to why a party would do this in a hypothetical negotiation. Indeed, they would not. *See id.* ¶ 21. For these reasons as well, the jury's rate would be the most appropriate, if this question is resolved now.

IV. SUPPLEMENTAL DAMAGES AND INTEREST

QIAGEN does not dispute the arithmetic set forth in Plaintiffs' papers concerning pre- and post-judgment interest. With respect to pre-judgment interest, however, the Court should exercise its discretion and apply the treasury bill rate. *See Phillips Petroleum Co. v. Rexene Corp.*, C.A. No. 90-208-LON, 1997 WL 781856, at *28 (D. Del. Sept. 4, 1997). QIAGEN's expert Mr. Martinez has applied the treasury bill rate in the accompanying declaration. Martinez Decl. tbl. 5. The reason that the lower treasury bill rate is appropriate (in lieu of the prime rate) is because Plaintiffs have not put forward any evidence of its borrowing rates at the relevant

time. *Id.* Thus, receiving a higher rate of interest on this record would be a windfall.

V. PLAINTIFFS' MOTION FOR ENHANCED DAMAGES SHOULD BE DENIED

Plaintiffs' motion for enhanced damages (D.I. 496 at 20-30)—a punitive remedy reserved only for egregious cases for defendants acting as “pirates”—should be denied. There was no pre-suit notice to QIAGEN. Nor could there be, as Plaintiffs sued QIAGEN the very day the '810 patent issued. QIAGEN disputed both infringement and validity, prevailing on many issues in this closely-fought litigation, including summary judgment that QIAGEN did not literally infringe any claim of the '810 patent. This is not an “egregious” case and none of the relevant factors favor enhancing damages as precedent from this District makes clear.

A. Legal Standards

As this Court is aware, “the court *may* increase the damages up to three times the amount found or assessed.” 35 USC § 284 (emphasis added). As indicated in the text of the statute, the Supreme Court has “emphasized that the word ‘may’ clearly connotes discretion.” *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 103 (2016). The *Halo* Court explained that enhanced damages are “designed as a ‘punitive’ or ‘vindictive’ sanction for egregious infringement behavior.” *Id.* “The sort of conduct warranting enhanced damages has been variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate.” *Id.* at 103-04. Plaintiffs bear the burden of proof, and enhanced damages should *not* be awarded in “garden-variety cases.” *Id.* at 107-09.

A finding of willfulness does not automatically lead to enhanced damages, and courts are well within their discretion in declining to award enhanced damages even where there has been a jury verdict. *Presidio Components, Inc. v. American Tech. Ceramics Corp.*, 875 F.3d 1369 (Fed. Cir. 2017). Indeed, a multitude of cases from this District indicates that enhanced damages are denied even with a jury verdict of willfulness. *See, e.g., Nox Medical Ehf v. Natus Neurology*

Inc., C.A. No. 15-709-RGA, 2018 WL 6427686 (D. Del. Dec 7, 2018) (declining to award enhanced damages); *Idenix Pharms. LLC v. Gilead Scis., Inc.*, 271 F. Supp. 3d 694, 698 (D. Del. 2017) (finding that a jury verdict of willfulness only “opens the door” to enhanced damages, but court retains discretion and declined not to award); *Greatbatch Ltd. v. AVX Corp.*, C.A. No. 13-723-LPS, 2018 WL 1568872, at *6-7 (D. Del. Mar. 30, 2018) (after jury verdict of willfulness, district court denied enhancement of damages).

There is no evidence that QIAGEN acted egregiously or that this is anything more than a typical patent infringement case, and the Court should not award enhanced damages.

B. The Jury’s Willfulness Verdict Is Not Dispositive and Was Tainted By Improper Arguments Seeking an Adverse Inference

Although the verdict of willfulness “opens the door” to consideration of enhanced damages, *Idenix Pharms. LLC*, 271 F. Supp. 3d at 698, in this case the willfulness verdict was tainted by counsel’s improper arguments and is subject to JMOL.

