Patent Eligibility: Overcoming Early Litigation Challenges

A Practical Guidance® Practice Note by Michael Furrow, Kilpatrick Townsend & Stockton LLP

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Introduction

This practice note considers strategies that you as the patentee may utilize when facing patent eligibility challenges early in litigation. Although much of the content is generalizable, special attention is given to inventions in the life sciences. In recent years, Section 101 challenges in the life sciences arena focus on claims directed to methods or tools that involve measurement of biological species (diagnostic methods and tools),, compositions of matter based on naturally occurring materials, or methods of treatment using compositions that are asserted to be naturally occurring.

Section 101 of the Patent Act provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. The Supreme Court has held that this section contains an important implicit exception for laws of nature, natural phenomena, and abstract ideas. Alice Corp. Pty. Ltd., v. CLS Bank Int'l, 573 U.S. 216 (2014) (citations omitted); Mayo Collaborative Servs., v. Prometheus Labs., Inc., 566 U.S. 66, 70 (2012) (citations omitted).

The Federal Circuit has expressed that patent eligibility is a threshold issue of law that may be amenable to resolution through an early dispositive motion, thereby minimizing unnecessary burdens on the parties and the court. See, e.g., Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 95 F.3d 743, 749 (Fed. Cir. 2020); SAP America, Inc. v. InvestPic, LLC, 898 F.3d 1161, 1166 (Fed. Cir. 2018); Aries Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1373–75 (Fed. Cir. 2015); Ultramercial, Inc., v. Hulu, LLC, 772 F.3d 709, 717–19 (Fed. Cir. 2014.

Two-Step Alice Framework

Following the Supreme Court's decision in *Alice Corp*., there was a significant increase in the number of patents challenged under Section 101. In resolving such disputes, courts follow a two-step framework to "distinguish[ ] patents that claim laws of nature, natural phenomena, and abstract ideas from those claiming patent-eligible applications of those concepts." Alice Corp. Pty. Ltd., 573 U.S. at 217–218 (citing Mayo, 566 U.S. at 77–80). At step one, courts must determine "whether the claims are *directed to* one of those patent-ineligible concepts." Id. (emphasis added).

It is not enough to "merely identify a patent-ineligible concept underlying the claim." Roche Molecular Sys., Inc. v. Cepheid, 905 F.3d 1363, 1368 (Fed. Cir. 2018). If the patent-ineligible concept is integrated into a practical application that imposes a meaningful limitation on the patent-ineligible concept, the claims can still be patent-eligible. See e.g. Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd., 887 F.3d 1117, 1135 (Fed. Cir. 2018) (holding that claims directed to a method of using iloperidone to treat schizophrenia are patent-eligible, because "[t]he inventors recognized the relationships between iloperidone, CYP2D6 metabolism, and QTc prolongation, but that is not what they claimed. They claimed an application of that relationship"); Endo Pharms. Inc. v. Teva Pharms. USA, Inc., 919 F.3d 1347, 1354-55 (Fed. Cir. 2019) (holding that claims directed to a method of treating pain

that involve the relationship with between oxymorphone and patients with renal impairment are patent eligible "because they are 'directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome" and "are thus directed to more than just reciting the natural relationship").

But if the claims as a whole are directed to a patent-ineligible concept, courts then proceed to step two: consideration of the elements of each claim both individually and "as an ordered combination" to determine whether additional elements transform the patent ineligible concept into a patent-eligible invention. Vanda Pharm., 887 F.3d at 1135. This second step is equated with "a search for an 'inventive concept' – i.e., an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." Id. (citing Mayo, 566 U.S. at 72–73).

Practical Considerations for Preparing for and Responding to a Motion to Dismiss

FRCP 12(b)(6), 12(c), and 56 Standards

Federal Rule of Civil Procedure (FRCP) 12(b)(6) governs a motion to dismiss a complaint for failure to state a claim upon which relief can be granted. The purpose of such a motion is to test the sufficiency of the complaint, not to resolve disputed facts or decide the merits of the case. See, e.g., Swierkiewicz v. Sorema N. A., 534 U.S. 506, 511 (2002); Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 563 n.8 (2007). A motion to dismiss may be granted if, after accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to the plaintiff, the plaintiff is not entitled to relief. See, e.g., In re Loestrin 24 Fe Antitrust Litigation, 814 F.3d 538, 549 (1st Cir. 2016); Maio v. Aetna, Inc., 221 F.3d 472, 481–82 (3d Cir. 2000); Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n, 776 F.3d 1343, 1349 (Fed. Cir. 2014).

