

The Continuing Evolution of Patent Eligibility Under 35 U.S.C. § 101

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I. Introduction

Since 2010, and most recently in June 2014, the Supreme Court has issued four opinions limiting the patent eligibility of various inventions under 35 U.S.C. § 101. In addressing an issue that had been left relatively untouched by the Court for several decades, these recent decisions have significantly changed the extent to which various types of inventions across multiple technology sectors, from business methods and software to methods of medical diagnosis and treatment to pharmaceuticals and biotechnological innovations, are eligible for patent protection, regardless of whether the other statutory requirements for patentability (novelty, nonobviousness, definiteness) have been met. The lower courts and the PTO, in turn, continue to try to interpret the Supreme Court's guidance so as to implement these significant changes in the governing law.

This article presents an overview of evolving developments in patent eligibility since the Court's 2013 decision in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*,¹ in which the Court held that genes are not eligible for patenting under section 101. First, it discusses guidance the PTO issued after *Myriad* and the Court's 2012 decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*² and the PTO's ongoing revision of that guidance in response to critical comments from the public and subsequent Supreme Court precedent. It also discusses lower court cases in which the patentee in *Myriad* is attempting to enforce patent claims related to, but separate from, those that were before the *Myriad* Court. Finally, it discusses the Supreme Court's most recent ruling on the patent ineligibility of "abstract" ideas implemented by a computer, in *Alice Corp. Pty. v. CLS Bank Int'l*,³ and the relationship of that decision to *Myriad* and *Mayo*.

II. *Mayo/Myriad* and the PTO's Guidance

Mayo and *Myriad* upended long-held understandings as to the scope of patent-eligible subject matter under section 101.⁴ In *Mayo*, the Court relied on the judicially created "laws of nature" exception to hold that a method for optimizing dosing of a therapeutic drug by measuring its metabolite levels in individual patients was not patent-eligible.⁵ The Court held that the claimed invention encompassed the application of a natural law (the relationship between metabolism rates and effective dosing) and that patent eligibility therefore required that the invention also include something in addition to that natural law that was more than "well-understood, routine, conventional activity previously engaged in by research-

ers in the field" and that was not "purely conventional or obvious."⁶ Because the Court found that the claimed invention lacked any such additional features, it held that the invention was not patent-eligible.⁷ However, the Court did not provide clear guidance for determining when a claim encompasses a natural law or for determining when adding something to the claim will suffice to avoid the natural-law exception.

In *Myriad*, the Court asserted the "laws of nature" exception to hold that isolated molecules of DNA, even if synthesized in a laboratory, are not patentable if their sequence matches that of naturally occurring genes, a reversal of several decades of PTO policy.⁸ In dicta, the Court stated that discovery of a gene's sequence still will enable inventors to claim applications of such knowledge.⁹ Nevertheless, the patent eligibility of such uses might be limited by *Mayo*. If a genetic sequence were not itself patent-eligible under *Myriad*, the *Mayo* holding that "one must do more than simply state [a] law of nature while adding the words 'apply it'"¹⁰ might suggest that the scope of patent-eligible applications of a newly discovered genetic sequence will be limited. In addition, although the specific "product of nature" at issue in *Myriad* was DNA, the Court did not explicitly indicate whether other isolated "natural products" were likewise subject to exclusion.

Thus, in March 2014, the PTO issued guidance (hereinafter "the Guidance") to assist its Examiners in applying the holdings of *Mayo* and *Myriad* to patent applications.¹¹ The Guidance instructed examiners to pose the following questions:

- (1) "Is the claimed invention directed to one of the four statutory patent-eligible subject matter categories: process, machine, manufacture, or composition of matter?";
- (2) If yes, "[d]oes the claim recite or involve one or more judicial exceptions?"; and
- (3) If yes, "[d]oes the claim as a whole recite something significantly different than the judicial exceptions?"¹²

Under the Guidance, patent eligibility requires an answer of "yes" to the first question and either "no" to the second question or "yes" to the third second and third questions.¹³

As to the second question, the Guidance stated that although *Myriad* was directed to the eligibility of isolated DNA, the overall rationale of the decision was not explicitly limited thereto.¹⁴ Thus, the Guidance instructed

Examiners to give a claim its “broadest reasonable interpretation” in determining whether a claimed invention falls within a judicial exception to patent eligibility.¹⁵ If any embodiment falling within that broadest reasonable interpretation “may” be characterized as a natural phenomenon or a law of nature, then the claim also must recite enough additional eligible subject matter in order to satisfy section 101.¹⁶

