



January 18, 2017

The Honorable Michelle K. Lee  
Under Secretary of Commerce for Intellectual Property and  
Director of the U.S. Patent and Trademark Office  
U.S. Patent and Trademark Office  
600 Dulany Street  
Alexandria, VA 22314

Via e-mail: [101Roundtable2@uspto.gov](mailto:101Roundtable2@uspto.gov)

**Re: HIPLA Comments on Patent Subject Matter Eligibility**

Dear Under Secretary Lee:

The Houston Intellectual Property Law Association (HIPLA) submits the following comments in response to the Office's "Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility," published at 81 Fed. Reg. 71485 on October 17, 2016.

HIPLA is an association of hundreds of lawyers and other professionals who predominately work in the Greater Houston area. The practice of most of the HIPLA membership relates in substantial part to the field of intellectual property law. Founded in 1961, HIPLA's mission is to promote the development and understanding of intellectual property law through regular meetings, sponsored CLE opportunities, and amicus briefs. After publication of the Office's request in the Federal Register, HIPLA solicited written comments from its members regarding patent subject matter eligibility. This submission is based on comments received, but does not necessarily reflect the views of each member.

The Supreme Court—driven perhaps by concern over patent trolls and the rising costs of healthcare—has attempted wholesale patent and economic policy change through

the blunt instrument of Section 101. Whatever their intent, the two-step analysis of *Mayo*<sup>1</sup> and the conclusion of *Myriad*<sup>2</sup> has resulted in whole swaths of healthcare inventions being unpatentable and existing patents being poured out of the courts as invalid.

It has long been true that laws of nature, natural phenomena, and abstract ideas are not patent eligible, at least under judicial doctrines, if not statute. *Mayo*, 132 S.Ct. at 1293 (“[L]aws of nature, natural phenomena, and abstract ideas’ are not patentable.”) (citations omitted).

The *Mayo* opinion extended this principle significantly, noting that mere recitation of a patent ineligible concept could render the entire claim unpatentable, unless there was something more to transform the claim into a patent eligible application of that concept. *Id.*, at 1297 (If a law of nature is not patentable, then neither is a process reciting a law of nature...). *Id.* at 1294 (“We must determine whether the claimed processes have transformed these unpatentable natural laws into patent eligible applications of those laws.”).

*Mayo* then indicated that routine and conventional activity is not enough for such a transformation. *Id.* at 1298 (“Purely ‘conventional or obvious’ ‘[pre]-solution activity’ is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.”). Under a blunt reading of the *Mayo* opinion, the decision can be seen as re-introducing a synergy requirement (*i.e.*, a more-than-a-sum-of-the-parts requirement) into the law.<sup>3</sup> For example, this Court noted in *Mayo* that “any additional

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<sup>1</sup> *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S.Ct. 1289, 566 U.S. \_\_\_\_ (2012) [hereinafter *Mayo*].

<sup>2</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 569 U.S. \_\_\_\_ (2013) [hereinafter *Myriad*].

<sup>3</sup> In making 35 U.S.C. § 103 part of the 1952 Patent Act, Congress was attempting to eliminate the “synergism” or “flash of genius” and other such patentability tests, in favor of the obviousness inquiry. See 35 U.S.C. § 103 (“Patentability shall not be negated by the manner in which the invention was made.”). Nevertheless, synergism has been difficult to stamp out. See *e.g.*, *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, at 1540 (Fed. Cir. 1983) (“A requirement for “synergism” or a “synergistic effect” is nowhere

steps consist of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant **beyond the sum of their parts** taken separately.” *Id.* at 1298 (emphasis added).

However, the two-step approach proposed by *Mayo* can yield illogical results. Consider, for example, that portions of the claim at issue in *Mayo*, *i.e.*, portions without the added offending natural correlation provided by the wherein clause, were not only patent eligible, but were in fact previously patented. *See* U.S. Patent No. 4,443,435 (“12. The method of eliciting the corresponding therapeutic response in a warm-blooded animal, which comprises administering to such animal an effective amount of a compound as defined by claim 1 [reciting prodrugs of MP, which would then be converted to TG in the body].”). Yet, when the natural correlation was added to a similar claim in U.S. Patent No. 6,355,623, the resulting claim became patent ineligible!

