

**The Role of Patents in the Fight Against Superbugs: Are Patent Laws Discouraging  
Investment in Promising Superbug Treatments?**

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ABSTRACT

Pharmaceutical companies invest significant resources in identifying and developing treatments for a variety of infectious diseases, including the current worldwide threat of superbugs. [1] It is essential that these companies commercialize these treatments and recoup their investments. [2] Therefore, as a policy matter, it is important to incentivize pharmaceutical companies to reap these financial rewards in order to motivate innovation and research. [3] Patents provide an incentive—a twenty-year term of marketing exclusivity. [4] However, as a result of the *Mayo/Alice* eligibility criteria that distinguish patent-ineligible laws of nature, natural phenomena, and abstract ideas from patentable inventions, the United States Patent and Trademark Office is likely to reject patents for many superbug treatments, such as antibiotics found in nature. [5] Consequently, other methods of incentivizing the development of superbug treatments, such as delinkage mechanisms, may be necessary. [6]

## **I. Background**

Patentability is essential to the commercialization of scientific research in the United States and worldwide. [7] Pharmaceutical companies invest significant time and financial resources in research targeted at identifying and developing treatments for a variety of infectious diseases. [8] These organizations seek to make economically wise investments as part of their business models. [9] Therefore, it is essential, when an organization discovers a viable treatment option that it commercializes that treatment and recoups its investment. [10] As a policy matter, it is important to incentivize pharmaceutical companies to reap these financial rewards in order to motivate innovation and research. For instance, during the twenty-year patent term established in Title 35 U.S.C. § 154, a company can exclusively market its product without fear of competitors reducing its profits. [11]

Currently, universities and corporations are engaged in extensive research to address the imminent public health threat of superbugs. [12] Superbugs are “strains of bacteria that are resistant to the majority of antibiotics commonly used today.” [13] These resistant strains cause serious drug-resistant ailments such as pneumonia, urinary tract infections, and skin infections. [14] Many of these microbes lack a known cure, and current research is focused on identifying their treatments. [15] A significant problem in the industry is that the perceived return on investment (“ROI”) for a superbug treatment is low compared to the perceived ROI for other treatments. [16] For instance, pharmaceutical companies often prefer to invest in treatments for chronic conditions due to the immediate high economic return from investing in this research. [17] Consequently, in this fight against superbugs, strong patents and predictable patent reliability are particularly important to motivate pharmaceutical companies to invest in these treatments. [18]

Of particular concern is that some promising superbug treatments are considered laws of nature and physical phenomena. [19] The recent United States Supreme Court (“SCOTUS”) decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Alice Corp. v. CLS Bank International* have limited the patent eligibility of laws of nature, physical phenomena, and abstract ideas. [20] When the United States Patent and Trademark Office (“USPTO”) applies the *Mayo/Alice* eligibility formula, it is likely to reject microbial patent applications due to its “blind servitude” to *Mayo/Alice*’s confusing eligibility standard. [21] If the USPTO rejects patent applications for superbug treatments, it may be more difficult to commercialize this research, “which means its development and testing may never make it to licensed distribution.” [22]

## **II. Courts’ Interpretations of the Patentability of Laws of Nature, Natural Phenomena, and Abstract Ideas**

Title 35 U.S.C. § 101 is the threshold test for a patentable invention; it states, “[w]hoever 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 therefore, subject to the conditions and requirements of this title.” [23] If an invention satisfies 35 U.S.C. § 101, then it must also “be novel, see § 102, nonobvious, see § 103, and fully and particularly described, see § 112.” [24]

However, SCOTUS in *Alice Corp.*, notes that, for more than one hundred and fifty years, it has interpreted 35 U.S.C. § 101 and its predecessors in light of the exception that laws of nature, natural phenomena, and abstract ideas *are not patentable*. [25] Underlying this exception is the primary goal of patent laws—the promotion of innovation. [26] Laws of nature, natural phenomena, and abstract ideas “are the basic tools of scientific and technological work.” [27] In

order to promote innovation, these basic tools are “free to all men and reserved exclusively to none.” [28] If a law of nature, natural phenomenon, or abstract idea were patented, that could result in monopolization, which would impede other parties from further innovation. [29]