The Guidance also included a nonexclusive list of subject matter the recitation or invocation of which may require further examination for the presence of something “significantly different” to confer eligibility, and it explained that the analysis applies where there is “any doubt” about whether an exception is involved.¹⁷ Examples of claimed subject matter that may trigger such an analysis include “chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature.”¹⁸

For example, the Guidance stated that gunpowder is a natural product because it is “a mixture of naturally occurring saltpeter, sulfur and charcoal.”¹⁹ It stated that a method for treating a mood disorder by exposure to a synthetic source of white light invokes a “natural principle or phenomenon.”²⁰ It also stated that an imaginary compound termed “Amazonic acid” purified from leaves of the “Amazonian cherry tree” and termed “Amazonic acid,” which is useful in treating breast cancer, implicates the natural products exception from eligibility.²¹ And it stated that a claim reciting pomelo juice mixed with “a preservative” would invoke an exception from eligibility because naturally occurring vitamin E is a preservative.²²

As to the third question, the Guidance contained a twelve-factor balancing test for determining whether a claim that does “recite or involve” a judicial exception also recites “something significantly different” from the exception, with six factors supporting eligibility and six factors indicating ineligibility:²³

Factors that weigh in favor of eligibility:

1. Product appears to be a natural product but turns out to be non-naturally occurring and “markedly different in structure” from natural products.
2. Claim meaningfully limits scope of method so that others are not substantially foreclosed from using an exception.
3. Claimed elements are more than nominally, insignificantly, or tangentially related to an exception.
4. Claims do more than describe exception with general instructions to apply or use it.

5. A machine or transformation of matter implements or integrates an exception, but the claim recites additional elements or steps.
6. Something more than well-understood, purely conventional, or routine is added to the exception.

Factors that weigh against eligibility:

1. Product is not markedly different in structure from natural product.
2. High level of generality encompassing substantially all practical applications of exception.
3. Recited elements/steps are those that are required by any application of the exception.
4. Recitations in addition to the exception are well-understood, purely conventional, or routine.
5. Recitations in addition to the exception are insignificant extra-solution activity, such as being merely appended to the exception.
6. Recitations in addition to the exception are merely a field of use.

As for the hypothetical inventions described above, the Guidance stated that none of the examples includes enough to make it “significantly different” from an exception so as to render it patent-eligible.²⁴ For example, even if, in nature, saltpeter, sulfur, and charcoal do not all exist in a single mixture, a mixture of them together to form gunpowder does not constitute something significantly different than a product of nature.²⁵ And because sunlight is generally known to affect mood, a novel method for treating a mood disorder (such as seasonal affective disorder) by exposing a patient to an artificial source of light is not significantly different from a (patent-ineligible) natural principle or phenomenon.²⁶ Furthermore, even if a person would have to eat thirty pounds of Amazonian cherry tree leaves per day in order to receive the same clinical effectiveness provided by ingesting one teaspoonful per day of purified Amazonic acid, the purified drug would be ineligible for patenting as not significantly different from a natural product.²⁷ And a claim reciting pomelo juice mixed with “a preservative” would be ineligible even though pomelo juice does not naturally contain the naturally occurring preservative vitamin E.²⁸ Thus, in addition to requiring a broad view of the exceptions to patent eligibility, the Guidance also imposed strict standards for what was required to confer eligibility on a claim that encompassed an exception.

The negative reaction of the patenting community to the Guidance was so strong that on May 9, 2014, the PTO held a public forum to explain the Guidance and to discuss its rationale.²⁹ During the forum, individuals and representatives from public advocacy groups (such as the Biotechnology Industry Organization (BIO), the American Intellectual Property Law Association, and the Intellectual

Property Law Section of the American Bar Association) expressed significant displeasure with the Guidance.³⁰ Complaints included the fact that the PTO had not solicited any public input or comment before releasing the Guidance; that the Guidance focused too much on an invention's structure over other attributes, such as function, in evaluating eligibility, in contrast to Supreme Court precedent; that it inappropriately blurred the distinction between patent eligibility under section 101 and patentability issues such as novelty under section 102 and nonobviousness under section 103; and that the PTO had focused too much on Supreme Court dicta rather than on trying to distill a coherent and useful direction from the Court's admittedly inconsistent rulings.³¹

