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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91194218
Party	Plaintiff Illumina, Inc.
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Submission	Reply in Support of Motion
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Date	07/23/2012
Attachments	20120723 ILLUMINA'S REPLY TO MERIDIAN'S OPPOSITION TO ILLUMINA'S MOTION FOR SUMMARY JUDGMENT.pdf (23 pages)(1785492 bytes)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Illumina, Inc.,	)	
	)	Opp. No. 91194218 (SN 77768176) (Parent)
Opposer/Petitioner,	)	
	)	Opp. No. 91194219 (SN 77775316)
v.	)	
	)	Can. No. 92053479 (RN 3887164)
Meridian Bioscience, Inc.,	)	
	)	Can. No. 92053482 (RN 3868081)
Applicant/Registrant.	)	

OPPOSER/PETITIONER'S REPLY TO APPLICANT/REGISTRANT'S OPPOSITION TO OPPOSER/PETITIONER'S MOTION FOR SUMMARY JUDGMENT

On May 29, 2012, Opposer/Petitioner, Illumina, Inc. ("Illumina"), through its undersigned attorneys, filed a motion for summary judgment against Applicant/Registrant, Meridian Bioscience, Inc. ("Meridian"), on the claims of likelihood of confusion made in the Notices of Opposition and Petitions to Cancel. On July 3, 2012, Meridian served its brief[1] in response to the motion for summary judgment. Pursuant to 37 CFR § 2.127(a) and without waiving the objections set forth in Section III. *infra*, Illumina hereby files its reply to Meridian's brief in response to the motion for summary judgment.

I. Facts

The parties have each provided a statement of facts. While Meridian asserts that there are genuine issues of material fact, it did not explicitly identify the material facts that are in dispute. *See* TMEP Section 528.01 ("The nonmoving party, in turn, should specify, in its brief in

opposition to the motion, the material facts that are in dispute."). Instead, Meridian makes vague assertions that there are genuine issues of material fact as they relate to the elements of a claim for likelihood of confusion. *See* Meridian's Memo in Opposition at p. 3.

II. Priority and Likelihood of Confusion

Meridian does not contest Illumina's standing in the oppositions or cancellations. While Meridian asserts that there is a dispute as to which party has priority, it fails to specify any material facts in dispute. Instead, it argues that, based on the undisputed facts, it has priority.

Although the four proceedings have been consolidated, each of the two oppositions as well as each of the two cancellations will still be decided on their own merits. Therefore, the issue of priority and confusion must be separately analyzed for each proceeding. *See, e.g., Tex. Dep't of Transp. v. Richard Tucker*, 95 USPQ2d 1241 (TTAB 2010).

With respect to the two oppositions, Illumina has, by making its registrations[2] of record with the filing of the Amended Notices of Opposition, conclusively established its priority. *See King Candy, Co. v. Eunice King's Kitchen, Inc.*, 182 USPQ 108 (CCPA 1974) (the issue of priority has been removed by virtue of the opposer's submission of status and title copies of its pleaded registrations.). Illumina also filed an intent-to-use application, Ser. No. 77747038, for the mark ILLUMINADX on May 28, 2009—prior to the filing of the opposed applications on June 25, 2009 (Ser. No. 77768176) and July 9, 2009 (Ser. No. 77775316). Either party may rely without further proof upon the filing date of its application as a "constructive use date" for

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[1] Illumina objects to Meridian's brief as exceeding the page limitation as discussed more fully in Section III *infra*.

purposes of priority pursuant to Section 7(c) of the Trademark Act[3]. *See Life Zone Inc. v. Middleman Group Inc.*, 87 USPQ2d 1953, 1960 (TTAB 2008). Lastly, Illumina has common law rights in the marks ILLUMICODE (August 2002) and ILLUMINOTES (April 2006) which were established prior to the filing of the two opposed applications in 2009. *See* Possemato Decl. at ¶¶ 5, 6. While Meridian argues that the use of the ILLUMICODE and ILLUMINOTES marks "appears" to be insufficient to "establish a family of marks", it does not dispute the dates of first use testified to by Illumina's witness which established Illumina's priority with respect to these marks. *See* Meridian's Memo in Opposition at pp. 6-7.