As this Court will recall, in the examination of QIAGEN witness Viola, Plaintiffs’ counsel referenced the hiring of outside counsel for due diligence and asked: “And you haven’t seen any freedom to operate that’s been admitted into evidence in this case; correct?” Tr. 864:22-24. QIAGEN’s counsel objected, and Plaintiffs’ counsel moved on. Tr. 864:25-865:7. But the improper seed had been planted. And in closing, Plaintiffs’ counsel took full advantage, arguing, “Let’s talk about willfulness” (Tr. 1243:11) and then asking the jury: “Did anyone see a freedom to operate of any kind?” (Tr. 1244:2-4). Counsel continued this improper dialogue, arguing QIAGEN’s Dr. Lader “wasn’t a patent expert” and again telling the jury: “You didn’t see a freedom to operate analysis or any responsible corporate analysis that they do for other companies but not Archer?” (Tr. 1245:23-25). QIAGEN objected (Tr. 1246:1-4), but the damage was done.

Counsel's question and argument was a clear attempt to imply to the jury that QIAGEN should have consulted an attorney and obtained an opinion of counsel, and that the absence of such an opinion demonstrates QIAGEN knew it was infringing and was willful. It was improper. Counsel's inference and argument violated, as a threshold matter, statutory law, which provides:

The failure of an infringer to obtain the advice of counsel with respect to any allegedly infringed patent, or the failure of the infringer to present such advice to the court or jury, may not be used to prove that the accused infringer willfully infringed the patent or that the infringer intended to induce infringement of the patent.

35 USC § 298. Indeed, a defendant's "decision not to seek an advice-of-counsel defense is legally irrelevant under 35 U.S.C. § 298." *SRI Int'l Inc. v Cisco Sys., Inc.*, 930 F.3d 1295, 1309 (Fed. Cir. 2019) (reversing willful infringement, vacating enhanced damages).

Not only does the Patent Act forbid counsel's inference, but the en banc Federal Circuit confirmed that "no adverse inference that an opinion of counsel was or would have been unfavorable flows from an alleged infringer's failure to obtain or produce an exculpatory opinion of counsel." *Knorr Bremse Systeme Fuer Nutzfahzuege Gmbh v. Dana Corp.*, 383 F.3d 1337, 1341, 1346 (Fed. Cir. 2004) (en banc).

Counsel's improper questions which implied to the jury that QIAGEN lacked an opinion of counsel and this should be held against it tainted the jury on the question of willfulness. As QIAGEN argued in its post-trial motion, willfulness should be vacated on this ground alone. D.I. 497 at 20-21. As it stands, given counsel's conduct, the jury verdict of willfulness should not support an award of enhanced damages and Plaintiffs should not be rewarded for their counsel's violation of basic patent law.

C. The *Read* Factors Favor Declining Enhanced Damages

One set of factors that a court may use to guide its decision on whether a defendant acted in bad faith are the "*Read*" factors derived from *Read Corp. v. Portec Inc.*, 970 F.2d 816, 826-27

(Fed. Cir. 1992). *See Liquid Dynamics Corp. v. Vaughn Co.*, 449 F.3d 1209, 1225 (Fed. Cir. 2006). These factors are not required for a decision on enhanced damages. *Presidio*, 875 F.3d at 1382-83 (affirming district court denial of enhanced damages). However, reviewing these factors demonstrates that enhanced damages should not be awarded in this case.

1. Read Factor 1: Copying

The centerpiece of Plaintiffs' case for enhanced damages is its recitation that QIAGEN personnel in 2014-15 investigated and tested Plaintiffs' "patented technology" (D.I. 496 at 22-24) and thus copied the patents. This is a red herring.