The PTO also requested the submission of written public comments on the Guidance. The written comments overwhelmingly urged the PTO to alter the Guidance,³² under which patent applicants were now receiving rejections for all kinds of inventions whose eligibility would not have been questioned just a short time before.³³ Consequently, in a presentation at the BIO International Convention in San Diego in June 2014, the PTO indicated that it would be updating the Guidance.³⁴ The PTO also stated that it had published several hypothetical exemplary claims and requested public recommendations as to how they should be analyzed for eligibility. In addition, the PTO invited the public to submit additional exemplary claims with suggestions as to how they should be examined under *Mayo* and *Myriad*.³⁵

Thereafter, in September 2014 at a Biotechnology/Chemical/Pharmaceutical Customer Partnership meeting held by the PTO³⁶ and again at an IP & Diagnostics Symposium held by IPO,³⁷ the PTO gave its strongest indications yet that the Guidance would be significantly altered. The PTO stated that its intention had not been to set a high bar to patent eligibility in response to *Mayo* and *Myriad*, and it acknowledged that the Guidance had signaled too broad a scope of inventions that would trigger patent-eligibility scrutiny by including those that "involve" or "recite" a judicial exception rather than only those "directed" to one.³⁸ In that regard, as discussed in Section IV below, its change in position on the Guidance may have been a response not only to public feedback but also to the Supreme Court's further discussion of patent eligibility in *Alice*, which was decided after the PTO issued the Guidance.³⁹ The PTO also explained that the Guidance's test as to whether a claimed invention was "significantly different" from a judicial exception had been too narrow, focusing exclusively on structural differences and not taking into account other issues, such as functional differences.⁴⁰ Furthermore, the PTO stated that the twelve-factor balancing test was too complex.⁴¹ As a result, the "significantly different" and twelve-factor balancing tests were to be removed from revised Guidance.⁴²

Thus, like the patent community in general, the PTO has wrestled with how to meaningfully implement the Supreme Court's patentability rulings. At least the apparent responsiveness of the PTO to public comment may offer hope that Examiners ultimately may implement *Mayo* and *Myriad* in the least disruptive manner. Applicants who receive rejections should understand that the PTO's Guidance is still evolving and, in any event, is not binding in court. Until a more comprehensive body of case law has developed establishing the new rules for patent eligibility, applicants may do well to challenge rejections by appealing to the Patent Trial and Appeal Board and, if necessary, to the courts, when doing so is feasible and financially justifiable.

III. Continuing Litigation of *Myriad*-Related Claims

The PTO is not alone in struggling to implement the Court's new patent-eligibility jurisprudence. District courts and the Federal Circuit also have had to confront this new landscape.⁴³ Of particular note are a number of patent infringement suits filed by the patentee in *Myriad* in which it has asserted other claims that had not been before the Supreme Court. Whereas the declaratory judgment plaintiffs in *Myriad* had successfully challenged the validity of claims to isolated DNA whose nucleotide sequence matches that of naturally occurring genes, other claims, such as to DNA "primers" (short, synthetic sequences of DNA used to fabricate copies of intrinsic genes) and methods of using copies of patients' DNA to determine whether they confer susceptibility to developing breast cancer, had not been adjudicated.⁴⁴

To enforce these claims, the patentee commenced preliminary infringement suits against multiple defendants, asserting that they had infringed these still-viable claims.⁴⁵ The patentee moved for a preliminary injunction to prevent one accused infringer from offering its diagnostic tests while the action was pending.⁴⁶ In opposing the motion, the defendant argued, among other things, that the patentee was not likely to succeed on the merits of its infringement claims, based, in large part, on the argument that even though the Court in *Myriad* did not rule directly on validity of the claims, the holding in that case required a finding that these claims also were drawn to patent-ineligible subject matter.⁴⁷

The district court agreed that the patentee was not likely to prevail on its infringement claims because the patent claims at issue were likely to be found invalid under section 101.⁴⁸ The court held that the claims to DNA primers covered sequences of nucleotides that were present in naturally occurring genes, molecules the *Myriad* Court had held were patent-ineligible products of nature whether or not they were assembled in a laboratory as primers are.⁴⁹ Surprisingly, the court also held that claims to primers modified by the addition of molecular

“tags”—appended molecules lacking from natural genes that enable detection of the primers to which they are attached and of larger sequences that incorporate such primers—also would have been drawn to ineligible subject matter.⁵⁰