SCOTUS has also recognized that this exception must not be interpreted too broadly to the point of defeating the purpose of patent law. [30] “[A]ll inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” [31] Therefore, an excessively broad interpretation “could eviscerate patent law.” [32] Consequently, SCOTUS has noted that this concern is relative: “how much future innovation is foreclosed relative to the contribution of the inventor.” [33]

SCOTUS’ opinion on inventions embodying some level of natural phenomena is reflected in a 1980 case, *Diamond v. Chakrabarty*, where the Court held that a microbiologist’s invention was patentable under 35 U.S.C. § 101 because it was a “manufacture” or “composition of matter” within the meaning of the statute. [34] The microbiologist invented a “human-made, genetically engineered bacterium...capable of breaking down multiple components of crude oil.” [35] No naturally occurring bacteria had this property, and the invention was valuable because it could be applied to treating oil spills. [36] The exception that laws of nature, physical phenomena, and abstract ideas are not patentable did not apply to this invention because it was “a product of human ingenuity ‘having a distinctive name, character [and] use.’” [37]

Similarly, in 1981, SCOTUS in *Diamond v. Diehr* held that “a process for curing synthetic rubber which includes in several of its steps the use of a mathematical formula and a programmed digital computer” was patentable subject matter under 35 U.S.C. § 101. [38] This invention was the first process to constantly measure the temperature inside the mold and calculate the correct time at which to open the press and remove the cured product. [39]

Although the process employed a mathematical equation, which courts had traditionally identified as a law of nature and therefore not patentable, this particular mathematical equation did not bar the process from being patentable. [40] The Court concluded that the inventors were attempting to patent the process, not the mathematical equation, and therefore it could be patented. [41]

In 1994, in *In re Alappat*, the United States Court of Appeals for the Federal Circuit (“Federal Circuit”) followed *Diehr*, further clarifying the patentability of natural phenomenon that “certain mathematical subject matter is not, standing alone, entitled to patent protection.” [42] In this case, the invention was an improvement in an oscilloscope that made the waveform on the digital screen appear smooth and continuous. [43] The Court held that this invention was patentable because it was a “machine” under 35 U.S.C. § 101, and the exception for laws of nature, natural phenomena, and abstract ideas did not apply. [44]

The Federal Circuit, interpreting SCOTUS’ decision in *Diehr*, states “that certain types of mathematical subject matter, standing alone...is not, in and of itself, entitled to patent protection” unless and until those abstract ideas are “reduced to some kind of practical application.” [45] If the claim as a whole is an abstract idea, then it is not eligible for patent protection. [46] However, the exception does not apply if an abstract idea is part of a claim, and the claim as a whole is not a law of nature, natural phenomena, or abstract idea. [47] Here, the claim as a whole was “a specific machine to produce a useful, concrete, and tangible result.” [48] When an abstract idea is reduced to a practical application in this way, it is patentable under 35 U.S.C. § 101. [49]

Similarly, in 1998, in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.* the Federal Circuit followed its holding in *Alappat*. [50] The invention—a machine that used a

series of mathematical calculations to transform data into a final share price—“constitute[d] a practical application of a mathematical algorithm, formula, or calculation, because it produce[d] ‘a useful, concrete, and tangible result.’” [51] Therefore, this invention was patentable under 35 U.S.C. § 101. [52]

In contrast to the aforementioned cases, in 2010, in *Bilski v. Kappos*, SCOTUS affirmed a patent examiner’s rejection of a patent application on the grounds that it was an unpatentable abstract idea. [53] The invention “explain[ed] how buyers and sellers of commodities in the energy market can protect, or hedge, against the risk of price changes.” [54] Hedging is an abstract concept, and SCOTUS distinguished this case from *Diehr*, where, the invention as a whole was a process under 35 U.S.C. § 101. [55] If the Court upheld the patent application, it “would preempt use of this [risk hedging] approach in all fields, and would effectively grant a monopoly over an abstract idea.” [56]

In *Bilski*, SCOTUS rejected the Federal Circuit’s adoption of the machine-or-transformation test as an exclusive test limiting process patents under 35 U.S.C. § 101. [57] The Federal Circuit had adopted the test as follows: “an invention is a ‘process’ only if: ‘(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.’” [58] Whereas, SCOTUS held that the machine-or-transformation test “is not the sole test for deciding whether an invention is a patent-eligible ‘process,’” but rather, it “is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101.” [59] SCOTUS also noted that courts should not “confine themselves to asking the questions posed by the machine-or-transformation test.” [60]