With respect to the cancellation proceedings, there are likewise no genuine issues of material fact. Meridian claims the November 17, 2008 filing date of the intent-to-use application that resulted in Registration No. 3868081 as its earliest priority date. *See* Meridian's Memo in Opposition at p. 4. Likewise, Meridian does not assert an earlier priority date than the April 1, 2009 filing of the intent-to-use application that resulted in Registration No. 3887164. To establish its priority, Illumina relies on its registrations of record for its ILLUMINA mark which issued and became incontestable prior to Meridian's earliest claimed priority date of November 17, 2008. *See Brewski Beer Co. v. Brewski Bros. Inc.*, 47 USPQ2d 1281, 1284 (TTAB 1998) ("Of course, petitioner or respondent may rely on its registration for the limited purpose of

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[2] Reg. Nos. 2632507, 2756703, and 2471539 for the mark ILLUMINA.

[3] An acceptable allegation of use (and a request to divide) was filed in connection with application Serial No. 77768176 resulting in the issuance of Reg. No. 4053668. Print-outs from the US PTO's TARR database and ASSIGN database satisfying the requirements of 37 C.F.R. § 2.122(d) for submitting a current status and title copy of the pleaded registration, Reg. No. 4053668, to make it of record, are submitted herewith as Exhibit A.

proving that its mark was in use as of the application filing date."). Also, it is not disputed that Illumina had acquired common law rights in the marks ILLUMICODE (August 2002) and ILLUMINOTES (April 2006) prior to Meridian's earliest priority date of November 17, 2008.

Rather than asserting that there are any material facts in dispute, Meridian first argues (without citing any support whatsoever for the proposition) that "the Board must determine which party has priority in relation to the *category of goods* in connection with which the parties' marks are used". Meridian's Memo in Opposition at p. 4 (emphasis added). There is no requirement that a party establish priority in the other party's category of goods. Such a requirement would eviscerate the concept of priority in all cases not involving identical goods.

Seemingly related to the first argument, Meridian next argues that because Illumina does not own a family of "ILLUMI-formative" marks, it cannot rely on "the seniority of its older registrations in order to defeat Meridian's priority". Meridian's Memo in Opposition at p. 5. For the straight-forward reasons expressed above, Illumina has established priority in both the oppositions and the cancellations. Nowhere in its brief does Illumina argue that it owns a family of marks or that it needed to "tack on" to its prior registrations. Therefore, even if Meridian's arguments relating to the absence of a "family" of marks and tacking were in theory relevant to the issue of priority in general, they are not relevant to these proceedings.

Meridian's last argument with respect to priority is that as of Meridian's priority dates, the "clinical diagnostic market" was not within Illumina's natural zone of expansion. First, Illumina notes that it has priority in the two oppositions with respect to clinical diagnostics

products by virtue of its ownership of Reg. No. 4053668 and, therefore, there is no need to apply the natural expansion doctrine in those cases. Second, the evidence of record establishes that clinical diagnostics was within Illumina's natural zone of expansion prior to the priority dates of Meridian's two registrations.

It has long been held that the protection accorded registered marks, even those that are not famous, includes a zone of natural expansion. *See Mason Eng'g & Designing Corp. v. Mateson Chem. Corp.*, 225 USPQ 956, 962 (TTAB 1985).

