An Early Look at Mayo's Impact on Personalized Medicine[1]

by Bernard Chao & Amy Mapes[2]

On March 21, 2016, a petition for *certiorari* was filed in *Sequenom v. Ariosa* asking the U.S. Supreme Court to clarify just what kinds of personalized medical inventions should be eligible for patent protection.[3] Many commentators had predicted that the Supreme Court's recent decisions in *Mayo v. Prometheus*[4]*,* and *Association for Molecular Pathology v. Myriad Genetics*[5] would radically limit the number and type of medical technologies entitled to patent protection. Indeed, Sequenom's petition argues that this is precisely what has happened and that "this error will fatally undermine the biomedical field."[6] Of course we can assess how medical inventions are currently faring at the patent office under the new rules for patent eligibility. That is precisely the kind of information that should inform decision makers as patent eligibility law continues to develop. Accordingly, this post reports on the preliminary results of a study, Amy Mapes J.D. '17, is currently conducting under the supervision of Bernard Chao at the University of Denver Sturm College of Law. Even though the study is not complete, we are sharing some of the data now because of the importance of Sequenom's pending petition.

Up until 2012, the idea of patenting medical breakthroughs was not particularly controversial. Laws of nature, natural phenomena, and abstract ideas were not eligible for patent protection under 35 U.S.C. § 101. However, the vast majority of medical inventions were not classified as mere laws of nature, but instead as patentable applications of those laws. As long as those inventions were new and non-obvious, their inventors could obtain patent protection. That suddenly changed

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[3] *Mayo Collaborative Servs. v. Prometheus Labs., Inc*., 132 S. Ct. 1289 (2012).

[4] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc*., 133 S. Ct. 2107, 186 L. Ed. 2d 124 (2013).

[5] Petition for Writ of Certiorari, *Sequenom, Inc. v. Ariosa Diagnostics Inc*., *et al.*, No. 15-1182 (petition for cert. filed March 21, 2016).

[6] *Id*. at. 30.

with the Supreme Court's 2012 *Mayo decision*.

Under *Mayo*'s two-step framework, the patent office must first determine whether a patent covers an unpatentable concept.[7] If it does, the office must determine whether the patent has added "enough" to render the claim patent eligible.[8] That means that the patent must add an "inventive concept" beyond the discovery of any underlying natural phenomena.[9]   Many commentators have theorized that this interpretation of § 101 would make it difficult for inventors to obtain patents on new medical therapies including personalized medicine technologies. Immediately after Mayo, one of the co-authors worried that *Mayo*'s "reasoning unnecessarily jeopardize[d] many deserving patents that have not previously been thought to have any exposure under 35 U.S.C. § 101."[10] Similarly, Christopher Holman argued that the "*Mayo* Court's interpretation of law of nature suggests that personalized medicine discoveries will be characterized as patent ineligible natural phenomena."[11] That fear was only reinforced after *Myriad* followed *Mayo*'s framework and invalidated claims covering isolated DNA that could be used to identify women predisposed to developing certain forms of cancer. Even though some claims (*i.e.* covering cDNA) were left intact, Rebecca Eisenberg wrote that "diagnostic technology" was no longer patent eligible.[12]

Based on these theorized fears, Chao and Lane Womack sought to determine what impact the Supreme Court's decisions in *Mayo* and *Myriad* have had on the eligibility of important medical breakthroughs.[13] In December 2014, they reported that the patent office had, at least initially, rejected applications on treatments for cancer, AIDS and tuberculosis on eligibility grounds because these inventions apparently just covered natural laws.[14] The report was admittedly limited. It did not randomly sample applications. Instead, the authors deliberately sought out applications covering specific medical therapies that were being rejected. Accordingly, they could not say how often these rejections were taking place nor could they compare these rejections to rejections that occurred prior to *Mayo*.

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[7] Mayo, 132 S.Ct. at 1296.

[8] *Id*. at 1297.

[9] Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 645 (2015) (noting that "Mayo's inventive concept requires inventive application for a law of nature or abstract idea to become patent eligible.").

[10] Bernard Chao, *Moderating Mayo*, 107 NW. U. L. REV. 423 (2012).

[11] Christopher M. Holman, *Mayo, Myriad, and the Future of Innovation in Molecular Diagnostics and Personalized Medicine*, 15 N.C. J. L. & TECH. 639, 677 (2014).

[12] Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256, 285 (2015).

[13] Bernard Chao & Lane Womack, *USPTO Is Rejecting Potentially Life-Saving Inventions*, Law360 (December 18, 2014).

[14] *Id.*

To fill in this gap, we (Chao and Mapes) began to systematically assess the impact of *Mayo* on medical inventions. An important caveat, this project started in January 2016 and we expect to publish a more complete analysis at a later date. However, because of Sequenom's petition, we thought it was important to disclose the data that we collected to date. Any decision the Supreme Court makes on patent eligibility 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.

Personalized medicine applications appear to be concentrated in art units 1634, 1637, 1639, 1644, 1648, 1651, 1652, and 1674. Because of the large number of patent applications in these art units, we decided to limit the initial analysis to unit 1634. That art unit appeared to have the largest number of personalized medicine applications. In general, art unit 1634 covers methods for measuring or testing processes involving enzymes or micro-organisms. Even then, there were 7,740 applications filed after January 1, 2006 (*Mayo* was decided on March 21, 2012).[15] To reduce the coding load, Mapes reviewed every 10th application resulting in 774 applications.[16] She then determined whether each application was drawn to personalized medicine technology.[17] The result was 294 applications in the data set discussed here. Mapes reviewed each office action for each application file history to determine whether it included any rejections based on subject matter eligibility grounds. Section 101 rejections that were not related to subject matter eligibility, such as lack of utility, were excluded. So that others can verify and build upon our findings, we have provided a link to the spreadsheet containing the data.[18]

The results show that § 101 rejections rose dramatically after *Mayo*. Over the 294 applications, 520 office actions were issued between August 2007 and March 2016. Of those office actions, 188 were issued pre-*Mayo* and 332 were issued post-*Mayo*. Only 15.9% of the office actions issued pre-*Mayo* had rejections under section 101 for subject matter eligibility. In contrast, 86.4% of the office actions issued post-Mayo had rejections under section 101 for subject matter eligibility. The chart below illustrates how these rejections breakdown in the years that precede and follow *Mayo*.