As to the claimed methods, the court found them ineligible as well. Generally speaking, the method claims recited testing whether portions of a person’s DNA contain a genetic mutation that confers susceptibility to breast cancer.⁵¹ The court noted that overall the naturally occurring sequence of the portion of DNA potentially containing the mutation had been held patent ineligible by the *Myriad* court.⁵² Once that patent-ineligible information was known, the court opined, the additional, previously known steps involved in analyzing that portion to determine its genetic sequence did not involve anything more than “conventional activities that were well-understood and uniformly employed by those working with DNA” at the time the patents were applied for.⁵³ This holding seems to conflict with dicta from *Myriad* that the patent eligibility of applications of knowledge about these genes’ sequences might survive that decision.⁵⁴ However, as noted above, the holding is not entirely unsurprising when *Myriad* is considered together with *Mayo*.⁵⁵

The denial of the preliminary injunction motion is currently on appeal to the Federal Circuit.⁵⁶ At oral argument, which was held on October 6, 2014, the court seemed to be having trouble reconciling seemingly incompatible aspects of *Mayo* and *Myriad*.⁵⁷ In particular, it appeared to struggle with the tension between the requirement from *Mayo* that something more than routine, conventional steps must be added where a claim involves a judicial exception, on the one hand, and the statement in *Myriad* that the patentee should be able to benefit from having identified genes’ sequences by patenting uses thereof even though the claims to the sequences themselves had been found patent-ineligible, on the other.⁵⁸ Pressing this point, the patentee stressed that the Supreme Court had held that some artificial sequences known as cDNA are patent-eligible even though creating cDNA is routine once the sequence of the gene on which it is based is known.⁵⁹

How the court resolves this tension will significantly shape how *Mayo* and *Myriad* influence patent eligibility.⁶⁰ As noted during oral argument, however, the court could affirm the denial of the preliminary injunction on the ground that some other essential showing required for injunctive relief was absent (e.g., that the balance of hardships tipped in favor of the defendant, as the district court found) without addressing patent eligibility.⁶¹ Or the court could affirm on the ground that the defendant had raised a sufficiently significant question of eligibility, without having to rule further on the patent-eligibility issue at this time.⁶² In any case, no matter what the final disposition of the present appeal, it is likely that the Fed-

eral Circuit, if not the Supreme Court, may yet rule again on the patent eligibility of claims in this patent family.

IV. The Interrelationship of the *Mayo/Myriad* Holdings and the Patent Eligibility of Computer-Implemented Inventions

While the PTO and district court were wrestling with the Supreme Court’s patent-eligibility rulings pertaining to natural laws and natural phenomena, the Court continued to address patent eligibility. On June 19, 2014, the Supreme Court handed down its decision in *Alice*,⁶³ in which the Court addressed a different patent-eligibility exception: that for abstract ideas. However, the Court relied on the eligibility analysis it had set out in *Mayo*, stating that the same test was applicable to any section 101 analysis:

First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts [natural phenomena, laws of nature, or abstract ideas]. If so, we then ask, what else is there in the claims before us? To answer that question, we consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application. We have described step two of this analysis as 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.⁶⁴

The Court characterized the claims at issue in *Alice* as drawn to a method for “intermediated settlement, i.e., the use of a third party to mitigate settlement risk.”⁶⁵ In that regard, the Court noted similarity between the claims before it and those that it held were drawn to a patent-ineligible abstract idea in *Bilski v. Kappos* in 2010.⁶⁶ Characterizing the claims in *Bilski* as drawn to the abstract concept of hedging risk, the Court stated that “there is no meaningful distinction between the concept of risk hedging in *Bilski* and the concept of intermediated settlement” at issue in *Alice*.⁶⁷ The Court therefore concluded that the answer to the first question stated above—whether the claims at issue were drawn to a patent-ineligible concept—was yes.⁶⁸

Turning to what it called “*Mayo* step two,” the Court considered whether the claims as a whole amounted to more than just instructions to apply the abstract idea of intermediated settlement.⁶⁹ Although the claims required performing settlement transactions via a computer, or a computer system or computer-readable medium for performing such method, the Court held that “the mere

recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention.”⁷⁰ Thus, the Court held that the claims were drawn to abstract subject matter and were invalid.⁷¹

As was the case with *Bilski*, *Mayo*, and *Myriad*, *Alice* has introduced uncertainty concerning the validity of issued patents and the eligibility of inventions claimed in pending applications. For its part, the PTO issued preliminary guidance to its Examining Corps on implementing *Alice*.⁷² This preliminary guidance prescribes a two-step analysis much like that the Court attributed to *Mayo* in *Alice*, and it repeats the Court’s position that the test, or something like it, should be applied to all types of patent-eligibility analyses.⁷³ The PTO also solicited written comments (to be submitted by July 31, 2014) in advance of issuing more formal guidance.⁷⁴