SCOTUS’ trend of finding processes patent-ineligible continued in *Mayo Collaborative Services*. [61] Here, the inventions were processes to help doctors determine whether a

pharmaceutical dosage for a patient suffering from an autoimmune disease is appropriate. [62] These processes were not patentable because they did not transform “unpatentable natural laws into patent eligible applications of those laws.” [63] According to the Court, “to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words ‘apply it.’” [64] Here, the claims merely described the natural laws, which doctors and scientists already understood well and used routinely, and the claims did not add anything significant. [65] If the Court upheld the patents, it would prevent other researchers from using these natural laws, and this would impede, rather than promote, innovation. [66] In particular, upholding these claims would threaten to limit future treatment decisions by healthcare providers and “inhibit the development of more refined treatment recommendations.” [67]

On the other hand, in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, no process was at issue because the processes used were well understood and widely used. [68] Rather, this case regarded the patentability of isolated naturally occurring deoxyribonucleic acid (“DNA”) segments and synthetically created complementary DNA (“cDNA”). [69] A research laboratory discovered “the precise location and genetic sequence of the BRCA1 and BRCA2 genes” which already existed in nature; therefore, the laboratory did not create or alter them in any way. [70] In contrast, when the laboratory removed the non-coding regions of DNA to create cDNA, it created something new. [71] Therefore, cDNA “is distinct from the DNA from which it was derived” and is not a product of nature. [72]

To determine whether the patents claimed anything new and useful or only naturally occurring phenomena, SCOTUS, akin to its analysis in *Mayo Collaborative Services*, considered the balance between incentivizing invention and impeding future invention. [73] If the Court

upheld the claims for the isolated DNA segments, it would give the laboratory the exclusive right to isolate the BRCA1 and BRCA2 genes and synthetically create BRCA cDNA. [74] Genetic testing for the BRCA1 and BRCA2 genes requires isolating those genes. [75] Therefore, upholding these patents would prevent other laboratories from conducting genetic testing for these genes. [76] As a result, SCOTUS held that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.” [77] In dictum, the Court suggested that, if the laboratory had “created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent.” [78]

In *Alice Corp.*, SCOTUS elaborated on its *Mayo Collaborative Services* test “for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.” [79] The Court held that generic computer implementation did not transform the abstract idea of intermediated settlement into a patent-eligible invention. [80] Therefore, “a computer-implemented scheme for mitigating ‘settlement risk’...by using a third-party intermediary” was not patentable. [81]

In its analysis, SCOTUS first compared the concept of intermediated settlement in *Alice Corp.* to the concept of risk hedging in *Bilski*, and concluded that, like risk hedging, intermediated settlement is an abstract idea. [82] Second, SCOTUS examined the elements of the claims and concluded that they “merely require[d] generic computer implementation.” [83] The Court found that the claims did not “contain[] an inventive concept sufficient to transform the claimed abstract idea into a patent-eligible application.” [84] Rather, the claims “d[id] [no] more than simply instruct the practitioner to implement the abstract idea of intermediated settlement on a generic computer.” [85]

When the Court considered each element separately, it found that “each step [did] no more than require a generic computer to perform generic computer functions,” and these computer functions were well-understood and routine in the industry. [86] When the Court examined the elements “as an ordered combination,” it established that the claims were merely “an instruction to apply the abstract idea of intermediated settlement using some unspecified, generic computer.” [87] An instruction to apply an abstract idea is not sufficient to transform “an abstract idea into a patent-eligible invention.” [88] Therefore, the claims were not patentable. [89]

The complex and confusing standards for patenting inventions set forth by these cases have discouraged patenting new methods for the treatment of infectious diseases caused by superbugs. [90]

### **III. Effects of Case Holdings on the Patentability of Laws of Nature, Natural Phenomena, and Abstract Ideas**

A superbug treatment could circumvent the above complex case law by avoiding the 35 U.S.C. § 101 exception for laws of nature, natural phenomena, and abstract ideas. [91] For instance, genetically engineered organisms, like in *Chakrabarty*, and abstract ideas reduced to practical applications, like in *Alappat* and *State Street Bank & Trust Co.*, may avoid this exception and be patentable under 35 U.S.C. § 101. [92] Similarly, cDNA, like in *Myriad Genetics, Inc.*, also avoids this exception and is patentable under 35 U.S.C. § 101. [93]