> Under the doctrine of natural expansion, the first user of a mark in connection with particular goods or services possesses superior rights in the mark not only as against subsequent users of the same or similar mark for the same or similar goods or services, but also as against subsequent users of the same or similar mark for any goods or services which purchasers might reasonably expect to emanate from it in the normal expansion of its business under the mark.
> *Id.* (citing *The May Dep't Stores Co. v. Prince*, 200 USPQ 803 (TTAB 1978)).
>
> Among the factors to be considered in determining whether an expansion, either actual or potential, is natural are: (1) whether the second area of business (that is, the subsequent user's area of business, into which the first user has or potentially may expand) is a distinct departure from the first area of business (of the prior user), thereby requiring a new technology or know-how, or whether it is merely an extension of the technology involved in the first area of business; (2) the nature and purpose of the goods or services in each area; (3) whether the channels of trade and classes of customers for the two areas of business are the same, so that the goodwill established by the prior user in its first area of business would carry over into the second area; and (4) whether other companies have expanded from one area to the other.
> *Mason Eng'g, supra* (citing *Central Soya Co., Inc. v. N. Am. Plant Breeders*, 212 USPQ 37 (TTAB 1981); and *Porta-Tool, Inc. v. DND Corp.*, 196 USPQ 643 (TTAB 1977).

With respect to the first factor, clinical diagnostics is not a distinct departure from Illumina's initial area of business—research and scientific use. As explained in the Declaration of Gregory

F. Heath, attached hereto as Exhibit B, Illumina is using the same technology and know-how that it developed for research and scientific use for clinical diagnostic applications. (Ex. B, Declaration of Gregory F. Heath, Senior Vice President of Illumina, Inc., ¶¶ 6-13; (April 10, 2012 Heath Declaration, ¶ 3). However, to expand from research and scientific use to clinical diagnostics, it was first necessary to conduct extensive trials in order to obtain FDA approval for clinical diagnostic applications. (Ex. B; ¶ 4). With respect to the second factor, the goods and services are used in the same manner and perform the same functions in both research and scientific applications and clinical diagnostic applications. (Ex. B; ¶ 7). The only difference is the use of the results generated by the products. In research and scientific applications, the results are typically used collectively to make general assessments about human diseases and conditions; whereas, in clinical diagnostic applications, the results are used for individual assessments of human diseases and conditions. With respect to the third factor, there is significant overlap in the channels of trade and classes of customers for both research and scientific applications and clinical diagnostic applications given that they are inextricably linked. (April 10, 2012 Heath Dec., ¶ 6). With respect to the last factor, several companies have expanded the use of their technology from research and scientific applications which do not require FDA approval to clinical diagnostic applications which do require FDA approval. Companies can profit from their technology in the scientific and research markets while waiting for the completion of the extensive tests required to enter the clinical diagnostics market. The evidence of record shows that numerous companies currently use their technology in products

sold in both fields. (April 10, 2012 Heath Dec.; ¶ 6). Illumina began the process of entering the clinical diagnostics market, and made numerous public announcements of its intention to do so, prior to the earliest priority date to which Meridian can point. Given the unavoidable time commitment to obtain the mandatory regulatory approval for the use of life sciences technology for clinical diagnostics applications, the evidence of record shows that Illumina expanded to clinical diagnostic applications in the natural and normal course for such expansions. Prior to the earliest priority date that Meridian can rely upon, Illumina was making concrete efforts to enter the clinical diagnostics market. Illumina had acquired technology that it intended to use for clinical diagnostic applications as early as April 2005. (Ex. B; ¶ 9). Illumina also went through the process of extensively testing its products using such technology in order to make the necessary showings to support its September 2009 application for FDA 510(k) market clearance of diagnostic products. (Ex. B; ¶ 9). In addition, Illumina created and obtained certification for a diagnostics services labratory to perform clinical diagnostic services in early 2009. (Ex. B; ¶ 8).