Of particular note, the Court’s pronouncement in *Alice* that the same two-step test for eligibility from *Mayo* should apply to all patent-eligibility analyses may partly explain the PTO’s shift regarding its *Mayo/Myriad* Guidance. For example, the Court held that the first question is whether claims are “directed to” a patent-ineligible concept.⁷⁵ The PTO’s Guidance, in contrast, had focused more broadly on claims “involving” or “reciting” a judicial exception. But after *Alice* was handed down the agency signaled it was abandoning this broader language in favor of the narrower “directed to” formulation.⁷⁶

V. Conclusion

It seems clear that it will take more time to sort out the ramifications of the Supreme Court’s recent decisions on patent eligibility. Hopefully, as alleged infringers challenge patent eligibility in the courts, and applicants appeal eligibility-based rejections, a body of case law will develop that brings clarity to this area. Meanwhile, practitioners are encouraged to stay abreast of the fast-moving developments.

Endnotes

- 133 S. Ct. 2107 (2013). For more background on *Myriad*, see Teige P. Sheehan, *The Supreme Court Holds Genes Are Patent-Ineligible Products of Nature*, 22 BRIGHT IDEAS No. 2 (Fall 2013), at 3.
- 132 S. Ct. 1289. For more background of the Court’s section 101 decision from 2012 in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* (132 S. Ct. 1289) (in which the Court held a method for optimizing drug dosing was a patent-ineligible law of nature), see Teige P. Sheehan, *Mayo v. Prometheus: The Overlap Between Patent Eligibility and Patentability*, 21 BRIGHT IDEAS No. 2 (Fall 2012), at 3.
- 134 S. Ct. 2347 (2014).
- See Sheehan, *supra* note 2, at 3; Sheehan, *supra* note 1, at 3.
- See Sheehan, *supra* note 2, at 3.
- Id.*
- Id.*
- The Court held that, as products of nature, such sequences fall “squarely within the law of nature exception” to eligibility. *Myriad*, 133 S. Ct. at 2117; Sheehan, *supra* note 1, at 3.
- Myriad*, 123 S. Ct. at 2120.
- Mayo*, 132 S. Ct. at 1294.
- Letter from Andrew H. Hirshfeld, Dep’y Comm’r Patent Examination Policy, U.S.P.T.O., to Patent Examining Corps, dated March 4, 2014, http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf (hereinafter “the Guidance”). The PTO also released a series of slides to help explain the Guidance. Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101: March 2014 Update, http://www.uspto.gov/patents/law/exam/myriad-mayo_slides_20140319.pdf (hereinafter “the Guidance Slides”).
- Guidance, *supra* note 11, at 1-3; Guidance Slides, *supra* note 11, at 14-16, 29.
- Guidance, *supra* note 11, at 1-3; Guidance Slides, *supra* note 11, at 14-16, 29.
- Guidance Slides, *supra* note 11, at 27-28.
- Guidance, *supra* note 11, at 1; Guidance Slides, *supra* note 11, at 8.
- Guidance Slides, *supra* note 11, at 30.
- Guidance, *supra* note 11, at 3.
- Id.*
- Id.* at 9.
- Id.* at 15-17.
- Id.* at 7-9.
- Guidance Slides, *supra* note 11, at 67-74.
- Guidance, *supra* note 11, at 3-5.
- Id.* at 3.
- Id.* at 9-10.
- Id.* at 15-17.
- Id.* at 7-9.
- Guidance Slides, *supra* note 11, at 67-74.
- Forum Input on PTO’s Myriad Eligibility Guidance Asks, “What Were You Thinking?,”* [2014] 88 Pat. Trademark & Copyright J. (BNA) No. 2163, at 179, 180 (May 16, 2014).
- See Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena & Natural Products (hereinafter “PTO *Mayo/Myriad* Webpage”), available at <http://www.uspto.gov/patents/announce/myriad-mayo.jsp>.
- Forum Input on PTO’s Myriad Eligibility Guidance Asks, “What Were You Thinking?,”* [2014] 88 Pat. Trademark & Copyright J. (BNA) No. 2163, at 179, 180-82 (May 16, 2014).
- New Patent Eligibility Comments Tell PTO Same Theme: Withdraw or Revise Guidance,* [2014] 88 Pat. Trademark & Copyright J. (BNA) No. 2176, at 1049 (Aug. 22, 2014).
- Posting by Courtenay Brinckerhoff to PharmaPatents, <http://www.pharmapatentsblog.com/2014/08/21/airing-the-usptos-naturally-occurring-dirty-laundry-the-subject-matter-eligibility-stain> (Aug. 21, 2014).
- Posting by Donald Zuhn to Patent Docs, <http://www.patentdocs.org/2014/07/docs-bio-uspto-provides-update-on-myriad-mayo-guidance.html> (July 1, 2014).
- See PTO *Mayo/Myriad* Webpage, *supra* note 30.
- Posting by Donald Zuhn to Patent Docs, <http://www.patentdocs.org/2014/09/uspto-expected-to-issue-revised-myriad-mayo-guidance-in-october.html> (September 17, 2014) (hereinafter “BCPCP Meeting”).
- Posting by Donald Zuhn to Patent Docs, <http://www.patentdocs.org/2014/10/uspto-outlines-changes-to-myriad-mayo-guidance-at-bio-symposium.html> (September 30, 2014) (hereinafter “BIO Symposium”).
- See BCPCP Meeting, *supra* note 36.