Perhaps some superbug treatments will be genetically engineered. However, many promising treatments are found in nature. [94] Patenting these potential treatments will require grappling with the exception for laws of nature, natural phenomena, and abstract ideas as well as

the complex patenting standards. Additionally, the case law indicates the importance of considering the policy underlying patent laws and the invention's value to society. [95]

In some situations, an otherwise unpatentable law of nature may be patented as part of a process. [96] *Diehr* explains that, if a process includes an unpatentable law of nature, that law of nature does not necessarily bar the process as a whole from being patentable under 35 U.S.C. § 101. [97] SCOTUS further clarifies that, despite including a mathematical equation, “the claims in *Diehr* were patent eligible because they improved an existing technological process.” [98] However, if an invention involves an abstract idea, and the invention as a whole is found to not be a process under 35 U.S.C. § 101, SCOTUS may find that the invention is not patentable, like in *Bilski*. [99]

In determining whether a process is patentable, a court may utilize the optional machine-or-transformation test. [100] The test states that “an invention is a ‘process’ only if: ‘(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.’” [101] However, SCOTUS’ *Mayo/Alice* eligibility criteria is binding on all courts in the United States.

#### **IV. The *Mayo/Alice* Eligibility Criteria**

The *Mayo/Alice* eligibility criteria distinguishes patent-ineligible laws of nature, natural phenomena, and abstract ideas from “patent-eligible applications of those concepts.” [102] “[P]atents that claim the buildin[g] block[s] of human ingenuity” are not patent eligible. [103] “[U]pholding the[se] patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.” [104] On the other hand, inventions “that integrate the building blocks into something more” are eligible because they “pose no comparable risk of pre-emption.” [105]

The *Mayo/Alice* analysis has two parts: (1) The court “determine[s] whether the claims at issue are directed to one of [the three] patent-ineligible concepts”—laws of nature, natural phenomena, or abstract ideas; and, if so, then (2) the court asks what else is in the claim. [106] In the second part of the test, the court “search[es] 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.” [107] To do this, the court considers each individual element of each claim on its own and all of the elements of each claim “as an ordered combination.” [108] Analyzing the elements in this way, the court “determine[s] whether the additional elements ‘transform the nature of the claim’ into a patent-eligible application.” [109] This transformation requires “more than simply stat[ing] the law of nature while adding the words ‘apply it.’” [110]

In *Alice Corp.*, SCOTUS provides examples of elements that are not sufficient to transform a claim from a law of nature, natural phenomena, or abstract idea to a patent eligible invention: (1) “the mere recitation of a generic computer;” (2) adding the words “apply it;” (3) adding the words “apply it with a computer;” and (4) “limiting the use of an abstract idea to a particular technological environment.” [111] Additionally, in *Alice Corp.*, SCOTUS explains that the claims in *Mayo Collaborative Services* were ineligible because the natural laws were already well-known, and the process merely amounted to “an instruction to doctors to apply the applicable laws when treating their patients.” [112] Specifying the steps that doctors take was not sufficient to make these claims patentable. [113]

## V. Recent Decisions Applying the *Mayo/Alice* Analysis

“In [three] recent cases, [the Federal Circuit] found claims ‘directed to’ a patent-ineligible concept when they amounted to nothing more than observing or identifying the

ineligible concept itself.” [114] In each case, the Federal Circuit applied the *Mayo/Alice* test to reach its decision. [115]

For instance, in *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation v. Ambry Genetics Corp.*, the Court utilized the *Mayo/Alice* eligibility criteria and determined that a method for comparing “wild-type BRCA sequences with the patient's BRCA sequences” was not patentable. [116] The Court found (1) that the claims “are directed to the patent-ineligible abstract idea of comparing BRCA sequences and determining the existence of alterations.” [117] Next, the Court determined (2) that the other elements of the claims were not sufficient to transform the claims into patent-eligible inventions because they were “well-understood, routine and conventional.” [118]

