June 27, 2013

PERKINELMER INC. V. INTEMA LTD. AND PATENT-ELIGIBILITY OF DIAGNOSTIC SCREENING METHODS AFTER MAYO V. PROMETHEUS

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PERKINELMER INC. V. INTEMA LTD. AND PATENT-ELIGIBILITY OF DIAGNOSTIC SCREENING METHODS AFTER MAYO V. PROMETHEUS

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Anticipated Graduation: Spring 2013 (JD)

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I. INTRODUCTION

In December 2011, the Supreme Court issued its ruling in *Mayo v. Prometheus*, reversing the Federal Circuit based on unpatentable subject matter in a diagnostic method patent. In *Mayo*, the patent disclosed a method for determining the correct drug dosage based on the drug’s metabolite in a patient’s blood. The method was declared patent-ineligible because instead of teaching an application of laws of nature, the teachings only directed doctors to “apply it” - all disguised under the conventional steps such as “administering”, “measuring” and “determining”.

Following the Court’s holding, the Federal Circuit in November 2012 issued a similar ruling in *PerkinElmer Inc. v. Intema Ltd.*, a case also involving a diagnostic screening method patent. The critical step of “comparing” markers from first trimester and second trimester using statistical methods to determine the likelihood of Down’s syndrome in fetus as in the court’s view, was nothing more than a mental step.

Although in *Intema*, the § 101 subject matter issue was raised primarily as an alternative theory for patent invalidity, the court focused on the § 101 subject matter issue exclusively. Notwithstanding the fact that Intema enjoyed a great deal of success in the

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2 See id. at 1294.
3 *PerkinElmer, Inc. v. Intema Ltd.*, No. 2011-1577, 496 F. Appx 65 (Fed. Cir. Nov. 20, 2012) (not reported in F.3d) [hereinafter Intema].
4 See id. at 70.
7 See Intema, 496 F. Appx at 67.
commercial world because of the breakthrough methodologies\(^8\), the court invalidated the patent. This is because as promulgated in *Mayo*, teaching the doctors to apply statistical modeling\(^9\) of data was patent ineligible.\(^10\)

This paper will examine the deficiencies in Intema’s claims in light of the court’s holding. Particularly, this paper will study how the teaching in *Mayo* was followed by the court in finding that Intema did not obtain claims to § 101 subject matter. As a practical matter, this paper will suggest the necessary modifications in Intema’s claims so that as a whole, the claims could be patent eligible under § 101. Along the way, this paper will try to point out any public policy noted by the court on how the diagnostic screening methods should operate under the patent system.

II. FACTS

Intema Limited (“Intema”, Defendant-Appellant) appealed the decision of the United States District Court for the District of Massachusetts granting summary judgment to PerkinElmer, Inc. and NTD Laboratories, Inc. (collectively, “PerkinElmer”, Plaintiff-Appellee). This appeal arose from an action seeking a declaratory judgment that PerkinElmer did not infringe Intema’s patent - U.S. Patent No. 6,573,103 (“the ’103 patent”),

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\(^9\) See *Mayo*, 132 S.Ct. at 1302 (“They tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe.”).

\(^10\) See *Intema*, 496 F. Appx at 73 (“It is the “two data points are better than one” concept which is the focus of the claims; that concept simply does not depend on the method by which the data points are obtained.”).
and that the '103 Patent was invalid. Intema separately filed suit against PerkinElmer for patent infringement in the Eastern District of New York. The New York court transferred the infringement suit to the District of Massachusetts. The district court ordered that the two cases be consolidated. Intema’s infringement claim became a counterclaim in this case. “The district court determined that the '103 patent was drawn to patent-eligible subject matter under 35 U.S.C. § 101, but held that the asserted claims were anticipated and obvious.”

The '103 patent disclosed specific statistical methods to estimate the risk of fetal Down’s syndrome. If the risk was high enough, the doctor would order invasive diagnostic testing to determine definitively whether the fetus has Down’s syndrome.” These tests, however, carried a significant risk of miscarriage. Doctors would prefer non-invasive, but accurate screening methods over performing unnecessary diagnostic testing.