39. See *infra*, notes 74-75, and associated text.
40. *Id.*; BIO Symposium, *supra* note 37.
41. See BIO Symposium, *supra* note 37.
42. Although revisions to the Guidance were expected by the end of October 2014, as of this writing they have yet to be released. *Id.*
43. See, e.g., *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 2013 WL 5863022 (N.D. Cal. 2013) (holding that a noninvasive method for prenatal genetic screening was ineligible for patenting because using cell-free fetal DNA (cffDNA) for this purpose as claimed involved “no more than well-understood, routine, conventional activity, previously engaged in by those in the field” and was therefore patent ineligible; the ruling is on appeal to the Federal Circuit (Case No. 14-1139); *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333, 1339 (Fed. Cir. 2014) (affirming the PTO’s rejection of claims to a cloned sheep as drawn to patent-ineligible subject matter).
44. Sheehan, *supra* note 1, at 4; *In re BRCA1-, BRCA2-Based Hereditary Cancer Test Patent Litig.*, 2014 WL 931057, at *1 (D. Utah 2014).
45. Several infringement suits were consolidated with several suits seeking a declaration of patent invalidity, which had been filed against the patentee, in the U.S. District Court for the District of Utah. *Id.* at n.3.
46. *In re BRCA1-, BRCA2-Based Hereditary Cancer Test Patent Litig.*, 2014 WL 931057, at *1.
47. *Id.*
48. *Id.* at *54.
49. *Id.* at *45.
50. *Id.* at *48.
51. *Id.* at *27-30.
52. *Id.* at *51.
53. *Id.*
54. *Myriad*, 133 S. Ct. at 2120.
55. See *supra* note 10 and associated text.
56. Case No. 14-1361.
57. An audio recording of oral argument is available at: <http://oralarguments.ca9.uscourts.gov/default.aspx?fl=2014-1361.mp3> (hereinafter “Oral Argument”).
58. *Id.*
59. *Id.*; see Sheehan, *supra* note 1, at 3.
60. Posting by Courtenay Brinckerhoff to PharmaPatents, <http://www.pharmapatentsblog.com/2014/10/07/federal-circuit-hears-arguments-on-other-myriad-gene-patents> (Oct. 7, 2014).
61. Oral Argument, *supra* note 57; *In re BRCA1-, BRCA2-Based Hereditary Cancer Test Patent Litig.*, 2014 WL 931057, at *56.
62. *Id.*
63. 134 S. Ct. 2347.
64. *Id.*, at 2355 (internal quotation marks, citations, and brackets removed).
65. *Id.* at 2356.
66. 561 U.S. 593 (2010).
67. *Alice*, 134 S. Ct. at 2357.
68. *Id.*
69. *Id.*
70. *Id.* at 2347, 2360.
71. *Id.* at 2360.
72. See Preliminary Examination Instructions for Determining Subject Matter Eligibility in view of *Alice Corp. v. CLS Bank*, http://www.uspto.gov/patents/announce/interim_alice_guidance.jsp.
73. *Id.*
74. *Id.*
75. *Alice*, 134 S. Ct. at 2355.
76. See BIO Symposium, *supra* note 37.

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