The first fatal flaw in Plaintiffs' analysis is that QIAGEN's alleged bad actions occurred *before* the '810 patent issued on July 10, 2018. And the '597 patent did not issue until October 22, 2019. Indeed, the premise for enhanced damages—a finding of willfulness—cannot apply to actions that predate issuance. *Gustafson v Intersystems*, 897 F.2d 508, 510 (Fed Cir 1990) (a party cannot willfully infringe a nonexistent patent); *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1341 (Fed. Cir. 2016) ("Knowledge of the patent alleged to be willfully infringed continues to be a prerequisite to enhanced damages."). As such, in exercising discretion with respect to enhanced damages, the copying facts should be of little moment. *Nox Medical Ehf*, 2018 WL 6427686, *3 (declining to award enhanced damages and reducing weight of copying evidence "because the actions pre-dated the issuance of Plaintiff's patent.").

To the extent Plaintiffs argue that the products were "patent pending," courts have also rejected that argument. *See Lift-U v. Ricon Corp.*, No. 10-CV-01850-LHK, 2012 WL 5303301, at *10-13 (N.D. Cal. Oct. 25, 2012) (granting summary judgment of no willful infringement because defendant was not aware of patent until complaint was filed and copying of "patent pending" product is legally insufficient). Courts have properly rejected that argument because

there is no way to know exactly what claims will issue until they do. Second, the evidence does not indicate that QIAGEN was copying Plaintiffs' product, but rather doing benchmarking and comparison of results. Third, Plaintiffs' patents teach away from the methods QIAGEN developed. In the vernacular of the trial, Archer's products use two panning-for-gold steps (Tr. 201:12-203:2 282:2-283:4), while QIAGEN's use only one (Tr. 519:23-520:4, 525:24-526:5, 527:14-25, 528:18-529:13; Tr. 908:6-25). QIAGEN did what Archer's inventors said it was unable to do: produce a product with only one enrichment step. Tr. 214:5-18, 215:12-18; Tr. 278:15-279:24; DX-44; DX-116. Archer's products contain nested adaptor and target specific primers—two enrichment steps and every publication describing the Archer products described them as such. Tr. 201:12-202:15, 211:25-212:10, 213:14-214:18, 334:12-335:23; DX-38; DX-44.4; DX-117.3. QIAGEN's product did just the opposite. Tr. 219:20-22, 537:11-12, 537:22-24, 549:2-14. There is simply no evidence of copying of products that would support enhanced damages.

2. Read Factor 2: QIAGEN's Investigation and Good Faith Belief

Plaintiffs' US Patent No. 9,487,828 ('828 patent) issued November 8, 2016. See JX-1 (continuation). All claims of the '828 patent require "nested" PCR, and all the examples in the specification use "nested" PCR. See Fernands Decl., Ex. 5. QIAGEN's Dr. Lader testified that before this lawsuit, he carefully studied the only patent that existed (the '828 patent) and concluded it was not infringed because it required nesting. (Tr. 691:7-23). Indeed, Plaintiffs never asserted the '828 patent against QIAGEN. Dr. Lader's conclusions about the unasserted '828 patent were reasonable given that Plaintiffs never asserted it. And when Plaintiffs did sue QIAGEN, it was under the '810 patent, a continuation of the '828 patent. Like the '828 patent, the examples in the '810 patent only contained nested PCR. JX-1.

Dr. Lader testified that after the lawsuit was filed in 2018 he reached the same conclusion as before—that the Archer '810 patent required nesting. (Tr. 692:10-19). The '597 patent issued October 22, 2019 (JX-3) while this lawsuit was ongoing, and Dr. Lader also reviewed it and did not believe it was infringed. (Tr. 701:4-10).³

Throughout this case QIAGEN vigorously argued that the patent claims in the '810 patent should be limited to nested PCR. D.I. 123 at 22, 34-38. QIAGEN's belief that the '810 patent had the same limitations as the '828 patent given the description of a second target-specific primer was well founded. See Fernands Decl., Ex. 5 col. 16:39-41. In its post-trial brief, it also showed how its single enrichment step was not equivalent to the two enrichment steps claimed in the '810 patent. See D.I. 497 at 12-17. Moreover, QIAGEN's belief that it did not use the '597 patent was well-founded. As the inventors testified, the '597 patent did not use an adaptor. Tr. 190:8-191:6 (Iafrate); Tr. 244:12-245:6 (Le). Rather, it used random primers and a target-specific primer. QIAGEN's belief that it did not use those elements is well-founded. See D.I. 497 at 2-5.