Similarly, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the Court applied the *Mayo/Alice* two-step test to reach the conclusion that a method for detecting cell-free fetal DNA (“cffDNA”) in maternal plasma or serum was not patentable. [119] The Court found (1) that the method claims were directed to natural phenomena of cffDNA because cffDNA is natural, and the invention did not create or alter it in any way. [120] Next, the Court determined (2) that there was no inventive concept because “the method steps were well-understood, conventional and routine.” [121]

Likewise, in *Genetic Technologies, Ltd. v. Merial L.L.C.*, the Court employed the *Mayo/Alice* analysis and decided that methods of analyzing DNA and detecting genetic variations were not patent eligible. [122] The Court found (1) that the claim “is directed to the relationship between non-coding and coding sequences” of DNA—which is a law of nature. [123] Then, the Court concluded (2) that “the additional elements of [the claim] are insufficient

to provide the inventive concept necessary to render the claim patent-eligible” because the steps were “well known, routine, and conventional.” [124]

In contrast, in another recent decision, the Federal Circuit in *Rapid Litigation Management v. CellzDirect, Inc.* applied the *Mayo/Alice* eligibility criteria and held that an improved process for preserving hepatocytes was patentable. [125] In step one of the *Mayo/Alice* test, the Court concluded that “the claims are not directed to a patent-ineligible concept.” [126] The inventors’ discovery that hepatocytes can survive multiple freeze-thaw cycles may be a law of nature; the Federal Circuit did not decide. [127] However, the inventors’ claims “are directed to a new and useful laboratory technique for preserving hepatocytes,” not “to the ability of hepatocytes to survive multiple freeze-thaw cycles.” [128] This new process was a significant improvement upon prior processes for the cryopreservation of hepatocytes. [129] This new and useful process did more than just “observ[e] or identify[] the ineligible concept itself;” therefore, this process was patentable. [130]

Even though it was not required here, the Federal Circuit applied the second step of the *Mayo/Alice* test as well. [131] “Under step two, claims that are ‘directed to’ a patent-ineligible concept, yet also ‘improve[] an existing technological process,’ are sufficient to ‘transform[] the process into an inventive application’ of the patent-ineligible concept.” [132] The Federal Circuit concluded that improved process for preserving hepatocytes is an inventive application because it is not “routine and conventional.” [133] Therefore, the Federal Circuit decided that this process is patentable. [134]

Although not part of the two-part test, the Federal Circuit also considered the policy underlying patent laws. [135] The Court noted “that the patent is not ‘directed to’ a patent-

ineligible building block of human ingenuity.” [136] Thus, the patent is unlikely to impede future innovation. [137]

## **VI. Recent Scientific Discoveries in the Fight Against Superbugs: Are They Patentable?**

Promising superbug treatments include natural antibiotics and antibodies; for instance, scientists discovered the antibiotic teixobactin in a screen of uncultured soil bacteria. [138] In mice studies, teixobactin has treated antibiotic-resistant tuberculosis and methicillin-resistant *Staphylococcus aureus* (MRSA) infections. [139] However, the USPTO decided that teixobactin was within the 35 U.S.C. § 101 exception for laws of nature, natural phenomena, and abstract ideas and rejected the patent. [140]

Similarly, another team of scientists discovered an antibiotic, lugdunin, produced by a bacterium found in the human nose. [141] In mice studies, lugdunin has treated MRSA skin infections and vancomycin-resistant *Enterococcus*. [142] It appears that the scientists have not attempted to patent lugdunin; however, the USPTO’s rejection of the teixobactin suggests that the USPTO would reject a lugdunin patent as well.

Rather than antibiotics, antibodies are an alternative treatment to drug-resistant infections. [143] For instance, scientists are researching antibodies that treat antibiotic-resistant bacteria such as MRSA and *Acinetobacter*. [144] The monoclonal antibody TPH 101 treats MRSA and other strains of *Staphylococcus aureus*. [145] Authorities in Japan, Canada, and Australia have issued patents for TPH 101. [146] Although it does not appear that the USPTO has issued a patent for TPH 101, the international patents at least indicate that antibody treatments for superbugs can be patented in some countries.

