NOTE: This opinion is nonprecedential.

United States Court of Appeals for the Federal Circuit

PERKINELMER, INC. AND NTD LABORATORIES, INC.,
Plaintiffs-Appellees,

v.

INTEMA LIMITED,
Defendant-Appellant.

2011-1577

Appeal from the United States District Court for the District of Massachusetts in case no. 09-CV-10176, United States District Judge F. Dennis Saylor, IV.

Decided: November 20, 2012

BRADFORD J. BADKE, Ropes & Gray LLP, of New York, New York, argued for plaintiffs-appellees. With him on the brief were NICOLE M. JANTZI, of Washington, DC, and DALILA ARGAEZ WENDLANDT, of Boston, Massachusetts.

LAWRENCE ROSENTHAL, Stroock & Stroock & Lavan LLP, of New York, New York, argued for defendant-

appellant. With him on the brief were ANGIE M. HANKINS, MATTHEW W. SIEGAL, and IAN G. DIBERNARDO.

Before BRYSON, O'MALLEY, and WALLACH, *Circuit Judges*.

O'MALLEY, *Circuit Judge*.

Intema Limited ("Intema") appeals from a decision of the United States District Court for the District of Massachusetts granting summary judgment to PerkinElmer, Inc. and NTD Laboratories, Inc. (collectively, "PerkinElmer"). The district court determined that U.S. Patent No. 6,573,103 ("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. On appeal, we consider only the issue of patent eligibility under section 101, reverse the district court on this point, and affirm summary judgment to PerkinElmer.

I. BACKGROUND

Doctors perform prenatal non-invasive screening to determine the risk that a fetus has Down's syndrome. If the risk is high enough, the doctor will order invasive diagnostic testing to determine definitively whether the fetus has Down's syndrome. These test, however, carry a significant risk of miscarriage and doctors seek to avoid them if possible. Accordingly, accurate non-invasive screening methods are desirable to avoid performing unnecessary diagnostic testing.

The '103 patent discloses specific screening methods to estimate the risk of fetal Down's syndrome. The processes use markers from both the first and second trimesters of pregnancy to determine the risk. Claims 1 and 20 are representative. Claim 1 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:

(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.

Claim 20 states:

> 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 first 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 . . . ;
>
> determining a first risk estimate of Down's syndrome by comparing the measured level of the at least one first screening marker level from the first trimester of pregnancy with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies;
>
> comparing the first risk estimate with a predetermined cut-off level to initially classify the pregnant woman as screen-positive or screen-negative based on the comparison;
>
> and if the pregnant woman is initially classified as screen-negative; 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:
>
> (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 level of both the at least one first screening marker from the first trimester of pregnancy and the at least one second screening marker from second trimester of pregnancy with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies.

The key difference between claims 1 and 20 is that, in claim 20, patients are screened into "screen positive" or "screen negative" groups, with only the latter undergoing testing in the second trimester. The "determining" step at the end of claims 1 and 20 is the key limitation. It was construed by the district court as follows:

> (1) determining the risk of Down's syndrome by comparing distributions of marker levels in Down's syndrome pregnancies, and in unaffected pregnancies, and
>
> (2) combining screening markers from the first and second trimesters into a single risk calculation.

Among other motions, Intema filed a motion for summary judgment of patent eligibility under section 101; PerkinElmer filed a corresponding cross-motion of ineligi-

bility under section 101. The district court granted Intema's motion and denied PerkinElmer's cross-motion. The district court held that the claims cover patent-eligible subject matter because, even though they recite an ineligible algorithm, they focus on a data-gathering method. *PerkinElmer, Inc. v. Intema, Limited*, Case No. 09-cv-10176, slip op. at 21 (D. Mass. Aug. 12, 2011) [hereinafter "Slip op."]. And "the process of gathering data by taking blood samples and measuring ultrasounds is manifestly statutory subject matter. . . ." *Id.* The district court found that the machine-or-transformation test confirmed its outcome because the data-gathering steps satisfy the test. The step of "assaying a blood sample" was transformative, according to the district court, because it changes the composition of the sample. *Id.* at 24. And the district court found that "measuring" an ultra-sound scan necessarily was tied to use of an ultra-sound machine. *Id.* at 25.