Before the 1990s, the screening methods involved looking at maternal age and certain biochemical screening markers from the second trimester of pregnancy. By the 1990s, however, doctors also considered the biochemical markers and measurements from

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12 Id.
13 Id.
14 Id.
15 Id.
16 Intema, 496 F. Appx at 66.
17 Id.
18 Id.
19 Id.
20 Id.
21 Markman Order, 2010 WL 2682423 at 1.
ultrasounds from the first trimester.\textsuperscript{22} The patent at issue in this case was obtained by Professor Nicholas Wald. The patent described the screening methods in which doctors estimated the risk of Down’s syndrome using markers from both the first and second trimesters based on the Gaussian distribution model and the multivariate Gaussian model.\textsuperscript{23}

According to Intema, the ‘103 patent subject matter eventually gained acceptance and became a standard in American Congress of Obstetricians and Gynecologists (ACOG), and was listed in ACOG as “best” screening tests in 2007.\textsuperscript{24} According to Intema, California had used the integrated tests since 2009 for thousands of tests,\textsuperscript{25} and PerkinElmer and NTD had employed a few Down’s syndrome tests that infringe on this patent.\textsuperscript{26}

\section*{III. LEGAL BACKGROUND}

When \textit{Intema} was appealed, the Federal Circuit had already ruled in \textit{Myriad} that “Myriad’s challenged method claims were indistinguishable from the claims the Supreme Court found invalid under § 101 in \textit{Mayo}.”\textsuperscript{27} Myriad claimed single-step methods for comparing DNA sequence to assess cancer risks.\textsuperscript{28} Although Myriad contended that, when combined with the DNA sequencing steps in the specification, its claims for comparing DNA

\textsuperscript{22} \textit{Id.}
\textsuperscript{23} \textit{Id.} at 72.
\textsuperscript{24} \textit{See the Appellant’s Brief} at 13.
\textsuperscript{25} \textit{See id.} at 26.
\textsuperscript{26} \textit{Markman Order}, 2010 WL 2682423 at 1.
\textsuperscript{27} \textit{See Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office}, 689 F.3d 1303, 1335 (Fed. Cir. 2012) cert. granted in part, 133 S. Ct. 694, 184 L. Ed. 2d 496 (U.S. 2012) [hereinafter \textit{Myriad}].
\textsuperscript{28} \textit{Id.} at 1309.
sequence would qualify the methods a § 101 subject matter. But the court decided against combining the DNA sequencing steps because that would mean reading the specification limitation into the claims. Therefore, although both Mayo and Myriad applied to Intema, Intema was truly the first case after Mayo in which the court ruled on a diagnostic method that had multiple steps in the claims.

IV. THE GUIDANCE OF THE SUPREME COURT

Patent-eligible subject matter is defined in 35 U.S.C. § 101 as: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this Title.” The Court has long held that this provision contains an important implicit exception. “Laws of nature, natural phenomena, and abstract ideas’ are not patentable.” The Court has repeatedly emphasized a concern that patent law not inhibit future discovery by improperly tying up the use of laws of nature and the like.” “Rewarding with patents those who discover laws of nature might encourage their discovery.” But because those laws and principles are the basic tools of scientific and technological work, there is a danger that granting patents that tie up their use will inhibit future innovation, a danger that becomes acute when a patented process is no more

29 See Id. ("Although the application of a formula or abstract idea in a process may describe patent-eligible subject matter, Myriad’s claims do not apply the step of comparing two nucleotide sequences in a process. Rather, the step of comparing two DNA sequences is the entire process that is claimed.").
30 See Intema, 496 F. Appx at 69 ("The Supreme Court's decision in Mayo and this court's recent decision in Ass'n for Molecular Pathology v. PTO . . ., dictate the result we reach today.").
32 Mayo, 132 S.Ct. at 1289.
33 Id. (quoting Diamond v. Diehr, 450 U.S. 175, 185).
34 Id. at 1292.
35 Id.
than a general instruction to ‘apply the natural law,’ or otherwise forecloses more future invention than the underlying discovery could reasonably justify.”  

Although the Court cautioned that there were inventive steps that could “transform an unpatentable law of nature into a patent-eligible application of such a law,” a patent must do more than simply state the law of nature while adding the words ‘apply it’. The Court was also wary that a clever draftsman would try circumventing the prohibition by adding “well-understood, routine, conventional activity previously engaged in by scientists in the field,” adding also that “the prohibition against patenting abstract ideas ‘cannot be circumvented by attempting to limit the use of the formula to a particular technological environment’ or adding ‘insignificant postsolution activity.’”

