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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ILLUMINA, INC., and ILLUMINA CAMBRIDGE LTD., Plaintiffs, v. BGI GENOMICS CO., LTD., BGI AMERICAS CORP., MGI TECH CO., LTD., MGI AMERICAS, INC., and COMPLETE GENOMICS INC., Defendants.	Case No. 3:20-cv-01465 **NOTICE OF MOTION AND MEMORANDUM IN SUPPORT OF PLAINTIFFS ILLUMINA, INC. AND ILLUMINA CAMBRIDGE LTD.'S MOTION FOR PRELIMINARY INJUNCTION** Date: April 8, 2020 Time: 2:00pm Courtroom: 2, 17th Floor Hon: William H. Orrick

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I. NOTICE OF MOTION

Pursuant to Federal Rule of Civil Procedure 65 and Civil L.R. 7, plaintiffs Illumina, Inc. and Illumina Cambridge, Ltd. (collectively "Illumina") move for a preliminary injunction prohibiting BGI Americas Corp. ("BGI Americas"), MGI Tech Co., Ltd. ("MGI Tech"), MGI Americas, Inc. ("MGI"), and Complete Genomics, Inc. ("Complete Genomics")[1] from further infringement of U.S. Pat. No. 7,541,444 ("the '444 Patent"), U.S. Patent No. 7,771,973 ("the '973 Patent"), and U.S. Patent No. 10,480,025 ("the '025 Patent"), collectively the "Asserted Patents." This motion is based on this submission, the Declarations of Mark Van Oene, Professor Kevin Burgess, and Christopher Lavin, and all other information properly considered. The hearing date is noticed for April 8, 2020 at 2:00 pm in Courtroom 2. This hearing date is based on the likelihood that this case will be deemed a related case to *Illumina, Inc., et al v. BGI Genomics Co., et al.*, Case No. 19-cv-03770-WHO, which is currently before Judge Orrick.

II. RELIEF SOUGHT

Illumina requests the entry of a preliminary injunction prohibiting Defendants from commercializing or using their infringing sequencing instruments and reagents in the United States in violation of 35 U.S.C. § 271, as more fully set forth in the proposed injunction submitted with this motion.

III. INTRODUCTION

Defendants have been selling their imitative sequencing instruments head-to-head against Illumina using Illumina's patented azido chemistry. To date, the distribution of Defendants' sequencers to customers has been focused on China where IP counterparts to the '444, '973, and '205 Patents do not exist. Until now, Defendants had not attempted general commercialization in the United States because of Illumina's patent rights.

Last Friday, MGI Tech announced a commercial launch of Defendants' "CoolMPS" sequencing reagents, which Defendants are touting as a "new" chemistry that can be used with their existing sequencers as an alternative to their existing "standardMPS" sequencing reagents.

[1] Collectively, they are referred to as "Defendants" or "BGI".

Declaration of Illumina Senior Vice President Mark Van Oene ("Van Oene Decl. "), Ex. LL. MGI Tech announced that its sequencing instruments and CoolMPS reagent kits will be commercially available for wide scale distribution in the U.S. starting in April of this year. *Id.* While MGI announced last October that it had obtained "early research results" for CoolMPS, it was not until last Thursday that MGI Tech revealed the technical specifics about CoolMPS that confirmed it uses Illumina's patented azido chemistry. Van Oene Decl., Ex. MM.

Defendants' sequencers and azido-based CoolMPS reagents compete directly with Illumina's sequencers and reagents, all of which use Illumina's patented azido chemistry. If Defendants are permitted to commercialize its infringing sequencers and CoolMPS products, that would disrupt the status quo and create a substantial risk of irreparable harm. All four preliminary injunction factors weigh strongly in favor of enjoining Defendants from doing so.

The Asserted Patents are key patents related to the azido chemistry that is core to Illumina's premier DNA sequencing technology. *See* Burgess Decl. ¶ 31. Through more than a decade of research and commercialization, and billions of dollars of investment, Illumina has successfully established the patented azido chemistry as the most efficient, accurate, and reliable sequencing technology in the world. Van Oene Decl. ¶ 11. As of 2010, this technology had made DNA sequencing more than a thousand times cheaper and a thousand times faster, and its continued development has revolutionized scientific research and healthcare. *Id.* ¶¶ 11-13. Illumina is well-known for its industry-leading azido-based technology. *Id*. Both Illumina Cambridge Ltd., the owner of the Asserted Patents by assignment, and Illumina Inc., the exclusive licensee of the Asserted Patents, have a role in selling and earn profits from sales of Illumina sequencing products in the United States. *Id.* ¶ 4.

In the face of Illumina's success moving the entire field of genomics forward with its patented azido chemistry, like others who have been enjoined before, Defendants could not resist the temptation to develop competitive DNA sequencers based on this approach. Defendants' announcements about CoolMPS immediately invited comparisons with Illumina. On October 17, 2019, MGI announced "early research results" for CoolMPS, claiming that "[r]esults were

comparable to existing platforms," i.e., Illumina. Van Oene Decl., Ex. HH ("MGI Demonstrates Success of New CoolMPS™ Sequencing Chemistry on PCR-free DNBSEQ™ Platform") at 1.

Although MGI claimed in October that CoolMPS was a "fundamentally unique chemistry," MGI Tech just revealed last week that CoolMPS actually uses "nucleotides with a 3'-O-azidomethyl blocking group," the same azido chemistry used by Illumina that is covered by Illumina's '444 and '973 Patents, among others. Van Oene Decl., Ex. MM. This azido blocking group prevents adding nucleotides into a molecule when it is unwanted, but is reliably cleavable (removable) so that nucleotide bases can be added stepwise when that is wanted. Burgess Decl. ¶¶ 28, 40. Defendants' use of this same azido group as a protecting group for sequencing in both its CoolMPS and standardMPS products thus clearly infringes.[2] The supporting expert declaration of Professor Kevin Burgess confirms this. *See generally* Burgess Decl. ¶¶ 35-45, 49-72.

Defendants have attempted to position their infringing products as providing comparable results to Illumina's technology, while undercutting Illumina on price. Van Oene Decl. ¶¶ 37, 65. Defendants can offer artificially low prices because they have used Illumina's patented innovations without incurring the sizeable research and development costs that enabled them. Van Oene Decl. ¶¶ 26, 68. The substantial risk of irreparable harm to Illumina if Defendants successfully meet their commercialization plans is explained in the supporting declaration of Illumina Senior Vice President Mark Van Oene.