II. DISCUSSION

Patent-eligible subject matter is defined in 35 U.S.C. § 101: "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 Supreme Court has long held that section 101, although broad, is subject to important limitations. "Laws of nature, natural phenomena, and abstract ideas are not patentable." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012) (internal quotation marks omitted). These exceptions make ineligible, for example, mental processes, *see Gottschalk v. Benson*, 409 U.S. 63, 67 (1972), and products of nature, *cf. Diamond v. Chakrabarty*, 477 U.S. 303, 313 (1980). But these exceptions are not boundless, "[f]or all inventions at some level embody, use, reflect, rest upon,

or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 132 S. Ct. at 1293. The key distinction, which bears on our decision today, is between claims that recite ineligible subject matter, and no more, and claims to specific inventive *applications* of that subject matter. *See Diamond v. Diehr*, 450 U.S. 175, 187 (1981); *see also Mayo*, 132 S. Ct. at 1294. Unlike the former, the latter do not risk the broad preemption of "the basic tools of scientific and technological work," *Benson*, 409 U.S. at 67, and therefore clear the threshold of section 101.

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." *Mayo*, 132 S. Ct. at 1294. 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." *Id.* Because they merely describe the ineligible concept, amounting to a claim on the concept, such claims run afoul of section 101. That is the case here.

PerkinElmer argues that the claims are directed to an ineligible mathematical algorithm and fail the machine-or-transformation test. According to PerkinElmer, pre-solution data-gathering steps, even if transformative or tied to a machine, do not render the algorithm patentable. PerkinElmer contends that the claimed process fails the machine-or-transformation test because the "determining" step is not tied to a machine and, since the "determination" is a calculation of risk based on data, nothing is physically transformed. Nor does PerkinElmer think the "measuring" step satisfies the test since measuring the results of an ultrasound scan requires no transformation

and it is not the ultrasound machine which does the "measuring" described in the claims.

Intema responds that the claims are directed to a specific medical test, not to an abstract method. Intema contends that the machine-or-transformation test is satisfied by the "assaying" measurement because the sample is chemically transformed. Intema also believes that the measurement of an ultrasound scan involves the transformation of data into a visual depiction, and thus relies on *In re Abele*, 684 F.2d 902 (C.C.P.A. 1982), to argue that this transformation satisfies the test.

The Supreme Court's decision in *Mayo* and this court's recent decision in *Ass'n for Molecular Pathology v. PTO,* 689 F.3d 1303 (Fed. Cir. 2012) [hereinafter *Myriad*], dictate the result we reach today. Those two cases dealt with process claims similar to those at issue here and, in both, the process claims were held ineligible under section 101. In *Mayo*, the claimed method was a diagnostic assay involving two steps: "administering" a thiopurine compound to a patient and "determining the level of 6-thioguanine," a metabolite of thiopurine, in the patient. The claims contained two "wherein" clauses which did not dictate any step in the process, but disclosed the metabolite concentration range necessary for effective treatment—the purported discovery embodied in the claims. This correlation, *i.e.*, that an effective dose of thiopurine produces a certain range of metabolite concentrations, was the result of the natural metabolic process. The claims in dispute thus were drawn to a law of nature and needed to "add *enough* to their statement of the correlation[] to allow the processes they describe to qualify as a patent-eligible processes that *apply* the natural laws." *Mayo*,132 S. Ct. at at 1297 (emphasis in original). This they failed to do:

> [T]he 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. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

Mayo, 132 S. Ct. at 1298.

The Supreme Court emphasized the "inventive concept" requirement of section 101, stating that "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 1300; *see also 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.") (internal quotation marks omitted); *id.* at 1299 (explaining that in *Parker v. Flook*, 437 U.S. 584 (1978), "putting the [ineligible] formula to the side, there was no 'inventive concept' in the claimed application of the formula," making the claims there ineligible since "'[p]ost-solution activity' that is purely 'conventional or obvious'" "'cannot transform an unpatentable principle into a patentable process.'") (quoting *Flook*, 437 U.S. at 589); *id.* ("These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field."); *cf. id.* at 1299 (explaining that the claims in *Diehr* were patent-eligible "because of the way the additional steps of

the process integrated the [ineligible] equation into the process as a whole," and the *Diehr* court "nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional.").