Meridian further argues that consumers of clinical diagnostics products "would have never even heard of Illumina at all because Illumina made no products for such personnel to use or purchase." (Patrick Dec.; ¶ 20). However, other than the personal experience of one of its employees described with minimal context, Meridian offers no evidence to support this statement. It is not in dispute that Illumina's scientific and research products are purchased by laboratories and hospitals just like Meridian's diagnostics products. (Patrick Dec.; ¶ 20). Meridian argues that the orders for such products come internally through different "sides" of

such institutions. However, the purchases are ultimately made by the same purchasing agents. With respect to the oppositions, Illumina's clinical diagnostic products are sold to exactly the same consumers as Meridian's clinical diagnostic products. (Compare Ex. B; ¶ 14 and Patrick Dec. ¶¶ 9-12). Therefore, the natural zone of expansion doctrine is not necessary to the finding of a likelihood of confusion in the oppositions. Illumina's ILLUMINA and ILLUMINADX marks are used in connection with the goods "clinical diagnostic reagents, reagent kits, and beads" for "clinical diagnostics purposes" set forth in Reg. No. 4053668 while Meridian's ILLUMIPRO and ILLUMIPRO-10 marks are sought to be registered in connection with "diagnostic machine, namely, a stand alone closed heater and turbidity meter to be used for the amplification and detection of a closed tube molecular assay". Clearly, both parties' marks are used in connection with goods used for diagnostic purposes. In addition, both parties advertise and promote their products through the same trade shows, press releases and trade magazines.

Meridian has submitted third party registrations[4] and pending applications (all of which are intent to use) for marks in the medical field beginning with the prefixes ILLUMI- and LUM- in an effort to show that the prefix is commonly used and therefore entitled to a narrow scope of protection. Absent evidence of actual use, third-party registrations have little probative value because they are not evidence that the marks are in use on a commercial scale or that the public has become familiar with them. *See Smith Bros. Mfg. Co. v. Stone Mfg. Co.*, 476 F.2d 1004, 177

[4] Illumina objects to the third party registrations on the grounds that they were not properly made of record pursuant to 37 C.F.R. § 2.122(d) as they do not show the current title to the registrations because no print-outs from the ASSIGN database were included.

USPQ 462, 463 (CCPA 1973) (the purchasing public is not aware of registrations reposing in the U.S. Patent and Trademark Office); and *Sports Auth. Mich., Inc. v. PC Auth. Inc.*, 63 USPQ2d 1782 (TTAB 2001). Of the third-party registrations, only six include wording having the prefix ILLUMI-. The remaining third party registrations and pending applications relate to prefixes that are not shared by any of the marks at issue in these proceedings and, consequently, lack probative value. Of those six, two appear to be owned by the same entity, IlluminOss Medical, Inc., and neither is used in connection with products marketed and sold in either the scientific and research or clinical diagnostics fields. Two other registrations of the six appear to be owned by the same entity, Cambridge Scientific Abstracts, and are used in connection with downloadable software for building and executing online searches of research databases. Because these registrations are not for goods in the same fields as the parties' goods and services in these proceedings, they lack probative value. Similarly, the mark set forth in Reg. No. 3608560 is not used in connection with goods marketed or sold in the scientific and research or clinical diagnostics fields. The last of the six registrations, Reg. No. 3734384, is not based on actual use but is instead an extension of protection of an international registration. Therefore, the evidence proffered by Meridian fails to show that the prefix ILLUM- is weak with respect to the parties' goods and services.

III. Objections

Illumina objects to Meridian's brief on the grounds that it does not comply with 37 C.F.R. Section 2.127(a) ("Neither the brief in support of a motion nor the brief in response to the motion shall exceed twenty-five pages in length in its entirety, <u>including</u> table of contents, index of

cases, description of the record, statement of the issues, recitation of the facts, argument, and summary.") (emphasis added). As explained in TBMP Section 502.02(b), "because 37 CFR § 2.127(a) does not require an index of cases and authorities or a table of contents, should a party elect to include these items, they will count as part of the page limit for the brief". *See also Mattel Inc. v. Brainy Baby Co.*, 101 USPQ2d 1140, 1141 (TTAB) (over-length reply brief included a table of contents and a table of authorities). In this case, Meridian's brief consists of thirty (30) pages. In addition to the twenty-five (25) numbered pages, there is a second page numbered "1" and four pages numbered "i" to "iv". Therefore, Meridian's brief and exhibits attached thereto should be given no consideration. *See Cooper Tech. Co. v. Denier Electric Co.*, 89 USPQ2d 1478 (TTAB 2008) (30 page and 27 page briefs not considered).

