

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

BECTON, DICKINSON AND COMPANY
and CELLULAR RESEARCH, INC.

Plaintiffs,

v.

10X GENOMICS, INC.

Defendant.

C.A. No. 18-1800-RGA

**DEFENDANT 10X GENOMICS'S REPLY BRIEF IN SUPPORT OF ITS MOTION
TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6)**

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BD is asserting *more than 180 claims* from the Fodor patents and ironically points to that impractically large number as a defense to ineligibility. However, BD fails to identify any improvement that any Fodor claim is “directed to” other than the use of different (or “diverse”) labels to label different molecules in order to count them. Because more easily distinguishing between similar objects is a well-understood benefit that humans have realized from using different labels to label different objects for centuries, the Fodor claims are directed to an ineligible abstract idea. Because BD also fails to identify any non-conventional elements of the claims other than this abstract idea itself, the claims also do not include “significantly more” than the abstract idea. BD has thus failed to rebut 10X’s showing that 358 patent claim 6 is both ineligible and representative, including that the independent claims of the Fodor patents (and various dependent claims) are all substantially similar and linked to the same abstract idea. Nor should a relaxed standard of eligibility apply to non-computer patents, as BD suggests. There is no dispute that claims to using conventional computer programming techniques to associate different file name labels with different data files to better organize, count, or analyze those files would not be patent eligible. The Fodor patents’ use of conventional lab techniques to achieve the same goals is no more eligible.

ARGUMENT

A. BD Fails To Identify Any Improvement That The Claims Are Directed To Other Than The Abstract Idea Of Labeling Different Objects With Different Labels.

Although BD argues that the Fodor claims are directed to “a specific improvement for quantitating and detecting target molecules” (D.I. 21 “Opp.” at 7-9), BD fails to identify any improvement other than the use of different (what BD calls “diverse”) labels to label (and count) the different instances of the target molecules. This is the same “improvement” humans have recognized from the application of this same abstract idea in contexts other than DNA for centuries: when trying to distinguish between multiple instances of similar objects (*e.g.*, to count them) it is helpful to label each instance with a different label. D.I. 19 (“Br.”) at 4-5 (describing

long-practiced applications of this idea, such as by giving different serial numbers to different units of the same television model). BD's Opp. fails to refute that the Fodor claims are directed to the ineligible abstract idea of labeling different objects with different labels under *Mayo* step 1.

1. BD Incorrectly Suggests That A More Relaxed Standard For Patent Eligibility Applies To Claims That Do Not Involve A Computer.

BD's assertion that § 101 eligibility caselaw developed in the context of computer-implemented inventions is "inapplicable" to the Fodor claims (Opp. at 1) and BD's suggestion that a more relaxed standard of patent eligibility applies to non-computerized claims (*id.* at 1, 5-6, 9, 11-12, 19), are not supported by even a single citation to any case adopting those views. To the contrary, § 101 eligibility law applies to the Fodor patents and requires finding them ineligible.

Neither *Bilski* nor *Mayo* involved computerized inventions. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Bilski v. Kappos*, 561 U.S. 593 (2010). And although *Alice* did involve computer-implemented inventions, *Alice* repeated *Bilski* (and *Flook*'s) bright-line rule that "the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 222-23 (2014). Tellingly, *Alice* did not limit this rule to "a particular computerized implementation"—rather, it broadly prohibits attempts to claim abstract ideas by limiting the idea to *any* particular technology. That courts have repeatedly found labeling, analyzing, and otherwise organizing information to be an abstract idea (Br. at 10-11) in the context of computers does not mean that the idea of labeling information is any less abstract when applied, as here, to the context of counting DNA molecules.

BD's assertion that DNA-related claims have rarely been challenged or invalidated under § 101 is also incorrect. *See* Opp. at 5-6. Courts have repeatedly found DNA-related claims ineligible, including claims directly analogous to the asserted Fodor claims. *Ariosa* and *Mayo* found ineligible DNA-related claims that, like the Fodor claims, merely added conventional lab

techniques to ineligible subject matter. Br. at 16-17. They are far from the only cases to do so.