3. Read Factor 3: QIAGEN's Behavior in Litigation

QIAGEN's actions after being sued were just as reasonable and do not reflect the actions of a "pirate." There were no sanctions or accusations of improper conduct. To the contrary, in this case, QIAGEN simply defended itself against charges of patent infringement.⁴ This case is not an extreme situation such as described in *SRI*, 930 F.3d at 1310-11 (describing that defendant

³ In questioning Dr. Lader, Plaintiffs' counsel insinuated that two rounds of amplification using a target-specific primer is not necessary in the '597 patent (Tr. 701:16-18) but claim 1 of the '597 patent does have that requirement. (JX-3 col. 46-48, claim 1 step (c)).

⁴ Indeed, QIAGEN successfully defeated Plaintiffs' multiple claims other than patent infringement as Plaintiffs dropped its counts for trade secret misappropriation (Am. Compl., Counts I, IV-VI); false advertising (Count III); deceptive trade practices (Count IX); and tortious interference (Count X). See D.I. 413.

“pursued litigation about as aggressively as the court has seen in its judicial experience”).

Indeed, this Court granted QIAGEN’s motion for summary judgment of no literal infringement of the ’810 patent. D.I. 447. Given these circumstances, it cannot be said that QIAGEN engaged in any litigation misconduct.⁵

4. Read Factor: QIAGEN’s Size and Financial Condition

This factor is neutral. Both companies are well-funded competitors.

5. Read Factor 5: Closeness of the Case

This was a close case, and this factor strongly supports declining to enhance damages. After being sued for patent infringement, as well as a host of other claims (D.I. 1), QIAGEN engaged litigation counsel. QIAGEN initially moved to dismiss the patent count (D.I. 15)⁶, and later filed an answer on those claims, contesting infringement and validity (D.I. 53).

In the complaint, Plaintiffs asserted infringement of claim 1 of the ’810 patent, which includes reference to “nested PCR.” After claim construction (D.I. 146, December 12, 2019), Plaintiffs dropped claim 1, thus demonstrating that QIAGEN’s pre- and post-litigation position that “nested PCR” does not apply to its products was correct. Indeed, the issue of whether the QIAGEN products contained a second target-specific primer was hotly contested throughout the case and was certainly not a frivolous position to take. In fact, QIAGEN was correct that its products did not have a second target-specific primer. And as explained in its post-trial brief, its process is not equivalent to having one given all the examples in the ’810 specification teaching

⁵ Especially when compared to Archer, which improperly sought adverse inferences based on QIAGEN’s privileged communications with counsel.

⁶ Although the Court denied the motion to dismiss as “essentially a premature motion for summary judgment,” (2/26/19 Tr. at 39:21-24) it noted that the “submissions and argument raised significant questions as to whether plaintiffs would ultimately prevail on their claims of literal infringement.” (*Id.* at 42:7-9).

that there must be nested adaptor and target specific primers and hemi-nested primers like QIAGEN uses produce bad results. *See* D.I. 497 at 14-15. With respect to the '597 patent, QIAGEN prevailed on claim construction for the terms “target-specific primer” and “target specific hybridization sequence.” The evidence presented at trial showed that QIAGEN’s products possessed neither, despite the jury’s finding to the contrary. *See id.* at 1-8. There were, therefore, genuine issues to be resolved at trial. *WesternGeco L.L.C. v. ION Geophysical Corp.*, 837 F.3d 1358, 1363 (Fed. Cir. 2016), *reversed on other grounds*, 138 S.Ct. 2129 (2018), and *reinstated in part*, 913 F.3d 1067 (Fed. Cir. 2019) (“After *Halo*, the objective reasonableness of the accused infringer’s positions can still be relevant for the district court to consider when exercising its discretion.”).