In *Myriad*, a panel of this court found certain process claims ineligible because they were drawn to abstract mental processes.[1] The stricken claims there are indistinguishable from those before us. The *Myriad* claims covered screening methods for cancer-predisposing mutations in human gene sequences. *Myriad*, 689 F.3d at 1309-10. One claim, for example, contained the sole step of "analyzing" a human gene sequence to identify a certain mutation. *Id.* at 1309. Another required the single step of "comparing" a gene sequence from a sample of a tumor with a sequence from a non-tumor sample to identify a certain mutation; the claim contained a "wherein" clause stating that a specific difference between the two sequences identifies the mutation of concern. *Id.* at 1310. This second claim, the panel held, "recites nothing more than the abstract mental steps necessary to compare two different nucleotide sequences." *Id.* at 1334. The claims were not over an *application* of the mental process of comparing. "Rather, the step of comparing two DNA sequences [was] the entire process that [was] claimed." *Id.* at 1335.

Here, Intema claims analytical methods to determine the risk of fetal Down's syndrome. Claim 10, for example, requires two "measuring" steps; a screening marker from the first trimester of pregnancy is observed; then, a

[1] The panel found patent-eligible a claim drawn to the method of screening potential cancer treatments by comparing cellular growth rates or treated and untreated cells, as well as composition claims over isolated DNA molecules.

marker from the second trimester is observed. The claim then contains a "determining" step in which the risk of Down's syndrome is calculated by comparing both screening marker measurements with known statistical information. Claim 20 adds a "determining" step in between the two "measuring" steps, in which the risk of Down's syndrome is calculated based on the first measurement. The second measurement is taken only if this first risk is below a predetermined level. The claims thus recite the mental process of comparing data to determine a risk level: data are gathered in the first trimester of pregnancy; data are gathered in the second trimester of pregnancy; those data are compared to known statistical information. No action beyond the comparison is required.

Intema also claims a law of nature: the relationship between screening marker levels and the risk of fetal Down's syndrome. That an increased risk of fetal Down's syndrome produces certain analytical results is a natural process, an eternal truth that "exists in principle apart from any human action." *Mayo*,132 S. Ct. at 1297. Since Intema's claims recite mental processes and natural laws, we must decide if Intema added enough to the statements of ineligible subject matter to direct the claims, not to the ineligible concepts themselves, but to applications of those concepts. We think not.

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. 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." *Mayo*, 132 S. Ct. at 1298.

Nor is the "determining" step sufficient. This step requires the ineligible mental step of "comparing" the measured markers "with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies" to determine the risk of fetal Down's syndrome. *See, e.g.*, '103 patent, col.17 ll.13-19. The statistical information mentioned in this step is insufficient to make the claim patent-eligible because it is well-understood, conventional information. *Id.* at col.6 ll.45-50 ("[T]he necessary statistical distribution parameters which specify the Gaussian distribution are the mean, standard deviation and correlations for the two distributions. These are known, being derivable from observed distributions . . . ."). And the unspecified and unclaimed statistical calculation for determining the risk is also known and conventional. *Id.* at col.6 ll.23-26 ("Any of the known statistical techniques may be used. Preferably the multivariate Gaussian model is used, which is appropriate where the observed distributions are reasonably Gaussian. Such multivariate Gaussian analysis is in itself known . . . .").

Looking to the claims as a whole, the steps in combination do not make the ineligible mental step and natural law patent-eligible. As the Court in *Mayo* reasoned, anyone who wants to use this mental step or natural law must follow the claimed process. *Mayo*, 132 S. Ct. at 1298. And, as in *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. *Id.* at 1297. The claims are thus ineligible under section 101.[2]

The claims held patent-eligible in *Myriad*, and the reasoning underlying that decision, bolster our decision here. The panel in *Myriad* found eligible claims to a screening method for cancer treatments. 689 F.3d at 1337. The claimed method consisted of "comparing" the growth rates of two sets of host cells that had been altered with a cancer-causing human gene—one set was treated with the potential therapeutic and the other was untreated. *Id.* at 1336. If the growth rate of the treated cells was slower than the untreated cells, the treatment was effective. *Id.* The comparison was an ineligible mental step. But the host cells did not occur naturally; they were man-made and, thus, were themselves patent-eligible subject matter. So, according to the panel, their inclusion in the process made the claims patent-eligible despite the reference to an otherwise ineligible mental step. *Id.* Here, the challenged claims include no patent-eligible subject matter along with the ineligible concepts. They include only "conventional steps, specified at a high