Illumina also objects to the Patrick Declaration proffered by Meridian to the extent that he makes statements about and/or characterizes Illumina, its products and services, and its customers, on the grounds that such statements lack foundation. *See, e.g.,* Patrick Dec. ¶¶ 13, 14, 16-21, 30. Likewise, Illumina objects to the Elagin Declaration to the extent that he makes statements about and/or characterizes Illumina and its products and services on the grounds that such statements also lack foundation.

Respectfully submitted,
ILLUMINA, INC.

Dated this 23th day of July 2012

By: _____
James R. Menker

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing "REPLY TO APPLICANT/REGISTRANT'S OPPOSITION TO OPPOSER/PETITIONER'S MOTION FOR SUMMARY JUDGMENT" was served on Applicant/Registrant's attorney, J. Michael Hurst of Keating Muething & Klekamp PLL, via first class mail to the address of record One East Fourth Street, Suite 1400, Cincinnati, OH 45202, today **July 23, 2012**.

By: _____
Laura K. Greer

EXHIBIT A

TO

Opposer/Petitioner's Reply to Applicant/Registrant's Opposition to Opposer/Petitioner's Motion for Summary Judgment

Thank you for your request. Here are the latest results from the TARR web server.

This page was generated by the TARR system on 2012-07-23 15:51:14 ET

Serial Number: 77982582 Assignment Information Trademark Document Retrieval

Registration Number: 4053668

Mark

ILLUMINADX

(words only): ILLUMINADX

Standard Character claim: Yes

Current Status: Registered. The registration date is used to determine when post-registration maintenance documents are due.

Date of Status: 2011-11-08

Filing Date: 2009-05-28

Transformed into a National Application: No

Registration Date: 2011-11-08

Register: Principal

Law Office Assigned: LAW OFFICE 102

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

Current Location: 650 -Publication And Issue Section

Date In Location: 2011-10-06

LAST APPLICANT(S)/OWNER(S) OF RECORD

1. Illumina, Inc.

Address:
Illumina, Inc.
5200 Illumina Way
San Diego, CA 92122
United States
Legal Entity Type: Corporation
State or Country of Incorporation: Delaware

GOODS AND/OR SERVICES

International Class: 005
Class Status: Active
Clinical diagnostic reagents, reagent kits, and beads with attached biomolecules, comprised primarily of oligonucleotides and other nucleic acids, natural and modified nucleotides, buffers, labels, and substrates, for clinical diagnostic purposes
Basis: 1(a)
First Use Date: 2010-03-19
First Use in Commerce Date: 2010-03-19

ADDITIONAL INFORMATION

Prior Registration Number(s):
2471539
2632507
2756703

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2012-03-08 - Applicant/Correspondence Changes (Non-Responsive) Entered

2012-03-08 - TEAS Change Of Owner Address Received

2011-11-08 - Registered - Principal Register

2011-10-07 - Notice Of Acceptance Of Statement Of Use E-Mailed

2011-10-06 - Law Office Registration Review Completed

2011-09-30 - Allowed for Registration - Principal Register (SOU accepted)