In *Roche Molecular Systems, Inc. v. Cepheid*, claims to a specific improved process for detecting tuberculosis that included attaching man-made short nucleic acid sequences (primers) to sample DNA, amplifying the (newly created) primer-DNA molecules via PCR, and analyzing the result were found to be directed to ineligible subject matter and invalidated. 905 F.3d 1363, 1366-67, 1369-71 (Fed. Cir. 2018). Claims to the specific man-made primers were similarly invalidated. *Id.* at 1369; *see also In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 761 (Fed. Cir. 2014) (“Primers . . . are patent ineligible”). The Federal Circuit has repeatedly found claims ineligible where, like the claims in *Roche* and the Fodor claims here, they include steps of attaching man-made nucleic acid sequences to sample DNA molecules, amplifying the combined molecules, and detecting or analyzing the result. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 752 (Fed. Cir. 2019) (invalidating claims to an improved method for detecting antibodies related to a neurological disorder); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1374-76 (Fed. Cir. 2016) (invalidating claims to “a method of detecting a coding region of a person’s genome by amplifying and analyzing a linked non-coding region”).

District courts have similarly applied *Alice*, *Mayo*, and *Ariosa* to find DNA-related claims ineligible. *See, e.g., XY, LLC v. Trans Ova Genetics, LC*, 333 F. Supp. 3d 1097, 1100-05 (D. Colo. 2018) (claims to a specific improved flow cytometry method for sorting semen for use in ensuring the gender of artificially inseminated offspring found abstract); *23andMe, Inc. v. Ancestry.com DNA, LLC*, 356 F. Supp. 3d 889, 897-907 (N.D. Cal. 2018) (claims to determining a relative relationship by comparing similarities between DNA found ineligible). Even BD admits that “life-sciences-related inventions” are ineligible if the claims are directed to steps “such as collecting and analyzing data or comparing two data sets . . .” Opp. at 5.

2. BD’s Own Characterizations Of The Fodor Claims Confirm That They Are “Directed To” The Abstract Idea Of Using Different Labels.

BD admits that the “Fodor patents are directed to quantitating the number of biomolecules in a sample.” Opp. at 2, 7-9. Beneath that overly scientific language, BD’s Opp. admits (and the specification confirms) that the patents are directed to a more simple-sounding problem: how to count the instances of a particular nucleic acid molecule present in a sample (*e.g.*, how to count the number of copies of a particular DNA or mRNA sequence). Opp. at 2; 358 patent at 1:19-4:2.

The improved counting method of the Fodor patents purporting to solve this problem starts with (1) a mixture of target nucleic acid molecules (*e.g.*, the sample, like a collection of mRNA molecules from a sample cell), then (2) attaches different labels (different nucleic acid “label tags”) to the target nucleic acid molecules, (3) amplifies the (now labeled) target nucleic acid molecules, and then (4) detects the amplified product (*e.g.*, to count the number of different label tags as a proxy for counting the number of target mRNA molecules that were present in the cell). *See* Opp. at 2-3; Br. at 5-10. The process thus starts with something naturally occurring (a sample of nucleic acid molecules), applies (via conventional lab techniques) the abstract idea of labeling each molecule of interest with a different label, and ends with abstract information about the sample (the number or count of the target molecules present in the naturally occurring sample).

However, the *only* purported improvement in this process described in the claims, specification, or in BD’s Opp., is the idea of attaching *different* labels to each of the instances of the target molecule (as opposed to the prior art attaching of copies of the same label to the target molecules, amplifying those labeled molecules, and then sequencing or otherwise detecting the result). Br. at 8-10, 12-17; *see, e.g.*, 358 patent at 2:15-34. Neither the Fodor patents nor BD’s Opp. identify any improved attaching, amplification, or detection techniques beyond the idea of using *different* labels. *See Section B* below.