In Mayo, the Court also set firm the strict exclusion of laws of nature regardless of how other provisions (e.g. § 102, § 103, § 112) could possibly supplement the § 101 inquiry. Because, “to shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.” Similarly, the Court voiced reluctance in giving varying § 101 scopes in different fields of endeavor because public policy issues must be dealt with by Congress.

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36 Id. (internal quotation marks omitted).
37 Id. at 1292 (“These additional steps transformed the process into an inventive application of the formula.” (citing Diehr as an example)).
38 Id., at 1290, 1294.
39 Id. at 1291, 1294.
40 Id. at 1294 (citing Bilski, 130 S.Ct. at 3230) (emphasis added).
41 Id. at 1304.
42 See id. at 1305 (“In consequence, we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary.”).
On the other hand, the Court in *Bilski*, *Diehr*, and *Chakrabarty* repeatedly warned that courts should not categorically reject a subject matter such as business methods, manufacturing process and living organisms, or read into patent laws limitation and conditions which the legislature has not expressed.

Federal Circuit took this issue seriously as well. It warned not to categorically reject such correlation based diagnostic methods. After all, laws of men are also laws of nature.

**V. THE MACHINE OR TRANSFORMATION TEST**

“The machine-or-transformation test is a ‘two- Branched inquiry,’ i.e., the patentee ‘may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article.’” The machine-or-transformation test has two further aspects: ‘the use of a specific machine or transformation of an article must impose meaningful limits on the claim’s scope to impart

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46 See *Myriad*, 689 F.3d at 1330 (“But the Supreme Court has more than once cautioned that courts ‘should not read into the patent laws limitations and conditions which the legislature has not expressed,’ *Bilski*, 130 S.Ct. at 3226 (quoting *Diehr*, 450 U.S. at 182, 101 S.Ct. 1048), and has repeatedly rejected new categorical exclusions from § 101’s scope, see id. at 3227–28 (rejecting the argument that business method patents should be categorically excluded from § 101); Chakrabarty, 447 U.S. at 314–17, 100 S.Ct. 2204 (same for living organisms).”).
47 See *Myriad*, 689 F.3d at 1331.
48 See *Id.* (“But the compositions here are not natural products. They are the products of man, albeit following, as all materials do, laws of nature.”).
patent-eligibility, and the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity.”50

Before the Supreme Court in Mayo reversed the Federal Circuit’s judgment, the Federal Circuit held that “the proper inquiry under § 101 is whether these methods meet the Supreme Court’s machine or transformation test articulated in Benson and Diehr, and applied in Bilski, and, if so, whether the machine or the transformation is central to the purpose of the claims.”51 It suggested that the process could be a § 101 subject matter by being embodied into a machine or being capable of transforming an article from one state to another.52 It insisted the § 101 subject matter was obtained under the machine or transformation test, because by administering specific drugs, the central transformative methods altered a patient’s body chemistry.53

But since Bilski, the Court held that the “machine or transformation test” is not a definitive test of patent eligibility, but only an important and useful clue.54

Again, in Mayo, the “machine or transformation test” was set aside by the Court, where the Court found relationship based claims55 needed “significantly more than simply describe these natural relations.”56 Instead of simply reversing the Circuit’s finding based

50 Id. at 1343 (quoting the circuit’s Bilski, 545 F.3d at 961-62).
51 Id. at 1345.
52 See id. (“We conclude that the methods of treatment claimed in the patents in suit squarely fall within the realm of patentable subject matter because they ‘transform an article into a different state or thing,’ and this transformation is ‘central to the purpose of the claimed process.’”).
53 See id. at 1347 (“The transformation is of the human body following administration of a drug and the various chemical and physical changes of the drug’s metabolites that enable their concentrations to be determined.”).
54 See Mayo, 132 S.Ct. at 1296.
55 See id. (“Prometheus’ patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.”) (emphasis added).
56 See id. at 1297.
on the step of administering drug to transform a human body\textsuperscript{57}, the Court posted the § 101 subject matter question on the post-solution step of determining results. The question was: 

“do the patent claims add \textit{enough} to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?”\textsuperscript{58}

In the Court’s eyes, the “administering”, “measuring” and “determining” steps were routine.\textsuperscript{59} To help answering the question, the Court directed the § 101 subject matter test to \textit{Flook}\textsuperscript{60} and \textit{Diehr}. If the post-solution activity was similar to \textit{Flook} (setting alarm limits), then the § 101 statutory subject matter was not obtained.\textsuperscript{61} If the post-solution activity was similar to \textit{Diehr} (automatically opening the press), then the § 101 statutory subject matter was obtained\textsuperscript{62}.