This result implies that patent ineligible concepts cast a long shadow—contaminating otherwise patent eligible material—and such toxic effect must be “significantly” overcome. *Mayo*, 132 S.Ct. at 1297 (“The question before us is whether the claims do **significantly more** than simply describe these natural relations.”) (emphasis added). This analysis seems especially suspect when one realizes that all patent claims necessarily function in accordance with all natural laws, whether recited or not, yet the mere recitation of one is enough to poison the claim under *Mayo*. According to such logic all one needs do is avoid the recitation of any natural law or any math to circumvent *Mayo*, and indeed the current PTO guidance confirms this.<sup>4</sup>

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found in the statute, 35 U.S.C.”). *See also*, Giles S. Rich, Laying the Ghost of the "Invention" Requirement, 1 AM. PAT. L. ASS'N Q. J. 26, 44 (1972), reprinted in AIPLAQJ 41(1): 5-28 (2012) (“A&P spoke of the “difficult and improbability finding of invention in an assembly of old elements,” and that the whole must in some way exceed the sum of its parts to produce unusual or surprising consequences. That is the “severe test.” It was indeed severe—it was an **impossible** test, so 103 was enacted to replace it.”) (emphasis added).

<sup>4</sup> *See e.g.*, Julitis claim 1 versus claim 2 in Subject Matter Eligibility Examples: Life Sciences (2016), available online at <https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-ex.pdf>.

In particular, an interpretation that requires a claim to sum to a value greater than the sum of its parts is not only illogical, but certain to create a patent hostile environment. As Judge Giles Rich famously said:

The laws of physics and chemistry in accordance with which all inventions perform do not permit of the judicial imagined magic accordingly to which  $2 + 2 = 5$ . Wherever such a spurious test prevails all patents are invalid. And there are those who think that is heaven.<sup>5</sup>

Today, such predictions have been fully realized. After surveying patent invalidations under 35 U.S.C. § 101 in the first six months after this Court's decision of June 19, 2014 in *Alice*, Robert Sachs found that the Federal Circuit held invalid 12 of 13 patents (91%), U.S. District Courts invalidated 56 of 76 patents (73%), and the Board invalidated 8 of 10 patents (80%).<sup>6</sup>

In a January 2016 update, Mr. Sachs wrote:

“The number of patents invalidated under Section 101 has increased dramatically from 243 as of October 2015 to 285, while the number of claims invalidated under Section 101 is now **over 7,500**. The courts routinely invalidate all of the claims of a patent based on a single ‘representative’ claim, including all dependent claims regardless of their level of specificity.”<sup>7</sup>

In a June 2016 update of computer and software related patents, Mr. Sachs concludes that the problem continues: “Last year at this time [the Federal courts] had decided only thirteen § 101 decisions, and found only one case, *DDR Holdings*, patent

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<sup>5</sup> Giles S. Rich, Laying the Ghost of the "Invention" Requirement, 1 AM. PAT. L. ASS'N Q. J. 26, 44 (1972); reprinted in AIPLA Q.J. 41(1): 1-26 (2012).

<sup>6</sup> “A Survey Of Patent Invalidations since Alice,” by Robert Sachs (LAW360, Jan. 13, 2015), available at <http://www.law360.com/articles/604235/a-survey-of-patent-invalidations-since-alice> (accessed April 8, 2016).

<sup>7</sup> “#ALICESTORM: WHEN IT RAINS, IT POURS...,” available at <http://www.bilskiblog.com/blog/2016/01/alicestorm-when-it-rains-it-pours.html>, a blog published by the Fenwick & West Intellectual Property Group (emphasis added) (accessed April 7, 2016).

eligible. In the year since, they have decided more than twice that many (27) cases and still found only one case with patent-eligible claims, *Enfish, LLC v. Microsoft Corp.*”<sup>8</sup>

Since the Supreme Court denied *certiorari* for the *Sequenom* case<sup>9</sup>, the Federal Circuit, realizing that no help is forthcoming, has begun to try to rein in the chaotic stampede.<sup>10</sup> However, it will take some time for the lower courts and Patent Office to follow the new lead, and in any event, damaging case law will remain on the books, continuing to wreak havoc.