Defendants cannot meaningfully contest Illumina's likelihood of success. First, Defendants' infringement based on the use of Illumina's patented azido chemistry is straightforward. Defendants' argument that CoolMPS is a "new" chemistry because it supposedly uses "unlabeled" nucleotides is irrelevant to infringement because the asserted claims in the '444 and '973 patent do not require a label. Second, Defendants' invalidity challenge is unlikely to

[2] Defendants also have recently informed Illumina that they plan to distribute their sequencers and standardMPS reagents to "key opinion leaders" ("KOLs") on "no-cost trial basis" in the U.S. Van Oene Decl., Ex. FF at 2. Because this activity is inherently commercial, Illumina filed a motion for preliminary injunction on February 19, 2020 in this Court in Case No. 3:19-cv-03770-WHO (N.D. Cal.), which involves two other Illumina patents related to the patents in this case. Because use of Defendants' standardMPS reagents also infringes all three Asserted Patents in this case, Illumina also moves to preliminarily enjoin these same activities in this case, as explained below.

succeed because the validity of Illumina's patented azido chemistry is battled-tested. The Asserted Patents each contain claim limitations focused on Illumina's azido chemistry that have withstood prior validity challenges in multiple IPR proceedings. The record here is similar to that before Judge Alsup when he enjoined the last multi-national that sought to use Illumina's azido chemistry for sequencers in the United States. *See Illumina, Inc. v. Qiagen, NV*, 207 F. Supp. 3d 1081 (N.D. Cal. 2016). Defendants' subsequent IPR invalidity attacks, which involved similar claims focused on Illumina's azido chemistry, have also failed. A preliminary injunction should be entered.

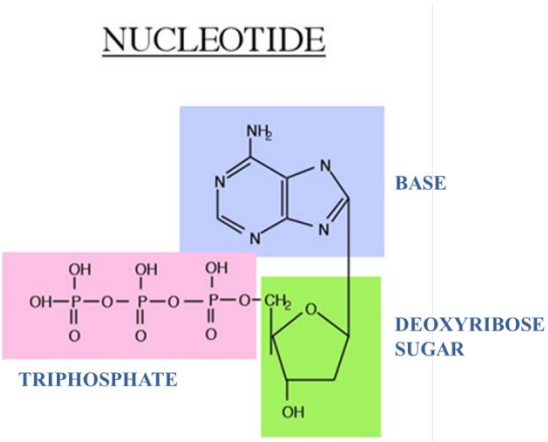
IV. FACTUAL BACKGROUND

A. Overview Of The Technology

Illumina's patented innovations have revolutionized the genetics field and established its proprietary SBS technology as the premier DNA sequencing method in terms of efficiency, accuracy, and reliability. *See* Van Oene Decl. ¶¶ 8, 11-13. Illumina is a recognized industry leader in DNA sequencing, and its technology is used to generate over 90% of the world's sequencing data. *Id.* at ¶¶ 13, 37.

The Asserted Patents generally relate to large-scale sequence determination using controlled and monitored incorporation of single nucleotides. Burgess Decl. ¶ 25. Briefly, the Asserted Patents describe methods and chemical compounds used to determine the sequence of a nucleic acid molecule, such as a DNA molecule, by incorporating into the nucleic acid molecule a nucleotide capable of identification. *Id*. These teachings build on the natural chemistry of DNA molecules, so a brief discussion of fundamental DNA chemistry is provided below. *Id*.

DNA is a molecule made up of four chemical bases: adenine, guanine, cytosine, and thymine. *Id*. ¶ 26. Each of the bases in DNA is also attached to a sugar fragment and a phosphate fragment. *Id*. The combination of the base, sugar, and phosphate molecule is called a nucleotide. *Id*.



The four chemical bases that make up DNA are: "A" for adenine, "G" for guanine, "C" for cytosine, and "T" for thymine. *Id.* ¶ . DNA consists of two paired strands of nucleotides that wind around one another to form a double helix. *Id.* In forming the double helix, the nucleotides of one strand pair up with nucleotides of another strand in a specific, complementary way: A only pairs with T, and G only pairs with C. *Id.* Thus, if the sequence of one strand is known, the sequence of the complementary strand can easily be deduced. *Id.* For example, if the sequence of one strand is known to be A-G-T-C, then the sequence of the complementary strand is T-C-A-G.[3] *Id.*

In the type of sequencing used by Illumina, the DNA strand of interest (the "target strand" or "target DNA") is sequenced by synthesizing a complementary strand (the "complementary strand" or "growing strand"). *Id.* ¶ 27. This is done by sequentially incorporating identifiable nucleotides into the growing strand. *Id.* After a nucleotide is incorporated into the growing strand, the nucleotide is identified, thereby revealing the identity of its compliment in the target strand. *Id.* Then, the next nucleotide is incorporated into the growing DNA strand, and that nucleotide is identified. *Id.* By repeatedly incorporating and identifying nucleotides, the DNA sequence of the target strand can be determined. *Id.*

Because each individual nucleotide is read after its incorporation into the growing strand, the rate of incorporation is controlled so that no additional nucleotides are incorporated into the growing strand until the last-incorporated nucleotide is identified. *Id.* ¶ 28. The Asserted Patents

[3] Although the complementary strand would be read in the opposite direction to the target strand, - the two strands run in opposite directions - making its actual sequence read out as G-A-T-C.

teach novel sequencing chemistry that exercises such control through the use of modified nucleotides with a 3'-O-azidomethyl blocking group (the "azidomethyl block"). *Id.* Below is a description of how this sequencing chemistry is used in the Illumina sequencing products.

In Illumina's commercial sequencing platforms, the sequencing process starts by hybridizing a "sequencing primer" to the target strand, the former of which is attached to a solid surface. *Id.* ¶ 29. By attaching the target strand to a surface, the target strand will stay at a fixed position throughout the sequencing process and can, thus, be more easily identified. *Id.* In the following illustration, the target strand is represented by the purple/green strand, and the primer is represented by the blue circles without letters. *Id.*

The next step is to add a single nucleotide to the primer. *Id.* ¶ 30. As discussed above, the nucleotide that gets added depends on the sequence of the next base in the target strand. *Id.* If the next nucleotide in the target is A, then a T will be added to the primer; if the next nucleotide is T, then A will be added; if the next nucleotide is G, then C will be added; if the next nucleotide is C, then G will be added. *Id.* In the illustration above, the first nucleotide in the target strand is an A, so a T will be added to the blue primer (i.e., the complementary strand). *Id.*

Each of these added bases is blocked in a way that only permits one base to be added at a time. *Id.* ¶ 31. The Asserted Patents teach the use of the azidomethyl block for this purpose. As discussed above, each nucleotide consists of a base, sugar, and phosphate molecule. *Id.* A hydroxyl group at the 3' position of the sugar reflects the natural state of the ribose or deoxyribose as found

in nature. *Id*. Only when the sugar is in its natural state with a hydroxyl group at the 3' position can another nucleotide be added to the growing DNA strand. *Id*. The azidomethyl block interacts with the hydroxyl group to prevent (or block) the next nucleotide from incorporation into the growing strand. *Id*. Thus, the azidomethyl block prevents the incorporation of additional nucleotides from proceeding until the previous nucleotide has been identified. *Id*. With the azidomethyl block in place, incorporation is essentially paused to allow time for the steps required to identify the new nucleotide. *Id*. Once the identification or read is complete, the azidomethyl block is cleaved to allow the incorporation of the next nucleotide. *Id*.