Rule 12(c) of the FRCP permits a party to dismiss a suit "[a]fter the pleadings are closed . . . but early enough not to delay trial." Fed. R. Civ. P. 12(c). A Rule 12(c) motion for judgment on the pleadings is "functionally identical" to a Rule 12(b)(6) motion to dismiss for failure to state a claim. See, e.g., SAP America, Inc. v. InvestPic, LLC, 898 F.3d 1161, 1166 (Fed. Cir. 2018); Cave Consulting Grp., Inc. v. Truven Health Analytics, Inc., No. 15-cv-02177-SI, 2016 U.S. Dist. LEXIS 8395 (N.D. Cal. Jan. 25, 2016) (citing Dworkin v. Hustler Magazine, Inc., 867 F.2d 1188, 1192 (9th Cir. 1989)); Affinity Labs of Texas, LLC v. Amazon.Com, Inc., No. 15-cv-29, 2015 U.S. Dist. LEXIS 77411 (W.D. Tx. June 12, 2015) (citing Doe v. MySpace, Inc., 528 F.3d 413, 418 (5th Cir. 2008)). Courts must accept all factual allegations in the complaint as true and construe them in the light most favorable to the non-moving party. See, e.g., Allergan, Inc. v. Athena Cosmetics, Inc., 640 F.3d 1377, 1380 (Fed. Cir. 2011); Johnson v. Rowley, 569 F.3d 40, 43–44 (2d Cir. 2009). The motion may be granted if the moving party establishes that no material issue of fact remains to be resolved, and the party is entitled to judgment as a matter of law. See, e.g., Mele v. Fed. Reserve Bank of N.Y., 359 F.3d 251, 253 (3d Cir. 2004); Colony Ins. Co. v. Burke, 698 F.3d 1222, 1228 (10th Cir. 2012).

Although the focus of this practice note is on eligibility challenges by motion under Rule 12(b)(6) or (c), Rule 12(d) states that "[i]f, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment." Summary judgment is appropriate if the evidence shows that there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); Celotex Corp., v. Catrett, 477 U.S. 317, 322 (1986). In determining whether a genuine dispute as to a material fact exists, the courts must view the evidence in the light most favorable to the non-moving party and draw all justifiable inferences in its favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Nonetheless, the party opposing summary judgment may not rely on mere conclusory allegations nor speculation, but instead must offer evidence in support of its factual assertions. See, e.g., D'Amico v. City of New York, 132 F.3d 145, 149 (2d Cir.1998); Thornhill Publ'g Co., Inc. v. GTE Corp., 594 F.2d 730, 738 (9th Cir.1979).

The Federal Circuit resolves motions to dismiss and summary judgment motions applying the procedural standards of the regional circuit of the district court from which the motion is appealed. See, e.g., Endo Pharms., 919 F.3d at 1352; XY, LLC. v. Trans Ova Genetics, LC., 968 F.3d 1323, 1329 (Fed. Cir. 2020); Illumina, Inc. v. Ariosa Diagnostics, Inc., 967 F.3d 1319, 1324 (Fed. Cir. 2020).

Claim Construction Obligations?

If there are claim construction disputes at the Rule 12(b)(6) stage, the court may proceed by adopting the non-moving party's constructions, BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC, 827 F.3d 1341, 1352 (Fed. Cir. 2016); Content Extraction & Transmission LLC v. Wells Fargo

Bank, Nat'l Ass'n, 776 F.3d 1343, 1349 (Fed. Cir. 2014), or by resolving those disputes material to the § 101 analysis, which may well be less than a full, formal claim construction, Genetic Techs. Ltd. v. Merial LLC, 818 F.3d 1369, 1373 (Fed. Cir. 2016); Aatrix Software, Inc. v. Green Shades Software, Inc., 882 F.3d 1121, 1125 (Fed. Cir. 2018).

Burden of Proof on Ineligibility?

The Federal Circuit has held that the level of proof required to succeed on a Section 101 challenge is the clear-and-convincing-invalidity standard of 35 U.S.C. § 252. Berkheimer v. HP Inc., 881 F.3d 1360, 1368 (Fed. Cir. 2018) ("The question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact. Any fact, such as this one, that is pertinent to the invalidity conclusion must be proven by clear and convincing evidence."). That said, because in early eligibility challenges all facts alleged by the patentee are taken as true, and disposition is an issue of law, many courts believe it makes little sense to consider an evidentiary standard. See, e.g., Mimedx Group, Inc., v. Nutech Med., Inc., No. 15-cv-369, 2015 U.S. Dist. LEXIS 158867 (N.D. Ala. Nov. 24, 2015); Esoterix Genetic Labs., v. Qiagen Inc., 133 F.Supp.3d 349 (D. Mass. 2015); Exergen Corp., v. Brooklands Inc., 125 F.Supp.3d 312 (D. Mass. 2015); see also Microsoft Corp., 131 S.Ct. at 2253 (clear and convincing standard applies only to questions of fact) (Breyer, J., concurring).