The situation is also dire for patent applications being prosecuted at the PTO. As expected, technology center groups 1600, 2100, 2400, and 3600—which are home to patent applications claiming biotechnology (1600: “*Biotechnology and Organic Chemistry*”), computer-science (2100: “*Computer Architecture and Software*”), networking (2400: “*Networking, Multiplexing, Cable, and Security*”), and e-commerce (3600: “*Transportation ...Electronic Commerce... National Security*”) related inventions—have the highest § 101 rejection rates<sup>11</sup>:

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<sup>8</sup> Sachs R., Two Years After Alice: A Survey Of The Impact Of A "Minor Case" (Part 1), available online at <http://www.bilskiblog.com/blog/2016/06/two-years-after-alice-a-survey-of-the-impact-of-a-minor-case.html> (cites omitted).

<sup>9</sup> *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 579 U.S. \_\_\_ (2016).

<sup>10</sup> See 10/19/2016, ALICESTORM UPDATE FOR FALL 2016, online at <http://www.bilskiblog.com/blog/2016/10/alicestorm-update-turbulence-and-troubles.html>.

<sup>11</sup> *Id.*

Tech Center	Before Alice	6/14 Preliminary Guidance	12/14 Interim Guidance	7/15 Update	5/16 Examiner Memos
1600 Biotech & Chem	10.4%	13.7%	13.1%	10.9%	10.0%
1700 Chem. Eng.	1.5%	1.5%	1.5%	3.2%	0.9%
2100 Comp. Architecture	15.3%	15.4%	14.7%	11.9%	10.9%
2400 Networks & Video	10.2%	10.2%	13.3%	15.5%	13.1%
2600 Communications	7.8%	7.6%	8.8%	8.1%	8.6%
2800 Semiconductor, Elec., Opt.	1.9%	2.6%	2.9%	2.5%	3.0%
3600 Transportation & Construction	3.3%	4.3%	3.9%	3.7%	3.5%
3600 Business Methods	35.3%	76.6%	87.2%	86.3%	88.7%
3700 Mechanical	3.7%	6.1%	7.5%	6.1%	5.8%
Grand Total	6.8%	9.6%	10.5%	9.5%	8.6%

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In digging deeper into patent applications examined in group 3600, the situation is particularly dire, with rejections reaching as high as 93% for e-commerce-related inventions. These numbers are especially telling when compared with the much lower rejection rates in art units of “other” technology centers: <sup>12</sup>

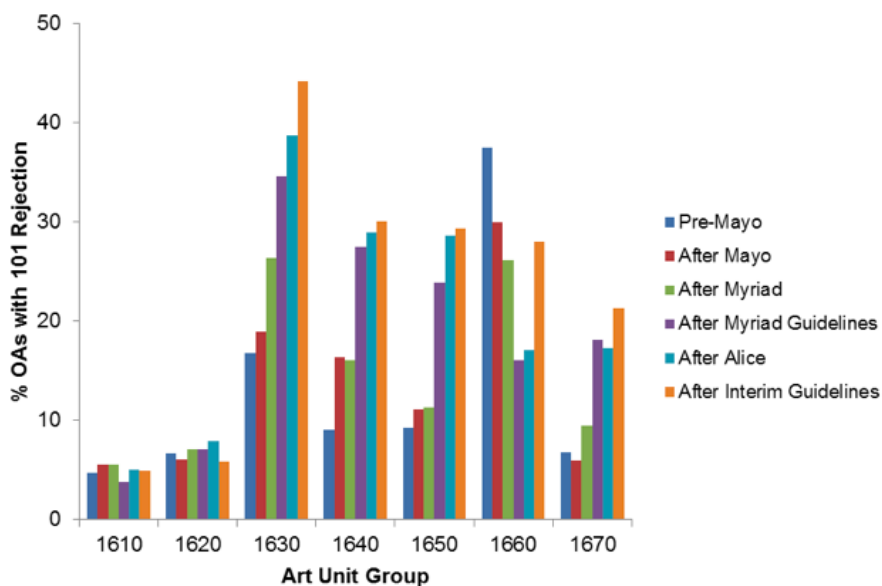
Percent of Non-Final v. Final Section 101 Rejections Per Guidance Period