The identity of the newly incorporated nucleotide can be determined in various ways, including but not limited to, fluorescently labelling the nucleotide and reading the fluorescent signal emitted. *Id*. ¶ 32. The nucleotide may be fluorescently labelled before or after incorporation into the growing strand, so long as the label is affixed prior to reading (i.e. identifying) the complementary strand. *Id*. Illumina's chemistry can be used to repeat this process of adding a nucleotide, identifying the nucleotide, and removing the block for multiple rounds. *Id*. In this way, Illumina's chemistry can reveal a sequence of nucleotides by monitoring the identity of each nucleotide incorporated into the complementary strand. *Id*.

Illumina's technology permits large-scale sequencing because it simultaneously sequences and records readings of multiple complementary strands during each sequencing cycle. *Id*. ¶ 33. Each complementary strand is located in a different area on the sequencing flow cell's surface. *Id*. Thus, the sequence of nucleotides at each complementary strand can be deduced by looking at the reads at each spot corresponding to a different DNA strand. *Id*.

B. The '973 Patent

The '973 patent relates to a method for determining the sequence of a target polynucleotide. Claim 13, which depends from claim 1 and is the sole asserted claim of the '973 patent, includes the following limitations:

> **Claim 1.** A method for determining the sequence of a target single-stranded polynucleotide, comprising monitoring the sequential incorporation of complementary nucleotides, wherein at least one incorporation is of a nucleotide having a removable 3′-OH blocking group covalently attached thereto, such that the 3′ carbon atom has attached a group of the structure

—O—Z . . .

and wherein the blocking group is removed prior to introduction of the next complementary nucleotide.

Claim 13. The method of claim 1 wherein Z is an azidomethyl group.

Burgess Decl., Ex. B ('973 patent) at 86:24-33; 88:37-38**.**

First, claim 1 recites a method for determining the sequence of a target single-stranded polynucleotide, comprising monitoring the sequential incorporation of complementary nucleotides, wherein at least one incorporation is of a nucleotide having a removable 3′-OH blocking group covalently attached thereto, such that the 3′ carbon atom has attached a group (—O—Z). *Id*. ¶ 38. Here, Z is the blocking group. Claim 1 then requires that the blocking group be removed before the incorporation of the next nucleotide. *Id*. As discussed above, the removal of the blocking group permits the incorporation of the next nucleotide. *Id*.

Claim 13 then adds the additional requirement that "Z" (the protecting group) is an azidomethyl group (e.g., the azidomethyl block). *Id.* ¶¶ 38-40. This is important. An OH group at the 3′ position of the sugar is the natural state of the sugar as found in natural nucleotides. *Id.* Only when the sugar is in this state with an OH group at the 3′ position can another nucleotide be added to the complementary strand. *Id.* Thus, the azidomethyl block required by claim 3 allows one to control when a nucleotide is added to the complementary strand. *Id.*

C. The '444 Patent

The '444 Patent generally relates to a modified nucleotide molecule. Claim 3, which depends from claim 1 and is the sole asserted claim of the '444 patent, includes the following limitations:

Claim 1. A modified nucleotide molecule comprising a purine or pyrimidine base and a ribose or deoxyribose sugar moiety having a removable 3′-OH blocking group covalently attached thereto, such that the 3′ carbon atom has attached a group of the structure

—O—Z . . .

wherein said molecule may be reacted to yield an intermediate in which each R″ is exchanged for H, which intermediate dissociates under aqueous conditions to afford a molecule with a free 3′OH; with the proviso that where Z is —C(R^{IV})$_2$—S—R″, both RIV groups are not H.

Claim 3. A molecule according to claim 1 wherein Z is an azidomethyl group.

Burgess Decl., Ex. C ('444 patent) at 85:65-86:36; 86:39-40**.**

Claim 1 recites a modified nucleotide molecule comprising a purine or pyrimidine base and a ribose or deoxyribose sugar moiety having a removable 3′-OH blocking group covalently attached thereto, such that the 3′ carbon atom has attached a group (—O—Z) where Z comprises one of various defined structures. *Id*. ¶ 42. Z is the blocking group. Claim 1 then requires that Z include a group that yields an intermediate structure where the protecting group is exchanged for a hydrogen atom such the that free 3' hydroxyl group is exposed. *Id*. This latter recitation is directed to the removal of the protecting group in order to expose the 3' hydroxyl group so that the next nucleotide may be incorporated, as discussed above. *Id*.

Claim 3 adds the requirement that Z (the protecting group) is an azidomethyl group (e.g., the azidomethyl block). *Id*. ¶ 43. The azidomethyl block in claim 3 is important for sequencing because it allows control over when a nucleotide is added to the complementary strand. *Id.*

D. The '025 Patent

The '025 Patent also relates to modified nucleotide molecules. Dependent claim 8, which depends from independent claim 1 of the '025 Patent, includes the following limitations:

> **Claim 1.** A nucleotide or nucleoside molecule having a ribose or deoxyribose sugar moiety and a base linked to a detectable label via a cleavable linker, wherein the sugar moiety comprises a protecting group attached via a 3′ oxygen atom, and wherein said protecting group comprises an azido group that can be modified or removed to expose a 3′ OH group.
>
> **Claim 8.** The molecule of claim 1, wherein the protecting group comprises azidomethyl (CH_2N_3).

Burgess Decl., Ex. D ('025 patent) at 21:19-24; 21:39-40**.**

Claim 1 recites a nucleotide or nucleoside molecule a ribose or deoxyribose sugar moiety and a base linked to a detectable label via a cleavable linker, wherein the sugar moiety comprises a protecting group attached via a 3′ oxygen atom. *Id*. ¶ 45. The cleavable linker connects the detectable label to the base as a method of identifying the nucleotide after incorporation. Claim 1 then requires that the sugar moiety include an azido protecting group that can be modified or removed to expose a 3' hydroxyl group. *Id*. This requirement for a 3' azido blocking group permits

the controlled incorporation of nucleotides, as discussed above. *Id*. Claim 8 further narrows the blocking group requirement of claim 1 by limiting it to an azidomethyl block. *Id*.

E. Defendants Have Been Selling Their Imitative Sequencers Using Illumina's Patented Azido Chemistry Outside The United States To Directly Compete Against Illumina's Sequencers

In 2017, the President of BGI Genomics stated publicly that the company plans to "dominate the market" in genomics. Van Oene Decl. ¶ 49, Van Oene Decl., Ex. BB at 1. Last year, Defendants announced that they had already placed over 1,000 sequencers in 16 different countries and had a 35% market share in China. Van Oene Decl., Ex. DD at 2. Last week, MGI Tech updated these figures, announcing that "[m]ore than 1,600 MGI sequencers, including DNBSEQ-T7 made available last September, have been installed worldwide, serving more than 460 customers in 38 countries," which shows intensifying competition and growth in the market. Van Oene Decl., Ex. LL at 2.