\section*{VI. HOLDING AND FINDING}

In \textit{Intema}, the court held that “purely ‘conventional or obvious presolution activity’ is normally not sufficient to transform an ineligible law of nature into a patent-eligible application of such a law.”\textsuperscript{63} The court found that was the case in \textit{Intema}. Once those conventional steps were eliminated from the consideration, the only remaining

\begin{itemize}
  \item \textsuperscript{57} See id. (“While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes.”).
  \item \textsuperscript{58} Id. (emphasis in original).
  \item \textsuperscript{59} See id., at 1298 (“A more detailed consideration of the controlling precedents reinforces our conclusion. The cases most directly on point are \textit{Diehr} and \textit{Flook}, two cases in which the Court reached opposite conclusions about the patent eligibility of processes that embodied the equivalent of natural laws.”).
  \item \textsuperscript{60} \textit{Parker v. Flook}, 437 U.S. 584, 98 S. Ct. 2522, 57 L. Ed. 2d 451 (1978).
  \item \textsuperscript{61} \textit{See Mayo}, 132 S. Ct. at 1299 (“The claim before us presents a case for patentability that is weaker than the (patent-eligible) claim in \textit{Diehr} and no stronger than the (unpatentable) claim in \textit{Flook.”}.
  \item \textsuperscript{62} See id.
  \item \textsuperscript{63} \textit{Intema}, 496 F. Appx at 71.
\end{itemize}
determining step was only a mental step, making the whole claimed invention a § 101 ineligible subject matter under *Myriad, Mayo* and *Flook*. 64

The court further said that, even if the test were satisfied, these claims would remain unpatentable because it was the “two data points are better than one” concept which was the focus of the claims. 65

**VII. ANALYSIS**

**A. THE BALANCE AMONG PATENTEES, COMPETITORS AND THE PUBLIC**

Besides claiming the unpatentable § 101 subject matters, *Mayo* and *Intema* have other common factors, such as the success in licensing and the timing of the litigation. In *Mayo*, Prometheus was the sole and exclusive licensee. Prometheus sold licensed tests to Mayo. 66 It was only after 2 years of using and practicing the patent, that Mayo decided to pursue an improved method of its own. 67 In *Intema*, again, Intema licensed its patent to 24 licensees through 2010. 68 That was 6 years before PerkinElmer decided to market the same diagnostic method. 69 As an equity matter, it would seem to be unfair for competitors to just wait out until patentees or licensees gained significant market success before claiming the patents invalid, all for the purpose of freely practicing the patented subject matters.

64 *See id.* at 72 (“The claims held patent-eligible in *Myriad*, and the reasoning underlying that decision, bolster our decision here.”) (“The purported transformation resulting from ‘assaying a sample’ is insufficient since it could be performed ‘without transforming the [sample], should science develop a totally different system for [assaying for a biochemical screening marker] that did not involve such a transformation.’” (quoting *Mayo*, 132 S.Ct. at 1303)) (“The claims do not require that an ultrasound be taken, only that data from previous ultrasounds be assessed. Even if required as part of the claimed processes, the data-gathering steps are conventional and obvious extra-solution activity that cannot save the claims.” (citing *Flook*, 437 U.S. at 590, 98 S.Ct. 2522)).

65 *See id.*

66 *See Mayo*, 132 S.Ct. at 1291.

67 *See id.*

68 *See supra* note 7, at 2.

69 Timing is based on the '103 patent grant date of 03/06/2003 and the initial litigation date in 2010.
A long time for competitors to catch on suggests that the diagnostic methods in *Mayo* and *Intema* were cutting edge technology at the time of their inventions. Nevertheless, they were held patent ineligible, even though they provided the public with appreciable knowledge by formulating the diagnostic methods that bridge the gap between a medical practitioner and a statistician. But precisely because the patents taught doctors how to analyze patient information without undue burden, over time, that knowledge gradually became well known.

As a result of the patented methodologies gaining acceptance, the competitors attempt to copy the methodologies, triggering suits like *Mayo* and *Intema*. The competitors and their supporters “argue strongly against a legal rule that would make the present claims patent eligible, invoking policy considerations that point in the opposite direction.”