Practical Considerations for Preparing for and Responding to a Motion to Dismiss

Draft the Complaint with Eligibility in Mind

In evaluating the sufficiency of a complaint, generally (with limited exceptions, discussed below), courts may consider the complaint, documents attached to the complaint, and documents referenced by the complaint. See, e.g., OIP Techs., Inc. v. Amazon.com, Inc., 788 F.3d 1359, 1363 (Fed. Cir. 2015); Lone Star Fund V (U.S.) L.P., v. Barclays Bank PLC, 594 F.3d 383, 387 (5th Cir. 2010). On appeal, the Federal Circuit, applying regional circuit law, generally will accept facts pleaded in the complaint as true. Thus, you should consider incorporating factual allegations pertinent to *Alice* steps 1 and 2, with supporting citations, into the complaint to aid in responding to any potential eligibility arguments. See, e.g., Xlear, Inc., v. STS Health, LLC, No. 14-cv-806, 2015 U.S. Dist. LEXIS 167707, at *4–5 (D. Utah Dec. 14, 2015).

Identify and Explain the Materiality of Disputed Facts

As with any opposition to a motion to dismiss, you cannot rely on bare assertions that dispositive facts are in dispute precluding resolution. As the patentee, you must explain how any purported factual disputes bear on resolution of the two steps in the eligibility inquiry. See, e.g., Genetic Techs. Ltd. v. Lab. Corp. of Am. Holdings, No. 12-cv-1736, 2014 U.S. Dist. LEXIS 122780, at *15 (D. Del. Sep. 3, 2014). Persuasively identifying and supporting such disputes—for example, concerning whether a person of ordinary skill in the art would view the limitations in the challenged claims as well-understood, routine, or conventional (see later discussion)—is the goal of any opposition to an early dispositive motion. See, e.g., Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, No. 15-cv-40075, 2016 U.S. Dist. LEXIS 114259 (D. Mass. Aug. 25, 2016); Classen Immunotherapies, Inc., v. Biogen Idec, No. 04-cv-2607, 2012 U.S. Dist. LEXIS 112280 (D. Md. Aug. 9, 2012).

Identify and Explain the Relevance of Non-trivial Questions of Claim Interpretation

If you can identify disputes concerning claim meaning that are material to the eligibility determination, the court may deny the motion or hold off on any determination until after the claim-construction record has been fleshed out. The Federal Circuit has recognized that "it will ordinarily be desirable—and often necessary—to resolve claim construction disputes prior to a § 101 analysis, for the determination of patent eligibility requires a full understanding of the basic character of the claimed subject matter." Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.), 687 F.3d 1266, 1273–74 (Fed. Cir. 2012). In practice, however, this can present a high bar. The court may be willing to take on a discrete legal question of construction, or simply express that its understanding of the claims is "sufficient" based upon the briefing for the purposes of the motion. Boehringer Ingelheim Pharms., Inc., v. HEC Pharm Co., Ltd., No. 15-cv-5982, 2016 U.S. Dist. LEXIS 169812 (D. N.J. Dec. 7, 2016). Or parties bringing a Section 101 challenge may argue that the dispute over meaning of claim language is immaterial because the outcome would be the same under either party's construction. See, e.g., Genetic Techs. Ltd. v. Lab. Corp. of Am. Holdings, No. 12-cv-1736, 2014 U.S. Dist. LEXIS 122780 (D. Del. Sept. 3, 2014); Cleveland Clinic Found. v. True Health Diagnostics, LLC, No. 15-cv-2331, 2016 U.S. Dist. LEXIS 21907, at *6–7 (N.D. Ohio Feb. 23, 2016). Thus, as is true with any disputed facts, you must explain out how the Section 101 analysis would materially change if certain terms are accorded your proposed construction rather than the challenger's, and you should articulate how the issues of construction are too complex or numerous to be fairly

resolved at a preliminary stage of litigation. See CyberFone Sys., LLC, v. CNN Interactive Grp., Inc., 558 Fed. Appx. 988, 992 n.1 (Fed. Cir. 2014); Bancorp Servs. L.L.C. v. Sun Life Assurance Co. of Canada, 687 F.3d 1266, 1273 (Fed. Cir. 2012); Genetic Veterinary Sci. v. Canine EIC Genetics, LLC, 101 F.Supp.3d. 833, 842–43 n. 3 (D. Minn. 2015).