Many people in the industry have recognized Defendants' sequencers as imitative of Illumina sequencing products. *Id.* ¶ 36. For example, based on interviews with MGI, GenomeWeb reported that MGI was using sequencing by synthesis (SBS) "chemistry [] similar to that used by Illumina and others." *Id.* ¶ 36, Van Oene Decl., Ex. L at 4. MGI itself has touted its own use of the "[p]roven sequencing by synthesis (SBS) chemistry" to potential customers to compete against Illumina. Van Oene Decl., Ex. O at 4, No. 3. When MGI entered the European market, it marketed its sequencers using the designation "MGISEQ," which is nearly identical to Illumina's registered European Union trade mark "MISEQ" for its sequencing systems and reagents. An industry commentator observed the remarkable similarity between the appearance and model names of Illumina's instruments and a BGI copy product, stating that Defendants' product "not only looks like an Illumina (NASDAQ:ILMN) sequencer but they're actually using the same naming convention as the Illumina machines." Van Oene Decl., Ex. P at 1 ("The BGI Genomics IPO – Is This a Chinese Illumina?"). MGI changed the name of its sequencing platforms after Illumina obtained a preliminary injunction in Latvia, the planned location for MGI's European distribution center, to prevent MGI's continued trademark infringement. Van Oene Decl. ¶ 36.

MGI attempts to position its imitative products as comparable to Illumina's sequencers in performance, while undercutting Illumina on price. Van Oene Decl., Ex. O at 3 ("a significant reduction in costs compared to Illumina instruments."); Van Oene Decl., Ex. L at 3 ("Tan said MGI's platforms will be very cost-competitive with Illumina's."). On October 17, 2019, MGI announced that CoolMPS had achieved comparable results to Illumina's NovaSeq 6000 system. Van Oene Decl., Ex. HH. In another press release of May 21, 2019, MGI claimed that "analyses have shown that MGI's data quality is comparable to data generated using a competitor's [i.e., Illumina's] technology, but that sequencing costs are lower." Van Oene Decl., Ex. R at 1. Industry analysts have also reported that MGI "compete[s] with Illumina on cost" and "may apply pressure to Illumina's margins." Van Oene Decl., Ex. D at 36, 84.

The direct competition between Illumina and MGI is also evident in MGI's marketing materials, which often use Illumina's sequencers as a benchmark, typically to make cost comparisons and performance comparisons based on comparative testing. Van Oene Decl. ¶ 39. MGI targets Illumina sequencers in its marketing efforts. For example, MGI uses an "NGS Running Cost Comparison" to support its claim that it provides equivalent NGS performance to Illumina, but at a lower price. *Id.* at 121. MGI's slides show a list price cost per GB of sequencing from $10-$143 for Illumina, as compared to $5-$32 for MGI. *Id.* For the highest-production sequencers, MGI shows up to a 75% discount for its DNBSEQ-T7 ($5 per GB) as compared to Illumina's NovSeq ($10-20 per GB). *Id.* In addition, the typical cost of reagents for sequencing a human genome using Illumina's NovaSeq 6000 platform is approximately $800. By comparison, in the above-mentioned GenomeWeb article, MGI advertises its equivalent DNBSEQ-T7 instrument as costing approximately $500 in consumables per human genome. Van Oene Decl., Ex. L at 3.

In "The Sequencing Buyer's Guide" (which is sponsored by MGI, among others), David Smith of the Mayo Clinic identifies "BGI-based sequencing" as a lower-cost substitute for Illumina's technology. He states, "[o]ne of the most attractive aspects of BGI-based sequencing is that they offer a price-point for WGS [whole genome sequencing] that is really hard to beat of $600. This is an all-in cost of library preparation, sequencing and post-sequencing analysis. As will be discussed later in this report, this is considerably less than the full cost of WGS on the only other

viable platform for WGS, namely Illumina." Van Oene Decl., Ex. JJ at 14. Mr. Smith also notes in The Sequencing Buyer's Guide that BGI's sequencers (such as the BGISEQ-500) "were mainly sold in China (most likely due to patent issues on the actual sequencing chemistry)" and further mentions that "there were a number of patent violation lawsuits filed between Illumina and MGI." *Id.* at 13-14.

MGI targets Illumina's existing customers and attempts to use existing Illumina infrastructure to induce Illumina's customers to replace their Illumina sequencers with MGI products, touting MGI's "[c]ompatibility with previous Illumina platforms." Van Oene Decl., Ex. O at 4. For example, MGI markets its DNBSEQ instruments as being "fully compatible with lab infrastructure that has been set up with Illumina's instrumentation," stating that they generate files that are "compatible with bioinformatics workflows written for sequencing data from Illumina instruments" and that "[l]ibraries already constructed with Illumina-style adapters can be converted easily to [MGI's] platform." *Id.* at 4-5. MGI also offers data analysis software to accompany the actual sequencing instrument that is similar to Illumina's offering. Illumina offers a variety of bioinformatics software to run with its sequencers. Van Oene Decl., Ex. X (Illumina MiSeq System web page). MGI has also marketed its products as being fully compatible with Illumina's platforms and related lab infrastructure, including Illumina's libraries and bioinformatics workflows. Van Oene Decl., Ex. O at 4-5.

F. Defendants Infringe Illumina's Patents In Its San Jose Facility And Are Collaborating For Broad Commercialization In The U.S.

Defendants operate a facility in San Jose where they have been operating the infringing sequencers. Each of the Defendants should be preliminarily enjoined because they are collaborating together to commit infringements and for potential commercialization in the U.S. *See* Case 3:19-cv-03770-WHO,[4] Dkt. No. 84-15 at 5-6. First, the Defendants have provided notice that MGI Americas, Inc. ("MGI") intends to supply accused BGI sequencers and accused reagents to key opinion leaders in the U.S. on a no-cost basis. Van Oene Decl., Ex. FF. Second, MGI Tech later

[4] All references to Case 3:19-cv-03770-WHO, refer to the *Illumina, Inc., et al v. BGI Genomics Co., et al.*, Case No. 19-cv-03770-WHO (N.D. Cal.).

issued a press release announcing that it would take steps to commercially launch CoolMPS in the U.S. Van Oene Decl., Ex. LL. Third, BGI Americas has a facility in San Jose, California and offers services related to its sequencing products, including "DNBseq™," to customers in North America. Christopher Lavin Decl., Ex. 1; *In re Application of Illumina Cambridge, Ltd.*, 19-mc-80215-WHO (N.D. Cal.) Dkt. 17 at 2-3. Fourth, CGI has listed job postings to hire salespeople in California to sell the accused products, including "MGI's NGS Sequencing instruments, reagents, software [and] solutions." Christopher Lavin Decl., Exs. 2-3.