Tech Type	Before Alice		6/14 Preliminary Guidance		12/14 Interim Guidance		7/15 Update		5/16 Examiner Instructions	
	Non-Final	Final	Non-Final	Final	Non-Final	Final	Non-Final	Final	Non-Final	Final
Biotech	20.2%	11.5%	24.3%	17.6%	21.5%	21.7%	18.9%	17.5%	16.9%	16.1%
Computers	20.3%	11.3%	21.2%	9.4%	23.0%	10.4%	23.0%	12.2%	20.0%	9.1%
Ecommerce	50.5%	32.6%	89.4%	53.4%	92.7%	92.3%	91.7%	89.6%	92.8%	92.0%
Other	6.2%	2.7%	7.9%	3.0%	8.1%	5.1%	7.7%	5.4%	7.2%	4.2%

The same trends are seen in “Trends in Subject Matter Eligibility for Biotechnology Inventions” by Gaudry, Grab and McKeon.<sup>13</sup> These authors collected 2012-2015 data from Group 1600 demonstrating that 101 rejections increased after each of Mayo, Myriad and Alice, and the problem got *worse* after the PTO published its Guidelines:

<sup>12</sup> *Id.*

<sup>13</sup> Published online at <http://www.ipwatchdog.com/2015/07/12/trends-in-subject-matter-eligibility-for-biotechnology-inventions/id=59738/>



Similar results were uncovered by Bernard Chao and Amy Mapes, who published an early analysis of their PTO data expressly for consideration in the *Sequenom* case.<sup>14</sup> Applications from art unit 1634 (“*Chemistry: Molecular Biology and Microbiology*”) have been coded, but to date only every tenth application has been coded (*i.e.*, 774 of 7,740 applications. From the 774 applications, 294 were selected as being drawn to personalized medicine).<sup>15</sup> However, the authors plan to continue their study and they “expect to publish a more complete analysis at a later date.”<sup>16</sup>

Based on this admittedly early data analysis, these authors concluded, “Only 15.9% of the office actions issued pre-Mayo had rejections under section 101 for subject matter eligibility,” but “[i]n contrast, 86.4% of the office actions issued post-Mayo had

<sup>14</sup> Bernard Chao & Amy Mapes, “*An Early Look at Mayo’s Impact on Personalized Medicine*,” 2016 PATENTLY-O PATENT L.J. 10, 12 (“Any decision the Supreme Court makes on patent eligibility [in *Sequenom v. Ariosa*] should be made with an understanding of how its decisions have impacted actual patent applications on new medical technologies, particularly in the emerging field of personalized medicine.”), available at <http://patentlyo.com/media/2016/04/Chao.2016.PersonalizedMedicine.pdf> (accessed April 7, 2016).

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

rejections under section 101 for subject matter eligibility.”<sup>17</sup> The authors further concluded, “Mayo has significantly increased patent eligibility rejection rates at the patent office” for at least this sampling of personalized medicine patents “with **rejection rates increasing over fivefold** after Mayo.”<sup>18</sup>

It seems that, while the Supreme Court cautioned us to “tread carefully in construing this exclusionary principle lest it swallow all of patent law,” *Alice Corp. v. CLS Bank Int’l*, 134 S.Ct. 2347, 2354, 573 U.S. \_\_\_\_ (2014), no one has been particularly cautious, with the result being administrative and judicial environments hostile to patent eligibility.