If Appropriate, Supplement the Record

You should also consider whether judicial notice could be employed to supplement the record. Judicial notice may be taken of facts that are "generally known" or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201. But where the movant reasonably disputes the accuracy or meaning of a factual assertion within a document, notice is generally denied. For example, although documents containing a patent's prosecution history and prior art references are publicly available, they may be inappropriate for judicial notice when the accuracy of factual statements within those documents may be disputed. See, e.g., ContourMed v. Am. Breast Care L.P., No. 15-cv-2769 (S.D. Tex. Mar. 17, 2016). Nevertheless, not every helpful fact will be subject to any reasonable dispute. For example, courts have taken notice of teachings in the art when well known to the relevant scientific community. See Ameritox, Ltd. v. Millennium Health, LLC, 88 F. Supp. 3d 885, 892 (W.D. Wis. 2015); Affinity Labs of Texas, LLC v. Amazon.com Inc., 838 F.3d 1266, 1270 (Fed. Cir. 2016).

Additionally, in rare circumstances as discussed above, courts may be willing to treat the motion as a summary-judgment motion, and consider evidence the patentee attaches to its response, particularly where the movant has itself gone beyond the record. Such instances tend to permit greater opportunity to supplement the record by, for example, attaching an expert declaration or exhibits explaining the features and advantages of the invention. See, e.g., Rutgers v. Qiagen N.V., No. 15-cv-7187, 2016 U.S. Dist. LEXIS 24736 (D.N.J. Feb. 29, 2016).

Life Sciences Claims That Are Often Targets of an Eligibility Challenge

As stated in the introduction, eligibility challenges to life-sciences patents commonly involve claims to methods or tools, e.g., for measurement of biological species, and applications thereof. Illumina, 967 F.3d at 1325 ("Under Mayo, we have consistently held diagnostic claims unpatentable as directed to ineligible subject matter."). For example:

- "A method of assessing a test subject's risk of having [a disease], comprising comparing levels of [an enzyme] in a bodily sample from the test subject with levels of [the enzyme] in comparable bodily samples from control subjects diagnosed as not having the disease . . . wherein the [relative] levels of [the enzyme] is indicative of the extent of the test subject's risk of having [the disease]." The Cleveland Clinic v. True Health Diagnostics LLC, 859 F.3d 1352 (Fed. Cir. June 16, 2017) (ineligible); see also Genetic Veterinary Sci., 101 F.Supp.3d. 833 (Ineligible: "A method for determining whether a dog has or is predisposed to develop [condition] . . . .").
- "A method for detecting [a naturally occurring nucleic acid] . . . which method comprises amplifying [the nucleic acid] from the serum or plasma sample and detecting the [nucleic acid] in the sample." Ariosa Diagnostics, 788 F.3d 1371 (ineligible).
- "A method of detecting human body temperature comprising: measuring temperature of a region of skin of the forehead; and processing the measured temperature to provide a body temperature approximation based on heat flow from an internal body temperature to ambient temperature." Exergen Corp. v. Thermomedics, Inc., 132 F.Supp.3d 200 (D. Mass. 2015) (ineligible).
- "A method [for diagnosing neurotransmission or developmental disorders related to MuSK in a bodily fluid of a mammal], comprising contacting MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid; immunoprecipitating any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid, and monitoring for said label… wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to MuSK." Athena Diagnostics, Inc. v Mayo Collaborative Servs., LLC., 915 F.3d 743 (Fed. Cir. 2019) (ineligible).

Claims to compositions of matter that are asserted to be naturally occurring materials have also been challenged. For example:

- "A pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by a polymerase chain reaction, the sequence of said primers being derived from human chromosome 17q, wherein the use of said primers in a polymerase chain reaction results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene." In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755 (Fed. Cir. 2014) (ineligible); see also, Roche Molecular Sys, Inc. v. Cepheid, 905 F.3d 1362 (Fed. Cir. 2018) (Ineligible: DNA primers used to detect *Mycobacterium tuberculosis*

found to be structurally and functionally identical to naturally occurring DNA sequences).