## VII. Conclusion and Future Implications

If superbug treatments, such as antibodies, are patentable, then this may provide an incentive for pharmaceutical companies to invest in their development. However, the current twenty-year patent term may not be sufficient in light of the fact that the ROI is poor compared to the perceived ROI for treatments for chronic conditions. [147] Therefore, extending the patent term, thus allowing a pharmaceutical company to exclusively market its product for a longer period of time, might encourage investing in superbug treatments. [148]

However, many lower courts applying the *Mayo/Alice* eligibility criteria are widely concluding that these types of claims are not patent-eligible. [149] Consequently, there is concern about how the *Mayo/Alice* analysis will impact the patentability of promising superbug treatments such as naturally occurring antibiotics. [150] If the most promising superbug treatments are not patent eligible, then other incentives are necessary to drive pharmaceutical companies to invest in these treatments.

The United Nations Secretary-General’s High-Level Panel on Access to Medicines “emphasizes that market-based models of innovation for AMR are unsustainable.” [151] Therefore, the High-Level Panel suggests that delinkage models, which “[d]elink[] the costs of research and development from the end product,” are one way to incentivize innovation. [152] These delinkage mechanisms include push mechanisms, pull mechanisms, pooling, open collaborative research, public-private partnerships, and product development partnerships. [153]

ENDNOTES

[1] Chris Gallagher, *The superbugs are here, but where are we?*, IPWATCHDOG (Jul. 14, 2016), <http://www.ipwatchdog.com/2016/07/14/superbugs/id=70874/>.

[2] *Id.*

[3] *Id.*

[4] 35 U.S.C. § 154 (2016).

[5] Chris Gallagher, *Public Health and Bioscientific War on Superbugs is Hobbled by IP Uncertainties*, IPWATCHDOG (Aug. 1, 2016), <http://www.ipwatchdog.com/2016/08/01/superbugs-hobbled-ip-uncertainties/id=71548/>.

[6] United Nations Secretary-General and Co-Chairs of the High-Level Panel, *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines*, UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES 1, 29 (2016), <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>.

[7] *Public Health and Bioscientific War on Superbugs is Hobbled by IP Uncertainties*, *supra* note 5; *The superbugs are here, but where are we?*, *supra* note 1.

[8] *The superbugs are here, but where are we?*, *supra* note 1.

[9] *Id.*

[10] *Id.*

[11] 35 U.S.C. § 154 (2016).

[12] C. Lee Ventola, *The Antibiotic Resistance Crisis*, PHARMACY & THERAPEUTICS 277, 277-283 (2015); Pritish K. Tosh, *What are superbugs and how can I protect myself from infection?*, MAYO CLINIC (Mar. 20, 2015), <http://www.mayoclinic.org/diseases-conditions/infectious->

diseases/expert-answers/superbugs/faq-20129283; *Public Health and Bioscientific War on Superbugs is Hobbled by IP Uncertainties*, *supra* note 5; *The superbugs are here, but where are we?*, *supra* note 1.

[13] Tosh, *supra* note 12.

[14] *Id.*

[15] *The superbugs are here, but where are we?*, *supra* note 1.

[16] *Id.*

[17] *Id.*

[18] *Public Health and Bioscientific War on Superbugs is Hobbled by IP Uncertainties*, *supra* note 5.

[19] *Id.*

[20] *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2347-2360 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1289-1305 (2012).

[21] *Public Health and Bioscientific War on Superbugs is Hobbled by IP Uncertainties*, *supra* note 5.

[22] *The superbugs are here, but where are we?*, *supra* note 1.

[23] 35 U.S.C. § 101 (2016).

[24] *Bilski v. Kappos*, 561 U.S. 593, 602 (2010).

[25] *Alice Corp.*, 134 S. Ct. at 2354.

[26] *Alice Corp.*, 134 S. Ct. at 2354.

[27] *Mayo Collaborative Servs.*, 132 S. Ct. at 1293.

[28] *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

[29] *Alice Corp.*, 134 S. Ct. at 2354; *Mayo Collaborative Servs.*, 132 S. Ct. at 1293; *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013). See *Bilski*, 561 U.S. at 611-12.

[30] See *Mayo Collaborative Servs.*, 132 S. Ct. at 1293.

[31] *Id.*

[32] *Id.*

[33] *Id.* at 1303.

[34] *Chakrabarty*, 447 U.S. at 309.

[35] *Id.* at 305.

[36] *Id.*

[37] *Id.* at 309-10.

[38] *Diamond v. Diehr*, 450 U.S. 175, 177 (1981).