Because this idea of using different labels to label the different molecules is the focus of the claimed advance over the prior art (as the specification and file history make clear, *see* Br. at

8-10, and as BD's Opp. confirms), this idea is also what the Fodor claims are "directed to" under Mayo step 1. *Affinity Labs of Texas, LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1257 (Fed. Cir. 2016) (step 1 "calls upon us to look at *the focus of the claimed advance over the prior art* to determine if the claim's character as a whole is directed to excluded subject matter")¹; *Genetic Techs.*, 818 at 1375 (similar). Attempting to limit the application of this idea to the technological environment of DNA does not render the claims eligible. *Alice*, 573 U.S. at 222 ("the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment."); *Parker v. Flook*, 437 U.S. 584, 593 (1978) (patent eligibility does not turn "on the draftsman's art."); *see also*, *Cleveland Clinic Found. v. True Health Diagnostics LLC*, No. 2018-1218, 2019 WL 1452697, at *4 (Fed. Cir. Apr. 1, 2019) (finding claims patentee redrafted after an earlier § 101 rejection still "only recite applying known methods to detect MPO levels" and were still "directed to" an ineligible natural law).

Although BD relies on the claims upheld in *Pac Biosciences* and *CellzDirect*, those cases involved claims to specific new lab techniques that were contrary to prior art teachings, something BD has not identified here. *Pac. Biosciences of Cal., Inc. v. Oxford Nanopore Techs., Inc.*, No. 17-1353-LPS, 2018 WL 1419082 (D. Del. Mar. 22, 2018) (upholding claims to a specific method for sequencing both strands of double-stranded DNA and comparing the results to check for errors, contrary to prior art teachings that it was only necessary to sequence one strand or the other); *Rapid Litig. Mgmt. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016) (upholding claims to method for preparing cells that subjected the cells to multiple freeze/thaw cycles contrary to prior art teachings to avoid multiple freeze/thaw cycles); *see also Roche*, 905 F.3d at 1373 (distinguishing *CellzDirect*, because the claims invalidated in *Roche* employed "only conventional, well-known laboratory techniques" which are "the opposite of those at issue in *CellzDirect*" because the *CellzDirect*

¹ Emphasis is supplied, and internal citations and quotations are omitted unless otherwise noted.

inventors claimed “freezing and thawing hepatocytes twice even though the prior art taught away from this process.”). Where, as here, the only improvements are within “the realm of abstract ideas” rather than “innovation in the non-abstract application,” the claims are ineligible. *SAP Am., Inc. v. Investpic, LLC*, 898 F.3d 1161, 1163-71 (Fed. Cir. 2018) (affirming finding of ineligibility).

3. BD’s Reliance On The Labeled Molecules And Amplified Molecules As “New” Or “Transformed” Molecules Under The Machine-Or-Transformation Test Is Contrary To Federal Circuit Precedent.

BD’s assertions that by attaching different labels to the target nucleic acid molecules of interest (via conventional attaching techniques) the claims “entail the physical transformation of tangible matter” and that by amplifying the labeled molecules (via conventional amplification techniques) the claims create “new, tangible matter” are similarly insufficient to save the claims. Opp. at 1, 6-7, 12-13. As this Court has recognized, after *Bilski*, the machine-or-transformation test is “not determinative” and the *Alice/Mayo* two step framework now controls the eligibility analysis. See *Messaging Gateway Sols., LLC v. Amdocs, Inc.*, No. 14-732-RGA, 2015 WL 1744343, at *2 (D. Del. Apr. 15, 2015). More importantly, the Federal Circuit has repeatedly held that merely adding man-made tags to a nucleic acid molecule and applying conventional techniques to amplify the tagged molecule are insufficient to render a claim eligible. *Roche*, 905 F.3d at 1366-71 (rejecting claims to processes that included adding primer nucleic acid tags to DNA molecules and amplifying the resulting molecules; and expressly rejecting patentee’s argument that “at *Alice/Mayo* step one, the primer claims [] are patent-eligible because they are directed to artificial, man-made primers that are different from naturally occurring DNA”); *Athena*, 915 F.3d at 752 (also invalidating process claims including the steps of attaching primer tags to DNA molecules and then amplifying the combined primer-DNA molecules); *Genetic Techs. Ltd.*, 818 F.3d at 1374-76 (same). The Supreme Court rejected an analogous argument in *Myriad. Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 593 (2013) (“Nor are Myriad’s

claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule.”).