Also, claims to methods of treatment using compositions that are asserted to be naturally occurring materials have been attacked, although these claims are more likely to survive early dispositive motions. Illumina, 967 F.3d at 1325-26 (distinguishing various types of claims and stating "we have held that method of treatment claims are patent-eligible"). For example:

- "A method of cleaning the nasopharynx in a human in need of said method which comprises nasally administering an effective amount of xylitol/xylose in solution." Xlear, Inc. v. STS Health, LLC, No. 14-cv-806, 2015 U.S. Dist. LEXIS 167707 (D. Utah Dec. 14, 2015) (12(b)(6) motion based on ineligibility denied).
- "A method of treating a lung cancer comprising administering a composition comprising a human or humanized anti-PD-1 monoclonal antibody to a human with the lung cancer, wherein the administration of the composition treats the lung cancer in the human." Bristol-Myers Squibb Co. v. Merck & Co., Inc., No. 15-cv-560, 2016 U.S. Dist. LEXIS 34292 (D. Del. Mar. 17, 2016) (12(b)(6) motion based on ineligibility denied).
- "A method of treating pain in a renally impaired patient, comprising… providing a solid oral controlled release dosage form, comprising …oxymorphone ...[;] measuring a creatinine clearance rate of the patient …[and;] orally administering to said patient, in dependence on which creatinine clearance rate is found, a lower dosage of the dosage form to provide pain relief; wherein after said administration to said patient, the average AUC of oxymorphone over a 12-hour period is less than about 21 ng hr/mL." Endo Pharms. Inc. v. Teva Pharms. USA, Inc., 919 F.3d 1347 (reversing dismissal under Rule 12(b)(6) based on ineligibility).

Of course, this list simply identifies targets that may be more likely to be challenged and is not meant to be exclusive.

Strategy Considerations for Identifying Material Disputed Facts Concerning Eligibility

Keep the Normative Point Central – The Public Here Is Not Foreclosed from Using a Law of Nature, Natural Phenomenon, or Abstract Idea

The overarching concern behind the implicit exception to Section 101 is one of preemption: the exception encompasses the "basic tools of scientific and technological work" and recognizes that authorizing "monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it." Mayo, 132 S.Ct. at 1293 (citing Gottschalk v. Benson, 409 U.S. 63, 67 (1972)). For example, the Federal Circuit has observed that "[c]laiming a result that involves application of a natural law without limiting the claims to particular methods of achieving the result runs headlong into the very problem repeatedly identified by the Supreme Court in its cases shaping eligibility analysis," namely, preemption. Am. Axle & Mfg., Inc. v. Neapco Holdings, LLC., 967 F.3d 1285, 1295-96 (Fed. Cir. 2020). Thus, you should focus on clearly illustrating how and why the claims under review do not preempt the public use of a law of nature, natural phenomenon, or abstract idea. See, e.g., Am. Axle, 967 F.3d at 1299-300 (holding that the additional limitation of "positioning the at least one liner" in claim 1 raises at least an issue of material fact as to whether claims to a method for manufacturing a shaft assembly were directed to nothing more than Hooke's law, and so reversing summary judgment with regards to claim 1); Endo Pharms., 919 F.3d at 1354-55 (emphasizing that "[t]he claims prescribe a specific dosage regimen through the wherein clause, under which the physician administers oxymorphone to achieve a specific range of AUC of oxymorphone based on the patient's creatinine clearance rate," as foreclosing concerns about preemption); Rapid Litigation Mgmt. Ltd., v. CellzDirect, Inc., 827 F.3d 1042, 1052 (Fed. Cir. 2016); Rutgers v. Qiagen N.V., No. 15-cv-7187, 2016 U.S. Dist. LEXIS 24736 (D.N.J. Feb. 29, 2016) (inventions limited to specific application of a diagnosis of a specific infection involving only specific antigens and causing a specific response where alternatives existed for each); Ameritox, Ltd. v. Millenium Health, LLC, 88 F. Supp. 3d at 916–17 (holding that some claims do not preempt a natural law while others do).

Strategy Considerations in Addressing Alice Step 1

The goal of the party seeking early resolution will be to characterize your method claims as nothing more than the observation, identification, or analysis of a natural phenomenon, and your composition claims as not materially distinct from naturally occurring material. For example:

- Claims directed toward amplifying specific sequences of cell-free DNA and detecting fetal aneuploidies "only enable aneuploidy detection if the non-random sequences retain their natural arrangement" and thus "end with a natural phenomenon." Illumina, Inc. v. Natera, Inc., No. 18-cv-01662-SI, 2018 U.S. Dist. LEXIS 106889, at *9 (N.D. Cal. June 26, 2018).
- A claim reciting methods for detecting a coding region of DNA based on its relationship to non-coding regions

amounted to nothing more than identifying "information about a patient's natural genetic makeup." Genetic Techs., Ltd. v. Merial L.L.C., 818 F.3d 1369, 1373–74 (Fed. Cir. 2016).