G. Defendants Reveal Their Commercial Plans in the U.S.

On February 21, 2020, MGI Tech announced a commercial launch of Defendants' "CoolMPS" sequencing reagents. Van Oene Decl., Ex. LL. MGI Tech announced that its CoolMPS reagent kits will be commercially available for wide scale distribution in the U.S. starting in April of this year, and that it will roll out its "G series DNBSEQ sequencers" (e.g., models DNBSEQ-G50, DNBSEQ-G400, and DNBSEQ-G400 FAST), and "T series DNBSEQ sequencers" (e.g., DNGSEQ-T7) in the U.S. in Q2 and Q3, respectively. *Id.*

Shortly before its commercial launch announcement, Defendants notified Illumina on January 28, 2020 that "MGI Americas may begin placing sequencers with key opinion leaders on a ***no-cost trial basis*** and may provide sequencing reagent kits to key opinion leaders on a no-cost basis (for their use with the sequencers or for sequencing performed by MGI Americas), where such kits may include, but are not limited to, those with the labeled nucleotides that are presently accused [e.g., standardMPS reagents]." Van Oene Decl., Ex. FF at p. 14 (emphasis supplied). Defendants also notified Illumina that MGI plans to commercially release a design-around attempt, which MGI Tech has since revealed is CoolMPS. *Id*. at pp. 10-14; Ex. LL.

On February 4, 2020, Defendants revealed that their engagement with key opinion leaders in the United States is "on-going" and that they are attempting to place their G400 sequencers (which have been on the market outside the United States for years) with key opinion leaders on a "no-cost, trial basis." *Id*. at pp. 6-8. Defendants did not agree that this would be the end of its commercialization effort – rather it is clear that it is part of their commercial launch for introducing both their infringing sequencers and CoolMPS products into the U.S.

Because Defendants' key opinion leader program is infringing and is likely to cause irreparable harm to Defendants, Illumina moved for a preliminary injunction in *Illumina, Inc. v. BGI Genomics Co.*, Case No. 19-cv-03770-WHO (N.D. Cal.), which is pending before Judge William H. Orrick. This ongoing case involves U.S. Patent Nos. 7,566,537 ("the '537 Patent") and 9,410,200 ("the '200 Patent"). In response to that motion Defendants have agreed "to refrain from transferring or distributing sequencing reagent kits containing the currently accused fluorescently labeled nucleotides to third parties in the United States until the Court resolves the Motion." Case 3:19-cv-03770-WHO, Dkt. No. 91 at 1.

Because the sequencers and standardMPS products that Defendants plan to distribute to KOLs on a "no-cost, trial basis" also infringe each of the '444, '973, and '025 Patents in the present case, Illumina also moves to preliminarily enjoin those activities in this suit.

V. ARGUMENT

"The factors the trial court considers when determining whether to grant a preliminary injunction are of longstanding and universal applicability. As the Supreme Court recently reiterated, there are four: "[a] plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375–76 (Fed. Cir. 2009). All these factors weigh strongly in favor of preliminarily enjoining Defendants from infringing the Asserted Patents by commercially releasing or using its sequencers and reagents in the United States, including through its key opinion leader program or other transfer to third parties.

A. Illumina Is Likely To Succeed On The Merits

A reasonable likelihood of success requires a showing of infringement and that the asserted patent will withstand a validity challenge. *See, e.g., Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994).

1. Defendants' Accused Sequencers And Reagent Kits Infringe The Asserted Patents

"Determining literal infringement is a two-step process: the 'proper construction of the asserted claim and a determination whether the claim as properly construed reads on the accused product or method.'" *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1319 (Fed. Cir. 2012).

Professor Burgess in his report establishes that the accused products use Illumina's patented azido chemistry and thus infringe Illumina's Asserted Patents. Burgess Decl. ¶¶ 35-72. All of the Defendants' accused sequencers and reagents infringe the '444 and '973 Patents because they use Illumina's azido chemistry. *Id.* ¶¶ 49-66. The '025 Patent covers Defendants' accused sequencers and standardMPS reagents because they use both Illumina's azido chemistry and the claimed labelled nucleotides in the '025 Patent. *Id.* ¶¶ 67-72. Dr. Burgess details how every claim element is satisfied when these products are used for their intended purpose. *Id*. Moreover, by encouraging their products use by others, including key opinion leaders, with knowledge that they infringe, Defendants induce infringement. *Global-Tech Appliances, Inc. v. SEB SA*, 563 U.S. 754 (2011). By supplying accused reagent kits that have no substantial non-infringing uses, Defendants also contributorily infringe. *Id.*

Defendants' infringement is straightforward because they admit that CoolMPS uses "nucleotides with a 3'-O-azidomethyl blocking group" for sequencing, which is covered by Illumina's '444 and '973 Patents. Burgess Decl. ¶¶ 49-66. The Defendants' standardMPS products infringe the '444, '973, and '025 Patents for similar reasons. *Id.* ¶¶ 35-72. Notably, in *Illumina, Inc. v. BGI Genomics Co.*, Case No. 19-cv-03770-WHO (N.D. Cal.), Defendants have not identified any non-infringement argument to deny that use of their standardMPS reagents are covered by the asserted claims in Illumina's '537 and '200 Patents, which are highly similar to the asserted claims in the related '025 Patent. *See* Case 3:19-cv-03770-WHO, Dkt. 84-16 at 6-7. They do not contend that any claim elements are unmet. *Id.* Illumina is likely to succeed on its infringement claims.

2. Defendants' Invalidity Position Is Not Likely To Succeed

Another multi-national, Qiagen N.V., attempted to introduce sequencers using Illumina's

patented azido chemistry in 2016. *See Illumina, Inc. v. Qiagen, NV*, 207 F. Supp. 3d 1081, 1084-1085 (N.D. Cal. 2016). Before doing so, it attempted to challenge the '537 Patent before the PTAB. The PTAB upheld Illumina's patent after a trial. *Id.* Qiagen appealed to the Federal Circuit, which also upheld Illumina's patent. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd*., 821 F.3d 1359 (Fed. Cir. 2016). In doing so, the Federal Circuit relied on the PTAB's finding that the use of an azidomethyl protecting group would have been non-obvious to a person of ordinary skill in the art. *Id.* at 1369 ("[A] person of ordinary skill in this field would not have been motivated to use the azidomethyl group of Zavgorodny as a 'protecting group [that] can be modified or removed to expose a 3′ [hydroxyl] group' of a nucleic acid molecule, as the claim requires. This is so because the azidomethyl group would have been expected to perform inefficiently in that role.").