As the *Athena* court explained, “the use of a man-made molecule is not decisive” where it amounts only to a routine step in applying the ineligible subject matter (in *Athena*, a natural law; in the Fodor claims, the abstract idea of using different labels). *Athena*, 915 F.3d at 752. The Fodor claims likewise attach labels and amplify the labeled molecules using only generic techniques in order to implement the abstract idea of using different labels to label and count the target molecules. These generic pre- and post-solution activities are insufficient to save the claims. *Bilski*, 561 U.S. at 610 (“*Flook* rejected the notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process.”).

B. BD Fails To Identify Any Inventive, Non-Conventional Elements Of The Claims Other Than The Abstract Idea Itself.

BD asserts that “[t]he specification makes clear that *none of* the claimed steps . . . were routine or conventional in the prior art.” Opp. at 1-2. But BD concedes that attaching labels, amplifying, detecting, and sequencing were all conventional at the time of the Fodor patents. Opp. at 14. BD asserts only that it was not conventional to perform these conventional steps *using “diverse” or different labels*. Opp. at 14-17. However, this is merely a statement of the abstract idea itself and so cannot transform the claims into “significantly more” than the abstract idea under step 2. *See Genetic Techs.*, 818 F.3d at 1379-80 (explaining that “the novelty of looking to non-coding DNA to detect a coding region allele of interest resides in the novelty of the newly discovered natural law . . . and adds little more than a restatement of the natural law itself”).

BD’s argument that “Attaching Diverse Label[]-Tags to Distinct Targets Was Not Conventional” focuses entirely on the use of (and purported benefits from using) “diverse” (that is, different) labels to label each of the instances of the target molecules. Opp. at 14-15. Neither BD’s Opp. nor the Fodor patents identify (let alone claim) *any* new, non-conventional attachment

techniques that were required to attach “diverse” (*i.e.* different) labels. To the contrary, the specification admits that “in one embodiment” of the invention “the label-tag is attached by ligation” and that “methods of ligation will be known to those of skill in the art.” Br. at 13.

BD’s arguments that “Amplifying Diverse Label-Tag-Targets” and “Detecting Diversely-Labeled Amplicons” were not conventional are flawed for the same reasons. Opp. at 15-16. Again, BD’s distinctions and purported benefits all relate solely to the abstract idea of using “diverse” labels, and BD fails to identify any new amplification or detection techniques necessary for amplifying or detecting diversely-labeled molecules. And again the specification admits that the invention merely uses conventional amplification and detection techniques. Br. at 13-14. Indeed, amplification using PCR is specifically claimed (*e.g.*, 358 patent claim 75) and PCR was indisputably routine at the time of the Fodor patents. *Id.*, *see also*, *Genetic Techs.*, 818 F.3d at 1377 (finding that PCR amplification and analyzing amplified DNA were conventional as of 1989.)

BD does not even dispute the specification’s admission that the ordered combination of steps claimed—apart from the abstract idea of using diverse or different labels—was routine and conventional (namely, attaching a nucleic acid label tag to a target nucleic acid molecule, amplifying the label-tag-target, and detecting and sequencing the amplified product). Br. at 13; 358 patent at 2:15-34. BD’s failure to identify any claimed elements other than the abstract idea that it contends were non-conventional renders the *Natera* case cited by BD inapposite. Opp. at 15. In *Natera*, the court found “the factual record is not sufficient” to conclude whether certain limitations were conventional. *Illumina, Inc. v. Natera, Inc.*, No. 18-1662-SI, 2018 WL 3126383, at *4 (N.D. Cal. June 26, 2018). Here, the specification admits (and BD does not dispute) that all of the limitations (other than the abstract idea itself) were conventional. Br. at 12-17.

C. BD’s Assertion Of More Than 180 Claims Only Increases Preemption Concerns And BD Fails To Rebut 10X’s Representativeness Showing.