The courts agreed with the competitors. The Court in *Mayo* noted that the competitors should be allowed to improve the diagnostic method disclosed by Prometheus, as the risk for tying up any further innovation, even long after the initial discovery, would outweigh

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70 In *Mayo* it took two years for competitor to copy the patent. In *Intema*, it took 6 years.
71 See *Graham v. John Deere*, 383 U.S. 1, 17 (1966) (“Objective evidence of non-obviousness (referred to as secondary considerations) may comprise commercial success, long felt but unresolved need, failure of others, copying, unexpected superior results over the prior art, praise for the invention or surprise at the making of the invention, and acceptance of licenses because of the merits of the claimed invention.”) (emphasis added).
72 See *Mayo*, 132 S.Ct. at 1289 (“While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”) (emphasis added)); see also *id.* at 1304 (citing several *amici* that “denying patent coverage here will interfere significantly with the ability of medical researchers to make valuable discoveries, particularly in the area of diagnostic research”); *Intema*, 496 F. Appx at 66 (“Accordingly, accurate non-invasive screening methods are desirable to avoid performing unnecessary diagnostic testing.”).
74 See *Mayo*, 132 S.Ct. at 1304-05 (citing various *amicus curiae* briefs against patentee).
75 See, e.g. *id.* at 1293; *Intema*, 496 Fed.Appx. at 69 (Both courts cited the Chakrabarty case in support, that “discoveries are manifestations of ... nature, free to all men and reserved exclusively to none.”).
the narrow scope of protection to Prometheus.\textsuperscript{76} The Court said that to continue giving Prometheus the patent rights was wrong because “they threaten to inhibit the development of more refined treatment recommendations (like that embodied in Mayo’s test), that combine Prometheus’ correlations with later discovered features of metabolites, human physiology or individual patient characteristics.”\textsuperscript{77}

Public interest, noted by the Court in\textit{ Mayo}, further complicated the equity issue between the patentees and their competitors.\textsuperscript{78} Perhaps the public are especially averse to paying for information that is old.\textsuperscript{79} That is because continuing patent protection would be an equivalent act of restricting the spread of information that is already in the public domain.\textsuperscript{80} Supporters of Prometheus said that without patent protection, it would be hard to ask inventors of diagnostic screening methods to disclose their expensive discoveries to the public.\textsuperscript{81} The public interest would be harmed if inventors of patentable methods were forced into choosing trade secret protection.\textsuperscript{82} But on balance, the Court in\textit{ Mayo} was not so convinced - citing W. Landes & R. Posner,\textit{ The Economic Structure of Intellectual Property}

\textsuperscript{76} See\textit{ Mayo}, 132 S.Ct. at 1302 (“The laws of nature at issue here are narrow laws that may have limited applications, but the patent claims that embody them nonetheless implicate this concern.”).

\textsuperscript{77} \textit{Mayo}, 132 S.Ct. at 1292.

\textsuperscript{78} Cf.\textit{ id}., at 1301 (quoting the Morse Court, “yet if it is covered by this patent the [future] inventor could not use it, nor the public have the benefit of it without the permission of this patentee.”\textit{ O’Reilly v. Morse}, 56 U.S. 62, 113, 14 L. Ed. 601 (1853)).

\textsuperscript{79} In\textit{ Mayo}, the patent was granted in 2002. In\textit{ Intema}, the patent was granted in 2003.

\textsuperscript{80} Cf.\textit{ Id}., at 1301 (“The Court has repeatedly emphasized this last mentioned concern, a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature.”).

\textsuperscript{81} See\textit{ Mayo}, 132 S.Ct. at 1304 (“On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery.”). Cf.\textit{ id}., (citing an argument from several amici, “that research, which includes research leading to the discovery of laws of nature, is expensive; it ‘has made the United States the world leader in this field’; and it requires protection.”).

\textsuperscript{82} See\textit{ Kewanee Oil Co. v. Bicron Corp.}, 416 U.S. 470, 489 (1974) (“The final category of patentable subject matter to deal with is the clearly patentable invention, i.e., that invention which the owner believes to meet the standards of patentability. It is here that the federal interest in disclosure is at its peak; these inventions, novel, useful and nonobvious, are the things which are worth to the public the embarrassment of an exclusive patent.” (internal quotation marks omitted)).
Law,\textsuperscript{83} that “the exclusion from patent law of basic truths reflects ‘both ... the enormous potential for rent seeking that would be created if property rights could be obtained in them and ... the enormous transaction costs that would be imposed on would-be users of those truths’.”