Although its validity challenges failed before the PTAB, Qiagen attempted to nevertheless introduce its infringing sequencers into the United States. In doing so, it attempted to argue that there were still substantial questions as to the validity of Illumina's '537 patent. Judge Alsup thoroughly rejected that argument and found that it is likely the validity of Illumina's patent rights will be upheld. *Illumina*, 207 F. Supp. 3d at 1087-93. Because of the strength of Illumina's azido patent rights, Judge Alsup found that Illumina presented a "powerful" case for an injunction. *Id.*

Because Defendants are so eager to introduce their imitative sequencers in the United States, and are so aware of Illumina's patent rights, in 2017 they invested in two IPRs trying to challenge the '537 Patent even though Qiagen's IPR had already failed. *See Complete Genomics, Inc. et al v. Illumina Cambridge Ltd. et al, IPR2017-02172 (PTAB), Decision Denying Institution (April 20, 2018); Complete Genomics, Inc. et al v. Illumina Cambridge Ltd. et al, IPR2017-02174 (PTAB), Decision Denying Institution (April 20, 2018).* The PTAB rejected Defendants' challenges because one was duplicative of Qiagen's prior failed IPR and their second IPR failed to show a reasonable likelihood on the merits that the '537 Patent was invalid. *Id.*

In a strained attempt to undermine Judge Alsup's analysis, the PTAB's three decisions and the Federal Circuit's decision, Defendants pled a meritless inequitable conduct argument in *Illumina, Inc. v. BGI Genomics Co.*, Case No. 19-cv-03770-WHO (N.D. Cal.) that dubiously argued that all those decisions were the product of fraud. This Court rejected Defendants' attempt to even

plead this inequitable conduct argument because Defendants' theory was implausible. Case 3:19-cv-03770-WHO, Dkt. 81 at 8-9.

Defendants' patent validity challenge will fare no better in this case. Each of the asserted claims here contain limitations requiring a modified nucleotide with a cleavable azido blocking group, which is the same limitation that drove the validity findings in Defendants' and Qiagen's failed IPR challenges. Burgess Decl. ¶¶ 53-56. Each of the '844, '973, and '025 Patents is related to the '537 Patent,[5] contains highly similar claim limitations for the azido chemistry, and is likely to withstand Defendants' invalidity challenges for the same reasons that the '537 Patent did. *Id.* Notably, Illumina did ***not*** argue that the "detectable label" in the '537 patent claims was a basis for validity in the IPRs, and the PTAB decisions upholding validity did not rely on the label. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Limited PTAB-IPR2013-00517*, Paper 32. Nor was that a basis for any of the decisions upholding Illumina's azido patent rights.

Additionally, Defendants' invalidity arguments focus on a 1991 article by Zavgorodny that was considered by the patent examiner during the prosecution of both the '444 Patent and the Patent before the Patent Office granted these patents. Lavin Decl., Ex. 4 at 3, Burgess Decl., Ex. C at 3. For example, during prosecution of the '444 Patent, the examiner cited Zavgorodny and then allowed the claims after it was shown that Zavgorodny fails to disclose a modified nucleotide with the azido blocking group. Lavin Decl., Ex. 5 at 7. Here, it will be even more difficult for Defendants to meet their clear and convincing burden to show invalidity because, as the Federal Circuit has recognized, "[a]rguments and references already considered by the Patent Office may carry less weight with the fact finder." *Guangdong Alison Hi-Tech Co. v. Int'l Trade Comm'n*, 936 F.3d 1353, 1365 (Fed. Cir. 2019).

In short, Illumina's patent rights to its azido chemistry are valid and battle-tested. Illumina is likely to win an invalidity challenge.

[5] Each of the '844, '973, '025, and '537 Patents claim priority at least to U.S. Patent Application No. 10/227,131. Burgess Decl. ¶ 54 n.1.

B. There Is A Substantial Risk That Illumina Would Suffer Irreparable Harm If Defendants Are Permitted To Proceed With Their Commercial Launch

If Defendants were permitted to pursue their commercial launch by distributing and using their infringing sequencers and reagents in the U.S., there would be a substantial risk Illumina would suffer irreparable harm. Defendants' commercialization plan for its imitative products includes (1) distribution and sales of sequencers and CoolMPS products, (2) free giveaways of sequencers and standardMPS products on a trial basis to key opinion leaders, and (3) Defendant's own internal infringing uses to drive marketing and sales. Each of these activities would cause Illumina to lose business opportunities, tarnish its reputation as the exclusive provider of its patented azido sequencing chemistry, and put downward pressure on its pricing, all of which are unquantifiable and classic irreparable harms. *See Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930–31 (Fed. Cir. 2012) (affirming a finding of irreparable harm based on "damage to [patentee's] price, reputation, and business opportunities" even where there was "difficulty quantifying the effect on reputation and business" to the patentee during "the growth stage of a product"); *see also Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F. 3d 1336, 1344–45 (Fed. Cir. 2013) (reversing denial of an injunction and finding clear error in lower court's irreparable harm analysis, which ignored that marketplace exclusivity itself "is an intangible asset that is part of the company's reputation"); *see also* Van Oene Decl. ¶ 75-76 (explaining why these harms are unquantifiable).

"So long as there is a significant threat of harm, a preliminary injunction may issue regardless of the magnitude of the harm." *QBAS Co., Ltd. v. C Walters Intercoastal Corp.*, 2010 WL 7785955, at *11 (C.D. Cal. Dec. 16, 2010). As the Federal Circuit has explained, a "party seeking injunctive relief must make a 'clear showing' that it is at risk of irreparable harm, which entails 'a ***likelihood*** of substantial and immediate irreparable injury.'" *Apple, Inc. v. Samsung Elec. Co., Ltd.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012) (citing *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 22 (2008) ("Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction.") (emphasis in original). When a patentee has demonstrated a risk of irreparable harm such as lost market share or foregone business opportunities, the availability of some monetary damages does not negate this

showing. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361–62 (Fed. Cir. 2008) (rejecting accused infringer's argument that harm to patentee was reparable due to availability of damages).

Illumina's Chief Commercial Officer, Mr. Mark Van Oene, submits a supporting declaration in which he explains the substantial risk of harm posed by Defendants' commercialization plans. *See* Van Oene Decl. ¶¶ 28-78.

1. Illumina And Defendants Are Direct Competitors

Until now, Defendants had not attempted general commercialization in the United States because of Illumina's patent rights. Elsewhere, Illumina directly competes against the Defendants for sales of sequencers, consumables, and services based on Illumina's patented technology. *Id.* ¶¶ 33-41, 47, 52, 57, 59. For example, MGI has marketed its entire line of sequencers in direct competition with Illumina's sequencers. *Id.* ¶ 47 (Van Oene Decl, Ex. T at 48). MGI Tech claims that Defendants have now placed over 1,600 sequencers abroad to over 460 customers in 38 countries. Van Oene Decl., Ex. LL at 2. MGI attempts to position its imitative products as comparable to Illumina's sequencers in performance, while undercutting Illumina on price. Van Oene Decl., Ex. O at 3 ("a significant reduction in costs compared to Illumina instruments."); Van Oene Decl., Ex. L at 3 ("Tan said MGI's platforms will be very cost-competitive with Illumina's."). The Defendants have been able to offer lower prices than Illumina by free-riding off of the enormous research and development investments that Illumina incurred in order to develop the innovations claimed by the Asserted Patents. *Id.* ¶¶ 19, 23, 60, 67. Illumina has already lost sales to the Defendants in markets outside the U.S. due to their price undercutting. *Id.* ¶ 57.