2011-09-20 - Notice Of Pseudo Mark Mailed

2011-09-19 - Statement Of Use Processing Complete

2011-09-16 - Use Amendment Filed

2011-09-19 - Divisional processing completed

2011-09-16 - Divisional request received

2011-09-16 - TEAS Request To Divide Received

2011-09-16 - TEAS Statement of Use Received

2011-08-16 - Notice Of Approval Of Extension Request E-Mailed

2011-08-15 - Extension 2 granted

2011-08-02 - Extension 2 filed

2011-08-15 - Case Assigned To Intent To Use Paralegal

2011-08-02 - TEAS Extension Received

2011-02-03 - Notice Of Approval Of Extension Request E-Mailed

2011-02-01 - Extension 1 granted

2011-02-01 - Extension 1 filed

2011-02-01 - TEAS Extension Received

2010-08-03 - NOA E-Mailed - SOU Required From Applicant

2010-06-08 - Official Gazette Publication Confirmation E-Mailed

2010-06-08 - Published for opposition

2010-04-30 - Law Office Publication Review Completed

2010-04-30 - Approved For Pub - Principal Register

2010-04-30 - Examiner's Amendment Entered

2010-04-30 - Notification Of Examiners Amendment E-Mailed

2010-04-30 - EXAMINERS AMENDMENT E-MAILED

2010-04-30 - Examiners Amendment - Written

2010-04-23 - Assigned To Examiner

2010-04-23 - Previous Allowance Count Withdrawn

2010-04-16 - Withdrawn From Pub - Og Review Query

2010-04-07 - Law Office Publication Review Completed

2010-04-07 - Assigned To LIE

2010-03-21 - Approved For Pub - Principal Register

2010-02-24 - Teas/Email Correspondence Entered

2010-02-23 - Communication received from applicant

2010-02-23 - TEAS Response to Office Action Received

2009-09-04 - Notification Of Non-Final Action E-Mailed

2009-09-04 - Non-final action e-mailed

2009-09-04 - Non-Final Action Written

2009-08-27 - Assigned To Examiner

2009-06-02 - Notice Of Pseudo Mark Mailed

2009-06-01 - New Application Office Supplied Data Entered In Tram

2009-06-01 - New Application Entered In Tram

ATTORNEY/CORRESPONDENT INFORMATION

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Fax Number: 858 876 1604

United States Patent and Trademark Office

Assignments on the Web > Trademark Query

No assignment has been recorded at the USPTO

For Serial Number: 77982582

If you have any comments or questions concerning the data displayed, contact PRD / Assignments at 571-272-3350. v.2.3.2
Web interface last modified: July 10, 2012 v.2.3.2

EXHIBIT B

TO

Opposer/Petitioner's Reply to Applicant/Registrant's Opposition
to Opposer/Petitioner's Motion for Summary Judgment

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Illumina, Inc.,	)	
	)	Opp. No. 91194218 (SN 77768176) (Parent)
Opposer/Petitioner,	)	
	)	Opp. No. 91194219 (SN 77775316)
v.	)	
	)	Can. No. 92053479 (RN 3887164)
Meridian Bioscience, Inc.,	)	
	)	Can. No. 92053482 (RN 3868081)
Applicant/Registrant.	)	

DECLARATION OF GREGORY F. HEATH IN SUPPORT OF OPPOSER/PETITIONER'S REPLY TO APPLICANT/REGISTRANT'S MEMORANDUM IN OPPOSITION TO OPPOSER/PETITIONER'S MOTION FOR SUMMARY JUDGMENT

I, Gregory F. Heath, Ph.D., declare as follows:

1. I refer to my declaration dated April 10, 2012, filed with Petitioner/Opposer's Motion for Summary Judgment (MSJ) and incorporate all statements herein by reference.

2. As stated in my declaration of April 10, 2012, I am a Senior Vice President of Illumina, Inc. ("Illumina") and, since March 2008, I have been the General Manager of Illumina's Diagnostics Business Unit. In my current role with the company, I am responsible for managing Illumina's emerging diagnostics business.

3. I have a B.S. in psychology from Illinois State University, an M.A. in experimental psychology from Hollins College, a Ph.D. in experimental psychology from Virginia Commonwealth University and I completed my post-doctoral work in behavioral pharmacology at Michigan State University. I have published more than 25 articles in science and business. I have more than 20 years of experience in the diagnostics field, including launching the first FDA-approved microarray for diagnostic use. I was previously employed at

Roche Molecular Systems where I held a number of senior executive positions including head of clinical genomics, senior vice president of global product marketing, senior vice president of global marketing and business development, and most recently, senior vice president of global business. In my last role at Roche Molecular Systems, I was responsible for new product development and global marketing activities for the infectious disease, blood screening, genetics and oncology portfolios. I was also responsible for the PCR (polymerase chain reaction) licensing, industrial business, and business development programs. From 2000 to 2003, I was head of business development and licensing for the diagnostics division of F. Hoffman La Roche in Basel and led the strategic planning, business development, and licensing activities of the molecular diagnostics, centralized diagnostics, applied science, near patient testing, and diabetes care business areas. Prior to this, I held numerous roles in marketing and business development with Roche Diagnostics' U.S. affiliate.