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[15] The sample set was limited to published applications.

[16] Only applications whose serial numbers ended in a zero (0) were examined.

[17] Applications directed to the diagnosis or treatment of a specific disease, or to specific markers were included. All other types of applications were excluded. For example, numerous applications directed to methods of working with DNA generally, but that did not reference a relationship between a marker and a disease or its treatment, were not included in the data set.

[18] Patentlyo.com/mapes-data-march-31-2016.

Office Actions with 101 Subject Matter Eligibility Rejections
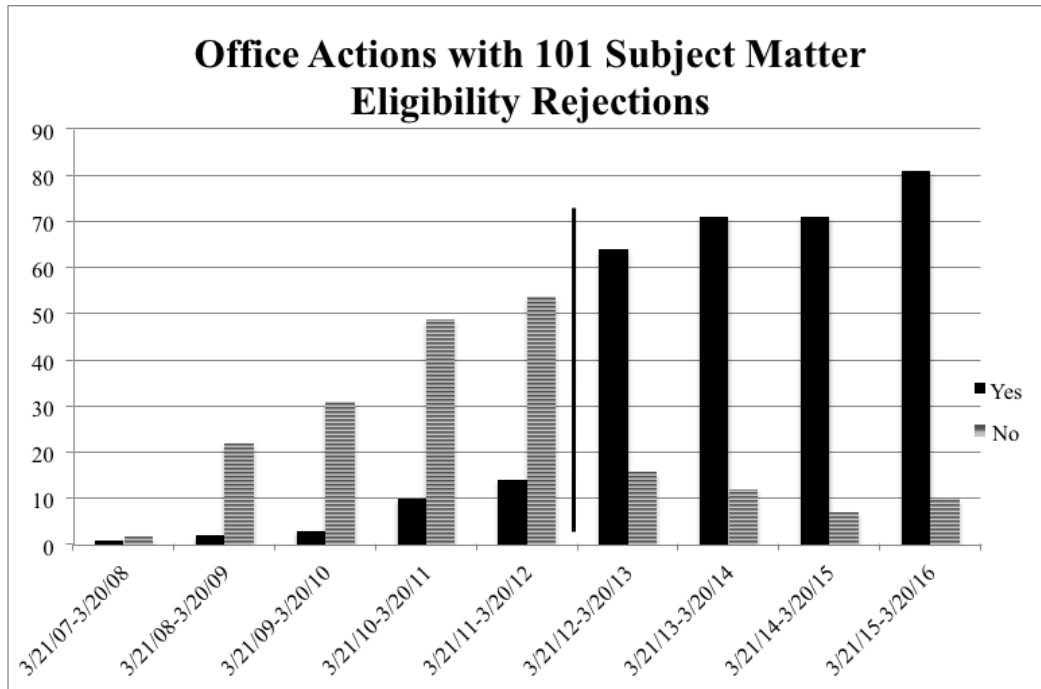
The percentage of office actions that contained § 101 subject matter eligibility rejections abruptly increased after *Mayo* was decided on March 20, 2012. The percentage of such rejections then continued to gradually increase every year until last year. Thus, it's clear that *Mayo* has significantly increased patent eligibility rejection rates at the patent office for at least one class of patents.

Now it is hardly surprising that fewer patents would issue after *Mayo*, *Myriad* and *Alice v CLS Bank*.[19] But as the courts and policymakers consider refining, or possibly changing, the limits of subject matter eligibility, it's important that they understand both the types and numbers of inventions that are being denied patent protection. We suspect that while there is some hostility to protecting software, most judges and legislators believe that patents on medicines and personalized medicine technology provide important incentives. To the extent that is true, our initial findings should raise some concern. The early look at the data suggests that protection for personalized medical inventions is in jeopardy with rejection rates increasing over five fold after *Mayo*.

Of course we hope to collect more data. It is quite possible that applicants can somehow overcome subject matter eligibility rejections.   Perhaps, certain arguments can persuade examiners to withdraw their rejections.   Alternatively, adding particular claim limitations might avoid subject matter eligibility rejections while still sufficiently covering the subject matter. If either of these possibilities

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[19] *Alice Corp. Pty. Ltd. v. CLS Bank Int'l.*, 134 S. Ct. 2347 (2014) (the Supreme Court's decision narrowing what software is now patent eligibility).

turns out to be true, applicants may still be able to obtain some level of protection for their personalized medicine inventions. Accordingly, we hope to examine different kinds of applicant responses and their effectiveness as well as overall application outcomes.

In addition, art unit 1634 may not be representative of the larger universe of personalized medical applications. To solve this problem, we just began working with Patent Advisor's prosecution history database.[20] We have asked Patent Advisor to generate pre-and post-*Mayo* metrics on patent applications in all eight of the art units identified earlier. Such metrics will be created by automated computer queries instead of the hand coding that we relied upon to date. We hope that policymakers will use both our current and future findings to understand the ramifications of the Supreme Court's recent subject matter eligibility revolution and make adjustments as appropriate.

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[20] As full disclosure, LexisNexis Patent Advisor has agreed to give Professor Chao discounted access to their database in exchange for explaining how he uses their data in blog postings.