Defendants have made clear that they plan for the use of CoolMPS reagents in their existing sequencers to present a viable and potentially long-lasting threat against Illumina's products. MGI has already targeted Illumina's instruments, claiming that CoolMPS had achieved comparable results to Illumina's NovaSeq 6000 system. Van Oene Decl, Ex. HH. Defendants claim that CoolMPS is compatible with its entire line of existing sequencers, which includes the "G series" and "T series" that compete directly against Illumina's sequencers. Van Oene Decl., Ex. LL. Defendants are also marketing CoolMPS as a replacement for their prior standard MPS reagents, which also directly compete with Illumina's products. Van Oene Decl., Ex. MM at Abstract.

"Where two companies are in competition against one another, the patentee suffers the harm—often irreparable—of being forced to compete against products that incorporate and infringe its own patented inventions." *Douglas Dynamics, LLC v. Buyers Products Co.,* 717 F. 3d 1336, 1344–45 (Fed. Cir. 2013); *see also Fresenius Med. Care Holdings, Inc. v. Baxter Int'1, Inc.*, 2008 WL 928496, at *3 (N.D. Cal. Apr. 4, 2008) (noting that "the law favors [the patentee's] right to the full value of its property, **particularly the ability to keep it out of its main competitor's hands**") (emphasis added). Based on the above evidence, there can be no dispute that Illumina and Defendants are direct competitors.

2. The Sequencing Market Is Rapidly Growing

The risk of irreparable harm is compounded in this case because Illumina and the Defendants are directly competing in a sequencing market that is rapidly growing. As Mark Van Oene explains, continued growth in the market for sequencing instruments is expected due to increasing applications for genetic screening, diagnosis, and therapy, as well as the increase in speed, cost, and accuracy of sequencing enabled by Illumina's technology. Van Oene Decl., ¶ 28. As of 2019, less than 0.01% of genomic species and less than 0.02% of human genomes have been sequenced, and less than 1% of variants in the human genome have been fully characterized, which illustrates the tremendous growth potential for applications using Illumina's patented technology. *Id.* Industry analysts have projected the market for DNA sequencing products to more than double from 2018 to 2024. *Id.*

As the Federal Circuit has explained, "[d]uring the growth stage of a product[,] it is particularly crucial to be able to distinguish oneself from competitors. This includes building the brand, expanding the customer base, and establishing one's reputation and leadership in the market." *See Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 931 (Fed. Cir. 2012) (affirming the district court's "finding that Celsis would suffer irreparable harm absent a preliminary injunction"). "[When a] Plaintiff is losing market share at a critical time in the market's development, [that is] market share it will not have the same opportunity to capture once the market matures." *Tivo, Inc. v. Echostar Commc's Corp.,* 446 F. Supp. 2d 664, 669–670 (E.D. Tex. 2006), *rev'd in part on other grounds,* 516 F.3d 1290 (Fed. Cir. 2008).

3. There Is A Substantial Risk That Illumina Would Suffer Reputational Harm From Defendants' Planned Infringements

Illumina is a recognized industry leader in DNA sequencing, and its technology is used to generate over 90% of the world's sequencing data. Van Oene Decl. ¶ 37. Allowing Defendants to proceed with their planned infringing activities would cause irreparable harm to Illumina's reputation as the industry leader and the only supplier of its industry-leading, patented technology, as it builds its brand and expands its customer base in a rapidly growing market. *Id.* ¶¶ 34-48.

The fact that Defendants are attempting to use infringement to spark collaborations with key opinion leaders as part of their commercial launch strategy compounds the potential for reputation harm to Illumina because key opinion leaders can greatly influence other customers in the marketplace, especially at a time when the market is rapidly growing and it is crucial to develop one's reputation, brand, and customer relationships. *Id.* ¶¶ 52-53. In the genetic sequencing field, suppliers routinely engage with key opinion leaders as a typical part of a commercial launch strategy. *See* Van Oene Decl. ¶¶ 29-31. Key opinion leaders are often associated with prestigious universities or research centers, and placing sequencers with them is important for a supplier's commercial reputation because they have substantial influence on the industry's perception of a brand and the purchasing decisions of other customers in the field. *Id.* ¶¶ 30, 54. The U.S. market is especially important for establishing and maintaining relationships with key opinion leaders because the U.S. includes a high concentration of key opinion leaders, including world renowned institutions with global reputations in sequencing expertise. *Id.*

Because key opinion leaders tend to be prestigious institutions that are highly visible in the marketplace, providing infringing BGI products to even a small number of key opinion leaders would likely cause substantial irreparable harm to Illumina's reputation, brand, and market position. *Id.* ¶ 58. Even a small number of key opinion leaders can influence many other key players in the marketplace, and the potential harm is especially severe because the Defendants could use infringement to usurp Illumina's customer relationships, goodwill, and brand recognition in a rapidly growing market. *Id.* ¶¶ 28, 58-59. The Defendants' planned infringements would irreparably harm Illumina's commercial reputation and its relationships with key opinion leaders,

while allowing Defendants to seed the market with their infringing products and use key opinion leaders to influence others in the field (both in the U.S. and abroad) to use Defendants' sequencers, reagents, and services instead of Illumina's patented products and services. *Id.* ¶¶ 53, 57, 59.

4. There Is A Substantial Risk That Illumina Would Lose Potential Market Share And Business Opportunities From Defendants' Planned Infringements

Because Illumina and Defendants are direct competitors, allowing Defendants to proceed with their planned infringing activities would likely cause Illumina to lose sales, business opportunities, and market share. *Id.* ¶¶ 59, 68. As explained above, Illumina has already lost market share to the Defendants in markets outside the U.S. due to their price undercutting. *Id.* ¶ 65. The U.S. is an especially important market for establishing and maintaining relationships with customers because it is the largest sequencing market in the world, and it is rapidly growing. *Id.* ¶¶ 28, 65. The harm to Illumina's market share and losses in business opportunities would be irreparable and particularly difficult to quantify at least because the losses would involve prospective customer relationships in a rapidly growing market. *Id*. ¶¶ 59, 76. Further, because sequencing customers tend to show significant loyalty to their initial supplier and are reluctant to change sequencing instruments once they become accustomed to them, it would be more difficult for Illumina to sell products to new or existing customers once Defendants have distributed infringing products to them, even if on a no-cost trial basis. *Id*. ¶¶ 32, 68-70.