While the above-noted statistics are worrisome to innovators and investors who rely on a functioning patent system to fund the development of new technology, a specific example might convey with greater force the inadequacies of continuing to broadly apply the two-step eligibility test of *Mayo*, at least in the healthcare industry.

Teixobactin (TXB) is one such specific example. TXB is a new small molecule antibiotic isolated from soil bacteria. TXB is heralded as representing the first new class of antibiotics since 1987,<sup>19</sup> and is highly potent against a broad range of Gram-positive microbes, including tuberculosis and the superbug methicillin-resistant *Staphylococcus aureus*—otherwise known as “MRSA”<sup>20</sup>—which kills more Americans each year than

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<sup>17</sup> *Id.*

<sup>18</sup> *Id.* at 13 (emphasis added).

<sup>19</sup> Ling L.L., et al., “A new antibiotic kills pathogens without detectable resistance,” *NATURE* 517: 455–59 (2015) [hereinafter “Ling”], p. 458 (“Teixobactin is the first member of a new class of lipid II binding antibiotics . . .”).

<sup>20</sup> Ling, at p. 456, Table 1.



AIDS.<sup>21</sup> Further, TXB binds to **two** different targets in the cell,<sup>22</sup> making it that much more difficult for bacteria to develop resistance against the drug. In fact, when scientists tried deliberately to evolve strains of bacteria that resist the drug, they failed.<sup>23</sup> TXB appears to be essentially free of resistance,<sup>24</sup> and holds great promise as a game changer in the fight against microbial infections.

Although a patent application was filed for isolated TXB, the application's claims were rejected by the PTO as not eligible for patenting under the PTO's interpretation of *Myriad Genetics* because TXB is a natural product, and such discoveries, without more, are not patent eligible.<sup>25</sup> *See also, Myriad Genetics*, 133 S.Ct. 2107, 2117, 569 U.S. \_\_\_\_ (2013) ("Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention. Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.").<sup>26</sup>

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<sup>21</sup> See <http://mrsa-research-center.bsd.uchicago.edu> ("What disease kills more Americans a year than AIDS? If you don't know about MRSA, you're not alone.") (accessed April 7, 2016).

<sup>22</sup> Ling, at Abstract ("Teixobactin inhibits cell wall synthesis by binding to a highly conserved motif of lipid II (precursor of peptidoglycan) and lipid III (precursor of cell wall teichoic acid).").

<sup>23</sup> Ling, at p. 456 ("Resistance has not developed to this compound.").

<sup>24</sup> Ling, *see* Title.

<sup>25</sup> *See, e.g.*, U.S. Patent Appl. Ser. No. 14/095,415 Office Action of Sept. 8, 2014. A child case was filed to further pursue drug claims, although originally these too were rejected under § 101. *See* U.S. Patent Appl. Ser. No. 14/789,819 Office Action of Jan. 15, 2016 (rejecting claims under § 101). A drug claim did eventually issue drawn to TXB plus a "pharmaceutically-acceptable carrier that efficiently solubilizes the compound." *See* U.S. Patent No. 9,402,878. However, like the method claims, solubilizing carriers are routine and conventional, and thus under a broad application of *Mayo*, such claims may be illusory at best, falling when challenged in court.

<sup>26</sup> *Cf.* U.S. Constitution, art. III, § 8 ("The Congress shall have power . . . To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries").

Eventually, Applicants cancelled all claims to isolated TXB and instead pursued claims relating to methods of using TXB, which eventually issued as a patent.<sup>27</sup> While not providing patent protection as broad as one might like, method claims do have value.

Or do they?

Actually, the method claims could easily be invalidated under a two-step *Mayo* eligibility analysis, and such invalidation process would be particularly easy if no presumption of validity was recognized for claims being attacked under § 101. *See, Ultramercial v. Hulu, LLC*, 772 F.3d 709, 720-21 (Fed. Cir. 2014), *concurrency* by Judge Mayer (“Although the Supreme Court has taken up several section 101 cases in recent years, it has never mentioned—much less applied—any presumption of eligibility. The reasonable inference, therefore, is that while a presumption of validity attaches in many contexts, no equivalent presumption of eligibility applies in the section 101 calculus.”) (citation omitted).