- Claims directed to identifying the presence of cell-free fetal DNA ("cffDNA") in a patient's bloodstream was claiming nothing more than the natural existence and location of cffDNA. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1373–74 (Fed. Cir. 2015).
- Claims reciting methods for screening human germline for an altered BRCA1 gene by comparing the target DNA sequence with wild-type sequence was nothing more than abstract mental process. BRCA1 & 2, 774 F.3d at 761–62.
- Claims directed to DNA primers used to detect *Mycobacterium tuberculosis* found to be structurally and functionally identical to naturally occurring DNA sequences. Roche Molecular Sys. v. Cepheid, No. 14-cv-03228, 2017 U.S. Dist. LEXIS 113280 (N.D. Cal. Jan. 17, 2017).

Focus on Elements That Take the Claims Beyond Excepted Subject Matter, even if the Elements Themselves Are Well-Known

Movants will invariably focus on certain aspects or perceived phenomena involved in your claim to characterize the claim as being directed to one of the excepted ineligible concepts. In so doing, movants often describe claims at such a high level of abstraction or through such a narrow lens that some courts have referred to the general approach as "reductionist simplicity." See Verint Syst., Inc., v. Red Box Records Ltd., 226 F. Supp. 3d 190 (S.D.N.Y. Dec. 7, 2016). The Supreme Court has acknowledged that "[a]t some level, 'all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.'" Alice, 134 S.Ct. at 2354 (citing Mayo, 566 U.S. at 1293). Thus, you will invariably have to explain how the challenged claim, when considered in its entirety, at most simply involves the allegedly ineligible subject matter but is not directed to it. See Enfish, LLC, v. Microsoft Corp., 822 F.3d 1327, 1335 (Fed. Cir. 2016); Rapid Litigation Mgmt., 827 F.3d at 1049. "Patenting the concept of lift is inappropriate under § 101. Patenting a particular airplane wing is not." Femto-Sec Tech., Inc. v. Lensar, Inc., No. 15-cv-1689, 2016 U.S. Dist. LEXIS 189327 (C.D. Cal. June 8, 2016).

For example, in *Illumina v. Ariosa*, the claims concerned a method for preparing a fraction of cell-free DNA that is enriched in fetal DNA based on the observation that fetal DNA fragments tend to be smaller than maternal DNA. 967 F,3d at 1322-23. The Federal Circuit concluded that "the claimed methods achieve more than simply observing that fetal DNA is shorter than maternal DNA or detecting the presence of that phenomenon" and so "the claims are *not* directed to that natural phenomenon but rather to a patent-eligible method that utilizes it." Id. at 1326 (emphasis in original).

Similarly, in Rapid Litigation Mgmt., the claim concerned a method for producing "a preparation of multi-cryopreserved cells." 827 F.3d at 1048. The movant focused on the cells' capability of surviving multiple freeze-thaw cycles, to identify what it called a "natural law." Id. The patentee explained that the claims are not directed to that feature of the cells, but rather a "constructive process" comprising concrete steps for preserving the cells. Id. ("Indeed, the claims recite a '*method of producing* a desired preparation of multi-cryopreserved hepatocytes.'").

In Kaneka Corp. v. Zhejiang Medicine Co., Ltd., No. 11-cv-02398, 2018 U.S. Dist. LEXIS 82023 (C.D. Cal. Apr. 5, 2018), the defendants argued that the asserted claims were directed to the natural phenomenon that certain microorganisms have the ability to produce reduced CoQ10. The court disagreed, and concluded that the claims were "directed to a superior method of producing a certain end product—in this case, efficiently creating oxidized CoQ10 on an industrial scale—rather than to the inherent properties of certain biological materials." Id. at *50.

In Baxter International, Inc. v. Carefusion Corp., No. 15-cv-9986, 2016 U.S. Dist. LEXIS 63581, at *24 (N.D. Ill. May 13, 2016), CareFusion argued that the claims at issue were directed to the abstract idea of calculating the remaining time on a battery, using well-known voltage and current measurements. In response, Baxter explained how CareFusion ignored components including medical infusion pump, battery, alarm, display and electrical circuits. Id. at 25. CareFusion's argument that the *Alice* step 1 analysis should focus on alleged "novel" features (arguing that all of the tangible components of the claims were well-known) was rejected as irrelevant to the *Alice* step 1 inquiry. Id. at 28.