Additionally, consumers often purchase sequencing products in bulk and at irregular versus predictable times, which signals irreparable versus reparable harm. *Id*. ¶¶ 32-33; *Celsis*, 665 F.3d at 930 (finding the relevant market was "particularly sensitive because customers buy in bulk and at irregular times, such that the loss of a single sale in this market may be more harmful than for products purchased daily.").

Moreover, Defendants' plan to use their infringing activities to develop collaborations and relationships with key opinion leaders increases the risk of irreparable harm to Illumina's business opportunities and market share. Key opinion leaders are an important revenue source for Illumina since they tend to be large customers that purchase instruments and substantial amounts of consumables and services for use in their academic work and research. *Id.* ¶¶ 31, 53, 67. Further,

key opinion leaders have sizable influence in market, so supplying Defendants' infringing systems to key opinion leaders (even on a "no-cost trial basis") would unfairly encourage these opinion leaders and others to use the infringing products and associated services instead of purchasing Illumina's technology. *Id.* ¶ 59. The goal of such placements is precisely to take market share from Illumina at a crucial time when the market is rapidly growing. *Id.* ¶¶ 28, 58-59.

5. There Is A Substantial Risk That Illumina Would Suffer Price Erosion From Defendants' Planned Infringements

Defendants' planned infringements would also likely cause price erosion. *Id.* ¶¶ 70-74. The Defendants have already caused Illumina to suffer price erosion in foreign markets such as China. *Id.* ¶¶ 71-72. Even if the Defendants' commercial launch is relatively unsuccessful, Defendants' mere presence in the market would likely cause price erosion. *Id.* ¶¶ 58, 74. Current and prospective customers often use Defendants' presence and cut-rate pricing to negotiate and attempt to extract price concessions from Illumina. *Id.* If MGI supplies sequencers or reagents to others at heavy discounts, then Illumina would likely have to offer substantial discounts or be faced with a loss of business and damage to its longstanding customer relationships. *Id.* ¶¶ 73-74. And once one customer receives a discount, then other customers will expect the same. *Id.* ¶ 58.

Any discounting that Illumina is forced to undertake in response to Defendants' planned infringements would likely be irreversible. *Id.* ¶ 73. This harm would be irreparable, at least because the impact on Illumina's customer relationships, customer goodwill, brand, and change in pricing structure cannot be easily quantified. *Id.* ¶ 70.

6. Defendants' Own Infringing Uses And Free Giveaways To Key Opinion Leaders Are Not "Incidental"

Defendants' own use of their infringing sequencers and sequencing reagents in their San Jose facility to promote them to potential customers or collaborate with key opinion leaders would be anything but incidental. It would create the same risk of harm to Illumina's business and reputation detailed above because (1) it is commercial activity undertaken to drive marketing and sales, and (2) key opinion leaders have immense influence in the market and are significant potential customers themselves. *Id.* ¶¶ 30, 54, 58. Consequently, Defendants should be enjoined from both distributing their infringing sequencers and sequencing reagents in the United States and using those

products in the United States themselves to collaborate with others or promote them to third parties such as key opinion leaders.

Similarly, Defendants' plan to provide certain of the accused products to KOLs on a "no-cost trial basis" does not negate the irreparable harm to Illumina. *Id.* ¶ 59. These infringements are anything but "incidental." *Id.* ¶¶ 53, 55. Placing instruments with key opinion leaders in the U.S. would seed the market with Defendants' products for commercialization. *Id.* ¶ 55. Even if Defendants' instruments were initially placed on a "no-cost trial basis," this would give them a key entry point into the U.S. market to allow them to embed themselves with Illumina's current and prospective customers, while taking KOL time and mindshare away from Illumina's products, as Defendants perform installs, troubleshooting, training, and services for these customers once their instruments are placed. *Id.*

Defendants' product give-away plan is not credibly for conducting research to develop new sequencers or reagents. *Id.* ¶ 61. It is the same commercial strategy that Defendants have used in other countries such as Germany to seed the market as part of their attempted commercial rollout in those countries. *Id.* Defendants do not need to do R&D on the accused chemistry in the U.S. (in part) because it is based on Illumina's already-proven technology, which Defendants have been offering in foreign markets since at least 2016. *Id.* Nor do Defendants need to distribute the DNBSEQ-G400 sequencer to U.S. KOLs to receive feedback on it or conduct research into its development because it is a mature product that MGI launched back in October 2017. *Id.* Defendants similarly have no need to distribute their instruments to key opinion leaders in the U.S. in order to perform research and development on CoolMPS because they have already done this elsewhere and published the results. *Id.* There is also no reason why Defendants cannot perform demonstrations or research to develop new products in China, where they claim to already have a 35% market share and operate a "test send out" service, or in a jurisdiction where Illumina does not have patents covering the technology. *Id.* ¶¶ 61-62.

C. The Balance Of Harms Favors A Preliminary Injunction

A court must consider the "harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the non-moving party will incur if the injunction is

granted." *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988). When considering such motions, courts favor the policy of preserving the status quo. *Cordis Corp. v. Medtronic, Inc.*, 780 F.2d 991, 994 (Fed. Cir. 1985) ("It is well settled that the purpose of an interlocutory injunction is to preserve the status quo."). Defendants cannot identify any cognizable hardship that would weigh against preserving the status quo by preliminarily enjoining further infringement. *See Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n. 12 (Fed. Cir. 1986) (granting an injunction because, in part, "requiring Bosch to compete against **its own patented invention**, with the resultant harms described above, places a substantial hardship on Bosch") (emphasis added).

D. The Public Interest Is Best Served By A Preliminary Injunction

It is well-established that "[i]n this case absent any other relevant concerns, … the public is best served by enforcing patents that are likely valid and infringed." *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006). Only "in rare instances" have courts "exercised their discretion to deny injunctive relief in order to protect the public interest." *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995). This is not a case that presents such a rare instance.

Defendants cannot demonstrate an important public need or any other "relevant concern" that outweighs the need to uphold and enforce Illumina's patent rights, and any evidence of even some general public benefit of allowing Defendant's infringing sequencers and reagents onto the market would be insufficient. *See Blackberry*, 2014 WL 1318689 at *13 ("[T]he mere fact that the allegedly infringing product may offer some benefit to consumers, without more, is not a critical public interest that precludes issuance of a preliminary injunction."). Especially here, where Illumina can meet the increased demand with its own sequencers and reagents, the public interest weighs in favor of an injunction. *See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 106 F. Supp. 2d 696, 707 (D.N.J. 2000).

VI. CONCLUSION

For the foregoing reasons, the Court should preliminarily enjoin the Defendants from further infringement of the '444, '973, and '025 Patents.

Dated: February 27, 2020

Respectfully submitted,

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