6. Read Factors 6 & 7: Duration of Misconduct & Remedial Action

There is no “misconduct” here and thus this factor is neutral. Plaintiffs sued QIAGEN on the day the '810 patent issued, and QIAGEN immediately engaged litigation counsel and defended itself, prevailing in several aspects of the patent assertions and in all of the other claims. It is not “misconduct” to defend oneself in a civil action.

Plaintiffs’ multi-count lawsuit was a bolt from the blue, asserting a patent that did not exist until the day Archer filed its complaint in this court. This is not a case where notice was provided prelawsuit or there were attempts to negotiate, and that those attempts were somehow ignored. QIAGEN formed beliefs about Plaintiffs’ patents before suit, and those positions carried on through the litigation. In other words, QIAGEN did not come up with its positions after the fact but has been consistent in seeking to vindicate its beliefs.

7. Read Factors 8 & 9: Motivation to Harm and Attempts to Conceal

These factors favor QIAGEN. As Archer concedes (D.I. 496 at 29), QIAGEN issued a

press release announcing the launch of its product. This is not concealment. QIAGEN had no duty—and there is none under the law—to give its competitor Archer a preview of its press release.

Archer also points to the parties’ relationship and argues that QIAGEN’s consent judgment related to fiduciary duties demonstrates *mens rea* to harm Archer. D.I. 496 at 29. Not so. Archer is referring to the fact that on July 23, 2021, QIAGEN made an Offer of Judgment under Rule 68 for \$100 that stated that “This offer shall not be deemed an admission (a) of liability by Defendants; (b) that Counts VII and VIII have any merit; or (c) that Archer has suffered any damages.” D.I. 423-1. Archer accepted the offer on August 3. D.I. 423-2. Notice of the offer was filed with the Court on August 4. D.I. 423. Thus, the consent judgment provides the *opposite* of what Archer argues because it was accepted without admission of liability. D.I. 423-1 at 3 of 5.

Archer also argues that QIAGEN’s status as a competitor favors enhancement. D.I. 496 at 30. But Archer argues in the same section that the companies are “business partners.” *Id.* at 29. Archer cannot have it both ways—asserting business partners for one argument, and competitors for another. With respect to motivation to harm, competition in the marketplace is not harm. *See State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235-36 (Fed. Cir. 1985) (“[K]eeping track of a competitor’s products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made and is supposed to benefit the consumer. ... It should not be discouraged by punitive damage awards except in cases where conduct is so obnoxious as clearly to call for them.”); *Nox Medical Ehf*, 2018 WL 6427686, at *4 (noting “harm incidental to direct business competition” does not support enhancement).

VI. CONCLUSION

For the reasons discussed above, Plaintiffs’ motion should be denied.

OF COUNSEL:

David Bilsker
Andrew Naravage
QUINN EMANUEL URQUHART & SULLIVAN LLP
50 California Street, 22nd Floor
San Francisco, CA 94111
Tel: (415) 875-6600

Anne Toker
James E. Baker
Anastasia M. Fernands
QUINN EMANUEL URQUHART & SULLIVAN LLP
51 Madison Ave., 22nd Floor
New York, NY 10010
Tel: (212) 849-7000

Jeffrey C. Wu
QUINN EMANUEL URQUHART & SULLIVAN LLP
60 E South Temple, Suite 500
Salt Lake City, UT 84111
Tel: (801) 515 7300

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Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: /s/ Stephanie E. O'Byrne
David E. Moore (#3983)
Bindu A. Palapura (#5370)
Stephanie E. O'Byrne (#4446)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com
sobyne@potteranderson.com

*Attorneys for Defendants Qiagen Sciences,
LLC, Qiagen LLC f/k/a Qiagen, Inc.,
Qiagen Beverly LLC, f/k/a Qiagen Beverly,
Inc., Qiagen Gaithersburg LLC, f/k/a
Qiagen Gaithersburg, Inc., Qiagen GmbH,
Qiagen N.V. and Jonathan Arnold*