4. Due to my aforementioned experience, I am very familiar with the time and costs involved in obtaining market clearance by the U.S. Food and Drug Administration (FDA) for products used for human *in vitro* diagnostic use. It is typical for a life sciences company to spend up to five years or more of internal development prior to submitting a diagnostic product to FDA for market approval because prior to the submission to the FDA, there must be extensive clinical trials the results of which can take years to complete and compile into meaningful data. Depending upon the results of clinical trials and the satisfaction of other FDA requirements, FDA approval can typically take from 9 months to 2 years before a product (with no known similar product that has already been cleared by the FDA) is cleared for commercial market use.

5. As discussed in my declaration of April 10, 2012, it is common for a company to produce and sell goods for research use only (ROU) in addition and prior to selling diagnostic

products. See also, Exhibit 4 to MSJ. Unless a company begins by licensing or purchasing an approved technology from another company who has already conducted years of research on said technology, it is a natural progression to start using a technology for research, developing and refining said technology, and then eventually putting said technology into use in a commercial setting for the benefit of humans.

6. In April 2005, Illumina acquired the VeraCode technology through its acquisition of CyVera Corporation with the intention of using the technology in products for the molecular diagnostics market.

7. Since at least as early as March 2008 when I joined the company, Illumina has been promoting its intention to enter the molecular diagnostics to its customers which include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations and biotechnology companies.

8. During the first half of 2009, Illumina completed its diagnostics services lab and received CLIA certification. Illumina's diagnostic services lab offers individual genome sequencing services for diagnostic purposes. This achievement was heavily promoted by Illumina to its customers, to the molecular diagnostics industry and to the general public.

9. In September 2009, Illumina formally submitted its BeadXpress system and VeraCode® Genotyping Test to the FDA for 510(k) market clearance.

10. On May 4, 2010, the FDA granted 510(k) market clearance for Illumina's BeadXpress system for multiplex genetic analysis. According to the FDA's indications of use, the BeadXpress system is an in-vitro diagnostic device intended for the simultaneous detection of multiple analytes in a DNA sample utilizing Illumina's VeraCode® holographic microbead technology.

11. On May 18, 2010, the FDA granted separate 510(k) market clearance for Illumina's VeraCode® Genotyping Test for Factor V (Leiden) and Factor II (Prothrombin).

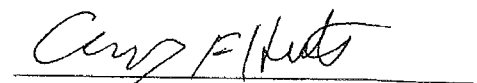
12. Illumina is currently seeking 510(k) market clearance for its iScan array reader for diagnostic applications. This information has been disseminated to Illumina's customers, to the molecular diagnostics industry and to the general public.

13. At least as early as August 2011, Illumina announced that it expects to submit its MiSeq platform to FDA for 510(k) market clearance approval for diagnostic applications before the end of 2012. This information has been disseminated to Illumina's customers, to the molecular diagnostics industry and to the general public

14. I am familiar with Illumina's customers and potential customers for molecular diagnostic tests, systems and services as well as how those customers order such products and services. The customers for our molecular diagnostic products and services typically include physicians, medical geneticists, hospital administrators, genetic counselors, lab directors and lab technicians but also include others interested in cancer, genetics, infectious diseases and transplantations. Our molecular diagnostic tests, systems and services can be ordered by our customers through all standard channels, including via direct telephone, via our web site, via email, at trade shows and through sales representatives, and internationally through distributors.

I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 19 day of July 2012



Gregory F. Heath, Ph.D.