On the other hand, the Federal Circuit in \textit{Myriad} was not so “focused on its concern that permitting patents on particular subject matter would prevent use by others.”\textsuperscript{84} Arguably, a gene is useful because of the information it contained.\textsuperscript{85} It is therefore surprising for the Federal Circuit in \textit{Myriad} to say that “permitting patents on isolated genes does not preempt a law of nature.”\textsuperscript{86} Although not as extensively as the Court in \textit{Mayo}, the Federal Circuit in \textit{Myriad} also discussed the public interest in gene research. In its holding, the Federal Circuit said that even if further research into a gene could be beneficial to the public, the public should still be preempted from using the patent by the full term of the patent, notwithstanding how short the patents were set to expire.\textsuperscript{87}

\textbf{B. SCREENING METHODS DRAFTING AFTER DIEHR}

In \textit{Diehr} - the invention of a process curing rubber in a press, Claim 1 is representative and reads:\textsuperscript{88}

1. A method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer, comprising:

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\textsuperscript{84} See \textit{Myriad}, 689 F.3d at 1331.
\textsuperscript{85} Cf. \textit{id.} at 1316 (“The court relied on the fact that, unlike other biological molecules, DNAs are the ‘physical embodiment of information,’ and that this information is not only preserved in the claimed isolated DNA molecules, but also essential to their utility as molecular tools.”).
\textsuperscript{86} Cf. \textit{id.}
\textsuperscript{87} See \textit{id.}, 689 F.3d at 1331 (“When the patent expires, the public is entitled to practice the invention of the patent. That is true of all inventions; during the term of the patent, unauthorized parties are ‘preempted’ from practicing the patent, but only for its limited term.”)
providing said computer with a data base for said press including at least,

natural logarithm conversion data (ln),

the activation energy constant (C) unique to each batch of said compound
being molded, and

a constant (x) dependent upon the geometry of the particular mold of the
press,

initiating an interval timer in said computer upon the closure of the press for
monitoring the elapsed time of said closure,

constantly determining the temperature (Z) of the mold at a location closely
adjacent to the mold cavity in the press during molding,

constantly providing the computer with the temperature (Z),

repetitively calculating in the computer, at frequent intervals during each
cure, the Arrhenius equation for reaction time during the cure, which is

\[ \ln v = C Z x \]

where \( v \) is the total required cure time,

repetitively comparing in the computer at said frequent intervals during the
cure each said calculation of the total required cure time calculated with the
Arrhenius equation and said elapsed time, and

opening the press automatically when a said comparison indicates
equivalence.

In the Court’s eyes, the industrial processes such as Diehr’s claims for transforming
raw, uncured synthetic rubber into a different state or thing were the types which had
historically been eligible to receive patent-law protection.\(^9\) The Court noted that the
combination of the press and computer was novel and unobvious.\(^9\) Not only the
temperature sensor readings inside the press were continuously put to use by the

\(^8\) Cf. Diehr, supra, 1053-1055.
\(^9\) See infra note 103 at 19.
computer program implementing the curing formula, but at the end, there was a concrete decision made by the computer control to open the press.\textsuperscript{91}

Contrast to \textit{Diehr}, in \textit{Mayo} and \textit{Intema}, the two diagnostic screening methods did not have any computer implementation and do not have a non-human decision step. Their novel methodology implementations were completely relying on the skills of doctors.

Perhaps the greatness of the novelty in the two diagnostic screening methods confused the issue of claiming the laws of nature in a narrow scope.\textsuperscript{92} They might be novel enough to get patents initially because they applied breakthrough methodologies in very specific fields. But after a few years of licensing, as the novelty of their methodologies wore out, the § 101 subject matter issue was back to the forefront. The two patented methods, as explained by the courts, however novel and nonobvious at the time, were no more than natural laws. They were subject to the same scrutiny as why $E=MC^2$ could not be patented.\textsuperscript{93}

It is tempting for a draftsperson to draft the claim of laws of nature into a process claim in an attempt to narrow the field of application. The Court said such attempts would be futile:

\begin{quote}
If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction “apply the law.” Einstein, we assume, could not have patented his famous law by claiming a process consisting of simply telling linear accelerator operators to refer to the law to
\end{quote}

\textsuperscript{91} See \textit{id}.
\textsuperscript{92} See \textit{supra} note 74 at 12.
\textsuperscript{93} See \textit{supra}, note 71 at 12.
determine how much energy an amount of mass has produced (or vice versa). Nor could Archimedes have secured a patent for his famous principle of flotation by claiming a process consisting of simply telling boat builders to refer to that principle in order to determine whether an object will float.  