In Viveve, Inc. v. Thermagen, LLC, No. 16-cv-1189, 2017 U.S. Dist. LEXIS 60478, at *2 (E.D. Tex. Apr. 20, 2017), the challenged claims concerned methods for heating tissue and remodeling it once heated. The movant focused on the natural phenomenon of collagen becoming malleable once heated. Id. at 3. The patentee, however, identified two steps that a physician must carry out: (1) heating the target tissue; and (2) remodeling the therapeutic zone. Id. at 9. "This type of constructive process, carried out by an artisan to achieve a new and useful end, is precisely the type of claim that is eligible for patenting." Id. at 14 (citing Rapid Litigation Mgmt., 827 F.3d at 1048).

In Rutgers v. Qiagen N.V., No. 15-cv-7187, 2016 U.S. Dist. LEXIS 24736, at *1 (D. N.J. Feb. 29, 2016), the challenged claims were to methods for detecting whether patients had been exposed to *Mycobacterium tuberculosis*. The patentee plausibly argued that the "polypeptides or antigenic segments thereof in the compositions or methods" had "no naturally occurring counterpart" and were "functionally distinct" from naturally occurring polypeptide antigens. Id. at 9.

For the purposes of Alice step 1, it should not matter if the elements that distinguish the subject matter from any ineligible aspect were themselves inventive or well-known. E.g, Illumina v. Ariosa, 967 F.3d at 1329 ("Moreover, while such conventionality considerations may be relevant to the inquiry under Alice/Mayo step two, … they do not impact the Alice/Mayo step one question whether the claims themselves are directed to a natural phenomenon.").

Challenge the Movant's Alleged Identification of Ineligible Subject Matter

You should also consider whether the movant actually even identified ineligible subject matter—sometimes, there is no plausible way to reduce the claim that far. For example, a movant was unsuccessful in claiming that ultrashort pulse laser beams were naturally occurring phenomena. Femto-Sec Tech., Inc. v. Lensar, Inc., No. 15-cv-1689, 2016 U.S. Dist. LEXIS 189327 (C.D. Cal. June 8, 2016). In another example, a court rejected the articulation of an alleged natural phenomenon underlying a claim as "heat denatur[ing] collagen and caus[ing] remodeling" because the "remodeling is a process comprising a doctor's application" of certain specific steps. Viveve, No. 16-cv-1189, 2017 U.S. Dist. LEXIS 60478, at *9.

Strategy Considerations in Addressing Alice Step 2

With respect to Alice step 2, the party seeking early resolution will characterize any additional claim terms beyond those pertaining to excepted subject matter, as conventional and assert that they have been applied in a routine manner. See, e.g., Mayo at 87 (steps of administering the drug, measuring metabolite levels, and adjusting dosage were well known; the only new knowledge was of the natural phenomenon); Ariosa, 788 F.3d at 1377 (method claimed amounted to "a general instruction to doctors to apply routine, conventional techniques); Genetic Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369, 1377-1380 (Fed. Cir. 2016) (steps conventional, just applied to newly discovered law of nature).

Focus on the Combination of Elements That Is Unconventional

In an approach akin to the reductionism discussed in connection with *Alice* step 1, movants will often pull out each claim limitation separately, and explain how they were well-known and conventional. Patentees should bring the focus onto the claim as a whole and an evaluation of whether the claimed combination of elements was routine.

For example, in *Rapid Litigation Mgmt*., although the "individual steps of freezing and thawing were well known, but a process of preserving hepatocytes by repeating those steps was itself far from routine and conventional." Rapid Litigation Mgmt., 827 F.3d at 1051.

In *Ameritox*, claim terms that "direct medical professionals to measure the level of a drug metabolite, to normalize data via a creatinine ratio, and then compare that value against the creatinine ratios of a population of individuals" were individually well known and routine, but the inventors' coupling of a normalization step and comparative step was unconventional. Ameritox, Ltd., 88 F.Supp.3d at 911.

In Idexx Laboratories, Inc. v. Charles River Laboratories, Inc., No. 15-cv-668, 2016 U.S. Dist. LEXIS 87888, at *15 (D. Del. July 1, 2016), blood collection cards, analysis of samples for a biological marker, and use of immunoassay were all well known, but the "ordered combination of limitations . . . describe a specific, novel implementation."