10X’s Opening Brief addressed the ineligibility of 358 patent claim 6; explained why the

independent claims of the other Fodor patents were substantially similar and linked to the same abstract idea of using different labels to label different molecules under step 1 (Br. at 5-8); and explained why each of the independent claims of the other Fodor patents (like 358 claim 6) and various dependent claims failed to add anything other than conventional lab techniques (Br. at 12-17). BD's decision to address only 358 claim 6 in the substantive portion of its opposition (Opp. at 4-17) thus waives any dispute that claim 6 is representative of at least all of the Fodor independent claims as well as the dependent claims whose limitations were addressed in 10X's opening brief. *See IPA Techs., Inc. v. Amazon.com, Inc.*, 352 F. Supp. 3d 335, 344 (D. Del. 2019).

Instead of disputing the similarities between claim 6 and the other independent Fodor claims that 10X addressed in its Opening Brief, BD's Opp. points to the sheer numerosity of its "**180+ other asserted claims**" to rebut representativeness. BD fails to actually identify and differentiate any particular claims as not represented by 358 claim 6. *See* Opp. at 18-19. BD merely presents a bulleted list of 5 "for example" categories of limitations that it asserts are not in 358 claim 6, but does not even identify how many of its more than 180 asserted claims include any of these categories, let alone why or how these categories alter the § 101 inquiry. That BD has asserted more than 180 different articulations of the same underlying abstract idea also only heightens the concern that the patents seek to preempt the abstract idea. *See CellzDirect*, 827 F.3d at 1052 ("while pre-emption is not the test for determining patent-eligibility, it is certainly the concern that undergirds . . . § 101 jurisprudence.") (citing *Ariosa* and *Alice*).

Nor should the Court allow the assertion of 180+ claims to shield the Fodor patents from the eligibility analysis. Courts routinely find even large numbers of claims ineligible based on analysis of representative claims. *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, 776 F.3d 1343, 1345, 1348 (Fed. Cir. 2014) (finding 242 claims ineligible based on 2 representative claims even where patentee challenged representativeness on appeal); *Alice*, 573

U.S. at 213, 225-27 (finding 245 claims from 4 patents ineligible based on 1 representative claim); *IPA Techs.*, 352 F. Supp. 3d at 338-46 (finding ineligible 177 claims from 3 patents based on 3 representative claims despite patentee disputing representativeness). If the Court disagrees that 358 claim 6 is representative, the Court should direct BD to identify which of its 180+ asserted claims it contends are representative for purposes of eligibility so that the parties can address them. *See, e.g., Triplay, Inc. v. WhatsApp, Inc.*, No. 13-1703-LPS, D.I. 82 (D. Del. Aug. 25, 2015) (ordering plaintiff to propose and meet and confer about representative claims for § 101 motion).

BD also fails to identify any factual disputes precluding resolution at the motion to dismiss stage. BD asserts this Motion cannot be resolved “without expert testimony and extrinsic evidence regarding, *e.g.*, the ‘background science’ and ‘technical terms’” (Opp. at 19), but BD fails to identify what science or terms it believes require additional evidence (let alone how this would impact the § 101 analysis). BD’s Opp. also confirms that the only claim element BD asserts to be non-conventional is the use of “diverse” (*i.e.*, different) labels to label the target molecules and that the other claim limitations (at least as to the use of non-diverse labels) are admitted by the specification to be conventional. *See* Opp. at 14-16, 20; Br. at 12-17. Because the use of different labels is the abstract idea itself, this is not a basis to delay resolution of 10X’s Motion.

D. BD Concedes Counts Not Supported By Factual Pleadings Should Be Dismissed.

BD does not dispute that counts 4 and 8-12 (D.I. 15) allege that the “Accused Products” (including Single Cell 5’ and Spatial Transcriptomics Products) infringe the Fodor 809 patent and the 4 Fan Patents. Opp. at 1, n.1; Br. at 20. Nor does BD dispute that it pleads zero support that the Single Cell 5’ Products infringe the 809 patent or that the Spatial Transcriptomics Products infringe the 4 Fan patents. *Id.* These counts should be dismissed as to these products. Br. at 20.

CONCLUSION

For the above reasons and the reasons given in D.I. 19, 10X’s Motion should be granted.

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