The Federal Circuit suggested for such process claim to be patent eligible, the claim must contain inventive concepts:

For a process claim to cover a patentable application of, for example, a natural law, it must contain other elements or a combination of elements, sometimes referred to as an inventive concept, sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself. Process claims fail this requirement if, apart from the ineligible concept, they contain nothing more than well-understood, routine, conventional activity previously engaged in by researchers in the field. Because they merely describe the ineligible concept, amounting to a claim on the concept, such claims run afoul of section 101.

How much inventive concept inventors need to do in order to transform a law of nature into a patent-eligible application of such a law? One should strive to achieve at least the level of specificity and novelty as in Diehr. Is this difficult? Let's look at the Intema's patent. Claim 1 of the '103 patent reads:

A method of determining whether a pregnant woman is at an increased risk of having a fetus with Down's syndrome, the method comprising the steps of:

measuring the level of at least one screening marker from a first trimester of pregnancy by:

(i) assaying a sample ...; and/or

(ii) measuring at least one first ultrasound screening marker from an ultrasound scan ...;

measuring the level of at least one second screening marker from a second trimester of pregnancy, the at least one second screening marker from the second trimester of pregnancy being different from the at least one first screening marker from the first trimester of pregnancy, by:

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94 *Mayo*, 132 S. Ct. at 1297.
95 *Intema*, 496 F. Appx 65, 68 (internal quotation marks omitted).
(i) assaying a sample ...; and/or

(ii) measuring at least one second ultrasound screening marker from an ultrasound scan ...;

and determining the risk of Down’s syndrome by comparing the measured levels of both the at least one first screening marker from the first trimester of pregnancy and the at least one second screening marker from the second trimester of pregnancy with observed relative frequency distributions of marker levels in Down’s syndrome pregnancies and in unaffected pregnancies.\textsuperscript{96}

Assuming we can always satisfy other patent provisions, such as § 102 novelty, § 103 obvious, and §112 description/enablement/best mode, how can one fix this claim? First, one should know that telling doctors to assay a sample would not work. Assuming there is a novel way to assay that would improve the accuracy of a marker reading, it could be a feature. Also if there is a particular new marker that is more useful than the others, then such novel marker would add a feature to the claim. Normally, diagnostic method researchers are experts in their fields, and most of the time, would have the depth of knowledge in analyzing large dataset. If they discover a new way or new marker to increase the overall accuracy significantly, then it could be the feature the Court in \textit{Mayo} was looking for.\textsuperscript{97}

Next, the measuring step would need to be significantly revamped. In \textit{Intema}, the court said “purely conventional or obvious \textit{pre-solution} activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.”\textsuperscript{98} Therefore, the “pre-solution” activity of measuring ultrasound marker should be done with a critical eye. As noted, the goal of this

\textsuperscript{96} \textit{Id.} at 66-67.

\textsuperscript{97} \textit{See supra}, note 88 at 16.

\textsuperscript{98} \textit{Intema}, 496 F. Appx at 69 (internal quotation marks omitted) (emphasis added).
patent depends on the accuracy.99 A researcher would know that measuring techniques could be a critical differentiator from an ordinary test. One must avoid the generic “measuring” langue in Intema.100 As Myriad illustrated, the pre-solution step in separating the cancer causing gene, combined with the mental step of comparing it with normal gene, would qualify the method claim for cancer screening a patent eligible subject matter.101 Following Myriad, if researchers have the information about a particular marker profile, then the timing or measuring method should be custom tailored for each patient to match the specificity level in Myriad. Again, maybe a guideline to that aspect would show the “process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself the invention.”102

Perhaps the difficulty would be too great for Intema to come up with a novel marker or an improved measuring technique. Another option for Intema could be to follow Diehr to “transform the process into an inventive application of the formula.”103 Therefore, the correlation analysis, needs to be more than just a mental