And in Exergen Corp. v. Kaz USA, Inc., 725 Fed.Appx. 959, 966 (Fed. Cir. 2018), claims directed to methods and apparatuses for detecting core body temperature (a natural phenomenon) using temperature scanning technology "incorporated that discovery into an unconventional method of temperature measurement."

Identify Problems in the Art and the Improvements the Invention Provides

Patentees should also identify the problems that existed in the art and how the invention—the claim as a whole—solved those problems or improved upon what was known and available. See DDR Holdings v. Hotels.com, 773 F.3d at 1257; Cal. Inst. of Tech. v. Hughes Communs., Inc., 59 F.Supp.3d 974, 1000 (C.D. Cal. 2014); cf. Alice, 134 S. Ct. at 2359 ("The method claims do not . . . purport to improve the functioning of the computer itself.").

For example, in Ameritox v. Millennium Health, Ameritox explained how prior protocols were restricted and could only test for the "presence or absence of a drug metabolite in

urine," which presented a "major difficulty" because of large variance in metabolite concentrations in urine. It was through the inventors' ingenuity that more accurate evaluation became available. Ameritox, 88 F.Supp.3d at 912.

In *Idexx*, the method provided clear advances over the prior art including "permit[ting] one to monitor the health of rodent populations without euthanizing animals, waiting for blood to clot in a centrifuge, or shipping blood serum overnight in a refrigerated container." Idexx, 2016 U.S. Dist. LEXIS 87888 at *14.

In *Rutgers*, the patentee plausibly alleged that the claimed single-visit *in vitro* objective blood tests for exposure to *Mycobacterium tuberculosis* provided great improvements over prior multiple-visit *in vivo* skin tests, in which tuberculosis antigens were injected into patients' arms, and the site is inspected for irritation days later and a subjective evaluation is made. Rutgers, 2016 U.S. Dist. LEXIS 24736 at *3–4.

In *Viveve*, the claims to heating and remodeling tissue provided improvements over the "only known methods for tightening the relevant tissue [which] required invasive surgical procedures which carried with them the risk of scarring." Viveve, 2017 U.S. Dist. LEXIS 60478 at *15.

Conclusion

If you plan to assert a patent with claims that may invite a Section 101 eligibility challenge, your defensive strategy begins with including factual allegations and supporting citations pertinent to the inquiries in Alice steps 1 and 2 in the complaint. If an early challenge does arise, identify material factual disputes and claim construction issues that warrant development of a full record. To do so, consider challenging the movant's alleged identification of excepted subject matter, and explain how the claim, when considered as a whole, is not in fact directed to that subject matter, but merely involves it. Also, explain how the claimed combination of elements is unconventional and provides improvements over the art. And keep the policy consideration central: the public is not foreclosed from using the alleged excepted subject matter because of the claim.

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Mike Furrow is a former medicinal chemist who counsels pharmaceutical and biotech innovators on all aspects of patent and related regulatory strategy from the early development stages through product launch and eventual high-stakes patent disputes. He has counseled on products covering dozens of therapeutic areas and has handled actions in federal courts and before the U.S. Patent and Trademark Office. Mike's background as a chemist affords him an intimate understanding of the challenges innate to the discovery of new medicines, and clients value his resulting drive to help them explore creative ways to maximize market exclusivities.

Combining his science background with his legal prowess, Mike is known for exhaustively exploring the facts and pushing the envelope on merits strategy. He engages with the technology at a level that permits him to develop strong relationships with inventors, scientific officers, and technical experts, and typically takes the lead on critical issues of patent infringement and validity throughout a matter, including trial. Mike has protected and defended innovation in all aspects of drug discovery, including new chemical entities, salt forms, prodrugs, solid-state forms, dosage forms, combination products, therapeutic methods, methods of manufacture, REMS programs, DNA polymerization, genetically modified organisms, and laboratory techniques and tools.

Mike has published several peer-reviewed scientific articles concerning novel stereoselective synthetic methods and was awarded an undergraduate research grant from the American Chemical Society. In graduate school, Mike's work on novel bond-forming and redox methods for synthesis of complex molecules resulted in several first-author publications in preeminent chemistry journals and was funded by a National Science Foundation Fellowship. Mike also worked for a period as a bench chemist conducting drug discovery on small molecule kinase inhibitor peptidomimetics at a leading biotechnology company that discovers and develops small molecule drugs for viral infections and liver diseases.

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