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[2] This court's decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) makes clear that, for this reason, Intema's claims are not drawn to patent-eligible applications of ineligible concepts. In *Classen*, the court found one set of claims directed to eligible applications of an abstract idea, while another set claimed only the abstract principle. *Id.* at 1067-68 ("The '283 claims do not include putting this knowledge to practical use, but are directed to the abstract principle that variation in immunization schedules may have consequences for certain diseases. In contrast, the claims of the '139 and '739 patents require the further act of immunization in accordance with a lower-risk schedule, thus moving from abstract scientific principle to specific application."). Here, no "further act" moves the recited concepts to a specific application.

level of generality," which are insufficient. *Mayo*, 132 S. Ct. at 1300.

The reasoning in *Myriad* also undercuts the main premise on which the district court relied. The district court distinguished *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989). That case held that "[t]he presence of a physical step in the claim to derive data for the algorithm will not render the claim statutory." *Grams*, 888 F.2d at 840. In other words, physical data-gathering steps, which may cover patent-eligible subject matter, are insufficient to make claims reciting abstract ideas patent-eligible applications of the ineligible concepts. The district court reasoned that *Grams* was of no moment because it concluded that the data gathering in the claims at issue here is "a focus of the claimed method, not a mere antecedent step." Slip op. at 21. Specifically, the brunt of the claims, according to the district court, is the use of data from both the first and second trimesters of pregnancy in combination; according to Intema, only one marker was previously used. Even assuming it is new or even inventive, this "two markers are better than one" concept is still a mental step or abstract idea, *i.e.*, it is ineligible subject matter. Unlike the patent-eligible host cells in *Myriad*, the data-gathering step of Intema's claims are no saving grace.

The machine-or-transformation test confirms our conclusion. As a threshold matter, the machine-or-transformation test does not trump the section 101 exclusions created by case law. *Mayo*, 132 S. Ct. at 1303 ("[W]e have neither said nor implied that the [machine-or-transformation] test trumps the 'law of nature' exclusion."). Thus, even if the test were satisfied, these claims would remain unpatentable. But the claims fail the test. The purported transformation resulting from "assaying a sample" is insufficient since it could be performed "with-

out transforming the [sample], should science develop a totally different system for [assaying for a biochemical screening marker] that did not involve such a transformation." *Id.* And the "measuring" of an ultrasound scan at most transforms data derived from the scan into data regarding the risk of fetal Down's syndrome. No tangible output or visual depiction of the risk is required.[3] 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. *See Flook*, 437 U.S. at 590 ("The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance."). It is the "two data points

[3] Intema argues that this transformation is sufficient, relying on *In re Abele*, 684 F.2d 902, 909 (C.C.P.A. 1982) *abrogated by In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008). In *Bilski*, this court stated that "the transformation [in *Abele*] of [] raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent-eligible." 545 F.3d at 963. Here, however, no physical depiction of the risk data is claimed. More importantly, in *Abele*, the claims reciting the ineligible algorithm were found eligible because they claimed an "improved CAT-scan process." *Abele*, 684 F.2d at 909. That is, the claims were drawn to a patent-eligible application of the algorithm, not to the algorithm itself. *See id.* ("What appellants have done is to discover an application of an algorithm to process steps which are themselves part of an overall process which is statutory.") Here, the claims cover at most an improved mental process—i.e., use two data points to make a decision instead of one. Unlike the one involved in *Abele*, this overall process is not statutory subject matter.

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.

III. CONCLUSION

Because the asserted claims recite an ineligible mental step and natural law, and no aspect of the method converts these ineligible concepts into patentable applications of those concepts, the claims cannot stand. Accordingly, we find the claims ineligible under section 101 and affirm the judgment for PerkinElmer.

AFFIRMED

COSTS

No costs.