Claim 1 of the method of use patent recites:

1. A method of treating a bacterial infection in a subject in need thereof, the method comprising administering to the subject an effective amount of a compound [TXB] or tautomer or pharmaceutically-acceptable salt thereof, thereby treating the bacterial infection in said subject.

According to the first step of the two-step analysis for patent eligibility under *Mayo*—at least as subsequently interpreted by the PTO and the Courts—TXB itself represents subject matter that is excluded from patent eligibility because it is a natural product.

The second step is to determine whether the claim further includes an inventive concept **beyond** any routine and conventional steps. *See, e.g., Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015) (“Because the claims at issue are directed to naturally occurring phenomena, we turn to the second step of *Mayo*’s framework. In the second step, we examine the elements of the claim to determine

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<sup>27</sup> *See* U.S. Patent No. 9,163,065 claiming methods of treating bacterial infections.

whether the claim contains an inventive concept sufficient to “transform” the claimed naturally occurring phenomenon into a patent eligible application.”).

Because administering antibiotics to treat infection has been around since penicillin was first developed for therapeutic use in the 1940s,<sup>28</sup> the method steps are routine and conventional. As such, a court could easily conclude that claim 1 offers nothing more than a patent ineligible concept (*i.e.*, natural product TXB) and the instruction to “use it” in a conventional way. Therefore, under the current understanding of *Mayo*, claim 1 could be held **not** patent eligible. *See Mayo*, 132 S.Ct. at 1300 (“simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.”); *Id.* at 1294 (“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.’”); and *Id.* at 1298 (“the claims inform a relevant audience about certain laws of nature; any additional steps consist of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.”).

Accordingly, a method-of-use claim for TXB does **not** offer “substantially more” than a routine use of a patent ineligible concept, which continues to poison the claim under the *Mayo* § 101 analysis as currently applied.

The TXB antibiotic does **not** represent an isolated example, nor an example of little practical relevance to society. Since the dawn of civilization, **most** pharmaceuticals have had their origins in natural products. Even today, significant percentages of drugs have active ingredients that are either found in nature, or are directly derived therefrom.

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<sup>28</sup> *See*, Susan Aldridge, John Parascandola & Jeffrey L. Sturchio, “*Discovery and Development of Penicillin*,” American Chemical Society & Royal Society of Chemistry (1999), available at <http://www.acs.org/content/acs/en/education/whatischemistry/landmarks/flemingpenicillin.html>, (“as of March 15, 1945, penicillin was distributed through the usual channels and was available to the consumer in his or her corner pharmacy.”; *Id.* at 8).

Indeed, in a review of new drugs approved over a recent thirty-year period, authors David Newman and Gordon Cragg have shown that each year roughly 30 to 40% of new drugs are either natural products or directly derived therefrom.<sup>29</sup> Therefore, a patent ineligibility holding under tests informed by *Mayo* (as currently applied) could be in the cards for 30 to 40% of new drugs. Since the Supreme Court declined to clarify *Mayo*<sup>30</sup>, *Mayo*'s impact on medicine is expected to be colossal, especially when the result in *Myriad* is taken in account.

In *Myriad*, the Supreme Court held that DNA is not patent eligible “merely because it has been isolated.”<sup>31</sup> However, most natural products have significant medical functionality not possible with the natural form of the product, and therefore should be patent eligible based on the new functionality imparted by isolation and/or purification.

Adrenaline is a good example. It was probably the first human hormone patented in 1906 in its purified form.<sup>32</sup> Adrenaline—also known as epinephrine—has saved countless lives and is still in use today. Indeed, many people carry an Epipen® and can testify to its life saving capabilities in the event of anaphylaxis.