[39] *Id.* at 177-79.

[40] *Id.* at 186-88.

[41] *Id.* at 192-93.

[42] *In re Alappat*, 33 F.3d 1526, 1543 (Fed. Cir. 1994).

[43] *Id.* at 1537.

[44] *Id.* at 1536.

[45] *Id.* at 1543.

[46] *Id.* at 1544.

[47] *Id.*

[48] *Id.*

[49] *Id.* at 1543-44.

[50] *State St. Bank & Trust Co. v. Signature Fin. Grp.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

[51] *Id.*

[52] *Id.* at 1370.

[53] *Bilski*, 561 U.S. at 609.

[54] *Id.* at 599.

[55] *Id.* at 611.

[56] *Id.* at 612.

[57] *Id.* at 602-04.

[58] *Id.* at 603.

[59] *Id.* at 604.

[60] *Id.* at 606.

[61] *Mayo Collaborative Servs.*, 132 S. Ct. at 1294.

[62] *Id.*

[63] *Id.*

[64] *Id.*

[65] *Id.* at 1297-98.

[66] *Id.* at 1294.

[67] *Id.* at 1302.

[68] *Myriad Genetics, Inc.*, 133 S. Ct. at 2119-20.

[69] *Id.* at 2111.

[70] *Id.* at 2116.

[71] *Id.* at 2119.

[72] *Id.*

[73] *Id.* at 2116.

[74] *Id.* at 2113.

[75] *Id.* at 2114.

[76] *Id.*

[77] *Id.* at 2111.

[78] *Id.* at 2119.

[79] *Alice Corp.*, 134 S. Ct. at 2355.

[80] *Id.* at 2352.

[81] *Id.*

[82] *Id.* at 2357.

[83] *Id.*

[84] *Id.* (internal quotation marks omitted).

[85] *Id.* at 2359.

[86] *Id.*

[87] *Id.* at 2360.

[88] *Id.*

[89] *Id.* at 2357.

[90] *Public Health and Bioscientific War on Superbugs is Hobbled by IP Uncertainties*, *supra* note 5; *The superbugs are here, but where are we?*, *supra* note 1.

[91] *See Chakrabarty*, 447 U.S. at 305-10; *State St. Bank & Trust Co.*, 149 F.3d at 1370-73; *In re Alappat*, 33 F.3d at 1543-44.

[92] *See Chakrabarty*, 447 U.S. at 305-10; *State St. Bank & Trust Co.*, 149 F.3d at 1370-73; *In re Alappat*, 33 F.3d at 1543-44.

[93] *Myriad Genetics, Inc.*, 133 S. Ct. at 2119.

[94] *Public Health and Bioscientific War on Superbugs is Hobbled by IP Uncertainties*, *supra* note 5.

[95] *Mayo Collaborative Servs.*, 132 S. Ct. at 1294-1302; *Myriad Genetics, Inc.*, 133 S. Ct. at 2113-16; *Diehr*, 450 U.S. at 177-79; *Chakrabarty*, 447 U.S. at 305.

[96] *Diehr*, 450 U.S. at 186-88.

[97] *Id.*

[98] *Alice Corp.*, 134 S. Ct. at 2358.

[99] *See Bilski*, 561 U.S. at 609-11.

[100] *Id.* at 602-06.

[101] *Id.* at 603.

[102] *Alice Corp.*, 134 S. Ct. at 2355.

[103] *Id.* at 2354 (internal quotation marks omitted).

[104] *Mayo Collaborative Servs.*, 132 S. Ct. at 1294.

[105] *Alice Corp.*, 134 S. Ct. at 2354-55.

[106] *Id.* at 2355.

[107] *Id.* (internal quotation marks omitted).

[108] *Id.*

[109] *Id.*

[110] *Mayo Collaborative Servs.*, 132 S. Ct. at 1294.

[111] *Alice Corp.*, 134 S. Ct. at 2359 (internal quotation marks omitted).

[112] *Id.* at 2357; *Mayo Collaborative Servs.*, 132 S. Ct. at 1299.

[113] *Alice Corp.*, 134 S. Ct. at 2357.

[114] *Rapid Litig. Mgmt. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048 (Fed. Cir. 2016).