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99 See supra note 19 at 4.
100 See Intema, 496 F. Appx at 69 (The “measuring” steps are insufficient to make the claims patent-eligible. They merely tell the users of the process to measure the screening markers through whatever known method they wish. In fact, the patent states: “The individual measurements are obtained through known methods.... Any markers which are effective at each particular stage may be selected.” 103 patent, col.5 ll.31 – 35. These steps tell the user “to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field.)
101 See supra note 28 at 9.
102 See supra, note 88 at 16.
103 Mayo, 132 S. Ct. at 1298-99 (“The Court pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole. Those steps included installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time. It nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional. And so the patentees did not seek to pre-empt the use of the
process by the doctors. It needs to have a transformation based on utilizing non-obvious, unconventional steps.\textsuperscript{104} Perhaps the analysis step should be implemented in a computer program. This would not only be non-obvious,\textsuperscript{105} but it would get rid of the concern that “telling a doctor to apply it.”\textsuperscript{106} Also, the analysis should have a step to track the accuracy of the prediction after the invasive diagnostic testing was performed – a step that existed in \textit{Diehr}.\textsuperscript{107} There should be a step to apply these feedbacks to the original dataset so to continuously improve the application modeling – a step that existed in \textit{Diehr}.\textsuperscript{108} Even more convincing, the analysis should have a step to produce a report that would indicate whether or not to perform the invasive diagnostic testing – an automatic step existed in \textit{Diehr} as well.\textsuperscript{109} Such report could use form paragraphs to eliminate any subjective mental deliberation by doctors – a problem noted by the court in \textit{Intema}.\textsuperscript{110}

Looking at the revised claim as a whole, all these improvement steps would tell the court that “that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of

\textsuperscript{104} See \textit{id.} (“[I]t nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional.”).

\textsuperscript{105} See generally \textit{Intema}, 496 F. Appx 65 (The court did not mention a computer was used.); \textit{But see id.} (“Those steps included . . . the use of the formula and a digital computer . . . ”).

\textsuperscript{106} See supra note 2, at 2.

\textsuperscript{107} See supra note 97, at 19 (“Those steps included . . . constantly determining the temperature of the mold . . . .”).

\textsuperscript{108} See supra note 97, at 19 (“Those steps included . . . constantly recalculating the appropriate cure time . . . .”).

\textsuperscript{109} See supra note 97, at 19 (“Those steps included . . . automatically opening the press at the proper time.”).

\textsuperscript{110} See \textit{Intema}, 496 F. Appx 71 (“And, as in \textit{Mayo}, there is no requirement that a doctor act on the calculated risk. There is at most ‘a suggestion’ that the doctor take the mental determination into account when assessing the patient.”) (citing \textit{Mayo}, 132 S. Ct. at 1297).
nature itself.” As said by the court in Mayo, the patent in Diehr made transformation from raw rubber into cured rubber in a computer controlled mold press. Although being a weak argument, the revised Intema patent in our case could also be said to transform a patient’s biological markers into a personalized diagnostic report in a computer controlled machine.

VIII. CONCLUSION

Intema denied patent eligibility to those natural law based diagnostic screening methods that do not go beyond the conventional pre-solution steps followed by the instruction of “apply it”. For a process claim to cover a patentable application of a natural law, it must contain inventive concept. For some patent claims such as the one in Intema, the whole inventive concept could be embodied in the “determining” step because it contains all the novelties. Yet, the Court was content with such “application of law of nature” step if it is a computer’s “determining” as opposed to men’s “determining”. Without a machine involved in the transformation step such as in Diehr, the courts in Mayo and Intema had trouble finding a valid § 101 subject matter.

New diagnostic screening method patents should look to add elements of personalization, physical transformation and computer “determining”. Existing patents should look to reissue to add dependent claims as a hedge to guard against invalid

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111 See supra note 88, at 16.
112 See supra note 85, at 15.
113 See Mayo, 132 S. Ct. at 1299 (“Those steps included ‘installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time.’”) (emphasis added).
independent claims, if possible. But the tradeoff for adding inventive steps in the claims in order to “not seek to pre-empt the use of the equation,” is that they are effective “only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.”

Going the trade secret route to protect diagnostic methods could be done, but at a cost to the society because it burdens the inventors and consumers alike, while taking away the teaching from the public. On the other hand, maybe only those weak patents should worry. In light of the newly effective first-to-file system starting March 16, 2013, it is possible that prospective patentees choosing to go the trade secret route could still apply for patents, if they can perfect the patentability in the meantime or should the law for patentability turns favorable.

114 See supra note 103, at 19.
115 See supra note 79, at 13.