The original adrenaline patent did not cover adrenaline in its natural form as found in a human being or animal. That could not be patented because it was not new. Instead, the patent only covered the purified form of the hormone, which at that time was new.<sup>33</sup> In fact, Judge Learned Hand noted that the inventor “was the first to make it available for any use by removing it from the other gland-tissue in which it was found,

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<sup>29</sup> David J. Newman & Gordon M. Cragg, “*Natural Products As Sources of New Drugs over the 30 Years from 1981 to 2010*,” J. NATURAL PROD. 75:311-335 (2012), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3721181/> See e.g., FIG. 5.

<sup>30</sup> *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 579 U.S. \_\_\_ (2016) (denying certiorari in spite of more than 20 amicus briefs urging the Court to take the case).

<sup>31</sup> *Myriad*, 133 S.Ct. at 2107.

<sup>32</sup> See U.S. 730,176 (1. A substance possessing the herein-described physiological characteristics and reactions of the suprarenal glands in a stable and concentrated form, practically free from inert and associated gland-tissue.”).

<sup>33</sup> *Id.*

and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.”<sup>34</sup> Thus, Learned Hand recognized that adrenaline as found in an animal’s glandular tissue had virtually no therapeutic use due to the low concentration and impurities, whereas the purified adrenaline had therapeutic (and commercial) value.

Insulin is another good example of a life saving natural product. It was first patented when Banting partially purified it from dog pancreas<sup>35</sup> and has saved countless lives since. One could treat diabetes by eating raw pancreas,<sup>36</sup> but that isn’t very practical in the event of diabetic coma. Thus, the discovery of at least partially purified insulin was a great therapeutic benefit to patients.

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<sup>34</sup> *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911) (the cited quote was arguably only dicta, but the analysis was correct).

<sup>35</sup> See U.S. 1,469,994, Extract obtainable from the mammalian pancreas or from the related glands in fishes, useful in the treatment of diabetes mellitus, and a method of preparing it. Claim 1: “A substance prepared from fresh pancreatic or related glands containing in concentrated form the extractive from the ductless portion of the glands sufficiently free from injurious substances for repeated administration and having the physiological characteristics of causing a reduction in blood sugar useful for the treatment of diabetes mellitus.”

<sup>36</sup> George Graham G., Treatment Of Diabetes By Raw Fresh Gland (Pancreas), *Br Med J.* 1(3357): 859–860 (1925).

Vitamin B12 is another natural compound patented in purified form.<sup>37</sup> Prior to the patent, anemia was treated by eating raw liver, and thus the discovery of purified B12 was great medical advance over consuming large quantities of raw liver.<sup>38</sup>

Even DNA has significant medical use when purified. Before any DNA is purified and sequenced it cannot be used in any diagnostic method. Indeed, before whole genome sequencing was invented no gene diagnostics could be performed without a small piece of purified DNA. Thus, at the time of the *Myriad* patents, even DNA had significant medical uses not possible using DNA in its natural form.

The Supreme Court came to the opposite conclusion:

Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention. Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry.<sup>39</sup>

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<sup>37</sup> U.S. 2,563,794 (“The compound vitamin B12 an organic substance containing cobalt, together with carbon, nitrogen, hydrogen, oxygen, and phosphorus, said compound being a red crystalline substance soluble in water, methyl and ethyl alcohol and phenol, and insoluble in acetone, ether and chloroform, and exhibiting strong absorption maxima at about 2780 A 3610 A. and 5500 5., and an L. L. D. activity of about 11,000,000 L. L. D. units per milligram.”). See also *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156 (4<sup>th</sup> Cir. 1958) (upholding Vitamin B12 patent U.S. 2,703,302 and stating “The patentees have given us for the first time a medicine which can be used successfully in the treatment of pernicious anemia, a medicine which avoids the dangers and disadvantages of the liver extracts, the only remedies available prior to this invention, a medicine subject to accurate standardization and which can be produced in large quantities and inexpensively, a medicine which is valuable for other purposes, as well as for the treatment of pernicious anemia. It did not exist in nature in the form in which the patentees produced it and was produced by them only after lengthy experiments. Nothing in the prior art either anticipated or suggested it.”).