[115] *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1374-80 (Fed. Cir. 2016); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1374-80 (Fed. Cir. 2015); *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp.*, 774 F.3d 755, 763-64 (Fed. Cir. 2014).

[116] *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d at 759.

[117] *Id.* at 763.

[118] *Id.* at 764.

[119] *Ariosa Diagnostics, Inc.*, 788 F.3d at 1373.

[120] *Id.* at 1376.

[121] *Id.* at 1377.

[122] *Genetic Techs. Ltd.*, 818 F.3d at 1371.

[123] *Id.* at 1374.

[124] *Id.* at 1377.

[125] *Rapid Litig. Mgmt.*, 827 F.3d at 1044-47.

[126] *Id.* at 1044.

[127] *Id.* at 1048.

[128] *Id.*

[129] *Id.* at 1045-48.

[130] *Id.* at 1048.

[131] *Id.* at 1050-51.

[132] *Id.* at 1050.

[133] *Id.* at 1051.

[134] *Id.* at 1050-51.

[135] *Id.* at 1052.

[136] *Id.*

[137] *Id.*

[138] Losee L. Ling, *A new antibiotic kills pathogens without detectable resistance*, NATURE 455, 455-459 (2015); John T. Aquino, *Great Discovery, But Maybe No Patent*, BLOOMBERG BNA: HEALTH CARE BLOG (Mar. 18, 2015), <http://www.bna.com/great-discovery-maybe-b17179924181/>; Brian Handwerk, *A New Antibiotic Found in Dirt Can Kill Drug-Resistant Bacteria*, SMITHSONIAN.COM (Jan. 7, 2015), <http://www.smithsonianmag.com/science-nature/new-antibiotic-dirt-soil-can-kill-drug-resistant-bacteria-180953828/?no-ist>.

[139] Ling, *supra* note 138, at 455-459; Aquino, *supra* note 138; Handwerk, *supra* note 138.

[140] Handwerk, *supra* note 138.

[141] Alexander Zipperer, *Human commensals producing a novel antibiotic impair pathogen colonization*, NATURE 511, 511-516 (2016); Lena H. Sun, *Scientists find new antibiotic in the human nose*, THE WASHINGTON POST (Jul. 27, 2016), [https://www.washingtonpost.com/news/to-your-health/wp/2016/07/27/scientists-find-new-antibiotic-in-the-human-nose/?hpid=hp\\_rhp-](https://www.washingtonpost.com/news/to-your-health/wp/2016/07/27/scientists-find-new-antibiotic-in-the-human-nose/?hpid=hp_rhp-)

[142] Zipperer, *supra* note 141, at 511-516; Sun, *supra* note 141.

[143] Laura Colarusso, *To Fight Superbugs, Scientists Are Turning Toward Antibodies*, NEWSWEEK (Feb. 7, 2016), <http://www.newsweek.com/2016/02/19/antibodies-fighting-antibiotic-resistant-bacteria-423778.html>.

[144] *Id.*

[145] *Telephus Advances TPH 101 Program Towards Candidate Selection*, TELEPHUS MEDICAL (Mar. 18, 2014), <http://telephusmedical.com/telephus-medical-advances-tp-101-for-prevention-of-joint-infection/>.

[146] Gareth MacDonald, *Telephus gets patents for superbug battling antibodies*, BIOPHARMA-REPORTER.COM (Feb. 12, 2016), <http://www.biopharma-reporter.com/Bio-Developments/Telephus-gets-patents-for-superbug-battling-antibodies>.

[147] *The superbugs are here, but where are we?*, *supra* note 1.

[148] Cory Fox, Comment and Note, *Resisting Antibiotic Resistance: Legal Strategies to Maintain Man's Dominion Over Microbes*, 12 HOUS. J. HEALTH L. & POL'Y 35, 45-48 (2011); Jessica P. Schulman, Comment, *Patents and Public Health: The Problems with Using Patent Law Proposals to Combat Antibiotic Resistance*, 59 DEPAUL L. REV. 221, 221-223 (2009).

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[150] *Public Health and Bioscientific War on Superbugs is Hobbled by IP Uncertainties*, *supra* note 5; *The superbugs are here, but where are we?*, *supra* note 1.

[151] United Nations Secretary-General and Co-Chairs of the High-Level Panel, *supra* note 6 at 31.

[152] *Id.* at 29.

[153] *Id.*