<sup>38</sup> Whipple G.H. & Robscheit-Robbins F.S., Favourable influence of liver, heart and skeletal muscle in diet on blood regeneration in anemia. *Am J Physiol.* 1925; 72:408–18. Indeed, George Hoyt Whipple shared the 1934 Nobel Prize in Medicine with 1934 with George Richards Minot, and William Parry Murphy "for their discoveries concerning liver therapy in cases of anemia." See [https://en.wikipedia.org/wiki/George\\_Whipple](https://en.wikipedia.org/wiki/George_Whipple)

<sup>39</sup> *Myriad*, 569 U.S., slip op. at 12.

Of course, the Constitution is the higher law and provides otherwise. Article 1, Section 8 of the Constitution of the United States of America, gives congress certain powers, including the power “To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries...” Thus, the Supreme Court’s holding regarding the ineligibility of discoveries such as DNA for patent is arguably unconstitutional.

Given the mess we find ourselves in, a legislative correction may indeed be required. However, economic and societal needs in healthcare differ considerably from needs in e-commerce. Therefore, any proposals must consider these different needs in the two industries. Further, any legislative correction must somehow prevent the Supreme Court from continuing to muddle with 101 topics, under statutory or doctrinal grounds.

It may have once made sense to say abstract ideas, natural laws, elements, and such are not patent eligible, but it seems apparent that 102, 103 and 112 are already sufficient protection against overly ambitious patent claims.

David Kappos proposes to remove 101 from the statute, especially since most countries lack a 101-equivalent. However, given the Court’s willingness to contradict the statute and the Constitution, both of which provide that discoveries are patentable, it may also be necessary to strip the Supreme Court of patent jurisdiction to keep them from meddling.<sup>40</sup> This would be difficult, if not impossible, to implement, and Roberts Sachs proposal to add to the definitions in the statute seems like more likely to be enacted.

Mr. Sachs in his article “Twenty-Two Ways Congress Can Save Section 101,”<sup>41</sup> proposes the following additions to the definitions:

100(b)(1) The term “process” means process, art, [[or]] method, or algorithm, and includes any [[~~new~~]] use of a known process, machine, system, computer, manufacture,

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<sup>40</sup> See Davis, R., Kappos Calls For Abolition Of Section 101 Of Patent Act, Law360, available online at <https://www.law360.com/articles/783604/kappos-calls-for-abolition-of-section-101-of-patent-act>.

<sup>41</sup> Published online at <http://www.bilskiblog.com/blog/2015/02/twenty-two-ways-congress-can-save-section-101.html>

composition of matter, or material, regardless of physical embodiment or means of implementation.

100(b)(2) The term “machine” means a system or apparatus, made by human agency, regardless of physical embodiment or means of implementation.

100(k) A “law of nature” means an express statement of a physical, causal relationship governing the natural properties or behaviors of physical objects, and that is recognized by the relevant scientific community.

100(l) A “natural product” means a material, substance, composition as entirely as it appears in nature without any processing by human agency, and excludes any purified, simulated, copied, isolated, replicated product.

100(m) An “abstract idea” means a purely mental concept that is incapable of any physical embodiment and excludes any process performed by a computer program.

35 U.S. Code § 101 - ~~Inventions patentable~~ Eligible Subject Matter

101(a) ~~Whoever invents or discovers~~ A claimed invention directed to 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~~ shall be eligible for patenting by its inventor.

The proposed amendments are precise and directed to the problems at hand, and have the benefit that definitions may be easier to implement than other statutory changes. Further, who could argue with the definition of natural law? That is what a natural law is, Supreme Court opinion to the contrary. It is possible to argue that a “copied” natural product should not be patentable—after it still has to be new—but at the very least these amendments suggest a good starting point for discussion.

In the interim, the Patent Office can assist by focusing Examiner training on those few cases where eligibility has been upheld, and developing examples around such cases. It does little to alleviate the problem by repeating illogical statements from *Mayo* or extending suspect principles from *Myriad* to all natural products.



Sincerely,

Tamsen Valoir, PhD  
on behalf of the Houston Intellectual Property Law Association