



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Table with columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO., EXAMINER, ART UNIT, PAPER NUMBER, NOTIFICATION DATE, DELIVERY MODE. Includes application details for 12/949,420 and 160605 7590.

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

- chen@venturepartnerllc.com
ipmail@venturepartnerllc.com
rao@venturepartnerllc.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BIAOYANG LIN

Appeal 2018-007658
Application 12/949,420
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and
JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 10 and 11. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as the inventor, Biaoyang Lin. Appeal Br. 2.

CLAIMED SUBJECT MATTER

The claims are directed to a reagent kit useful for diagnosing liver cancer. Claim 10, reproduced below, is illustrative of the claimed subject matter:

10. A reagent kit for the *in vitro* measurement of YKL-40 and MASP2 and diagnosis of cancer of a test individual, comprising:
- (1) capturing antibodies for capturing YKL-40;
 - (2) capturing antibodies for capturing MASP2; and
 - (3) detecting antibodies for detecting YKL-40 or MASP2 when YKL-40 or MASP2 is bound by the antibodies stated in (1) or (2),
- wherein the detected amounts of YKL-40 and MASP2, as compared to the amounts in a non-cancerous individual, are indicative of the occurrence of cancer in the test individual.

The Examiner has rejected claims 10 and 11 under 35 U.S.C. § 101 as directed to non-statutory subject matter.²

OPINION

Issue

The issue we are presented with is whether the Examiner has properly determined that the claims are directed to non-statutory subject matter.

The Examiner finds that claims 10 and 11 are directed to a natural phenomenon and a law of nature without significantly more. Final Act. 6. The Examiner applied the two step analysis outlined in the 214 Interim eligibility Guidance. *Id.* With respect to step 1, the Examiner found that the claims are directed to a product. *Id.* Turning to step 2A, the Examiner found that the claims are directed to a natural phenomenon as they claim

² Claims 10 and 11 were also rejected under 35 U.S.C. § 112, first and second paragraphs. Final Act. 2–6. Those rejections were withdrawn by the Examiner. Ans. 2.

Appeal 2018-007658
Application 12/949,420

antibodies which capture YKL-40 and MASP2, as well as antibodies that detect the proteins when they are captured. *Id.* at 6–7. The Examiner found that such antibodies occur naturally. The Examiner also found that the claims embrace a law of nature as the association of YKL-40 and MASP2 naturally correlates to the presence of cancer. *Id.* The Examiner found that

When the instant claims are viewed as a whole there are no markedly different characteristics to the nature-based products of antibodies that bind naturally occurring YKL-40 and MASP2. The enzymes and substrates for detection recited in claim 11, are also considered naturally occurring. Therefore the result of Step 2A analysis is that the claims are directed towards a judicial exception, i.e. natural phenomena of nature-based products.

Id. at 8.

Turning to step 2B, the Examiner found that the claims do not recite any additional steps or elements which amount to something significantly more than the judicial exception. *Id.*

Appellant contends that the claims are directed to antibodies which are made in vitro using modern biotechnology and are not naturally occurring. Appeal Br. 5. Appellant also contends that claims 10 and 11 recite something significantly more in that they produce the unexpected result of quickly and accurately diagnosing cancer. *Id.* at 5–6.

Analysis

An invention is patent-eligible if it claims a “new and useful process, machine, manufacture, or composition of matter.” 35 U.S.C. § 101. However, the Supreme Court has long interpreted 35 U.S.C. § 101 to include implicit exceptions: “[l]aws of nature, natural phenomena, and abstract ideas” are not patentable. *E.g., Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014).

To determine if a claim falls within an excluded category, we are guided by the Supreme Court’s two-step framework, described in *Mayo* and *Alice*. *Id.* at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). In accordance with that framework, we first determine what concept the claim is “directed to.” *See Alice*, 573 U.S. at 219 (“On their face, the claims before us are drawn to the concept of intermediated settlement, *i.e.*, the use of a third party to mitigate settlement risk.”); *see also Bilski v. Kappos*, 561 U.S. 593, 611 (2010) (“Claims 1 and 4 in petitioners’ application explain the basic concept of hedging, or protecting against risk.”).

Concepts determined to be abstract ideas, and thus patent ineligible, include certain methods of organizing human activity, such as fundamental economic practices (*Alice*, 573 U.S. at 219–20; *Bilski*, 561 U.S. at 611); mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594–95 (1978)); and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). Concepts determined to be patent eligible include physical and chemical processes, such as “molding rubber products” (*Diamond v. Diehr*, 450 U.S. 175, 191 (1981)); “tanning, dyeing, making water-proof cloth, vulcanizing India rubber, smelting ores” (*id.* at 187 n.7 (quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1854))); and manufacturing flour (*Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

In *Diehr*, the claim at issue recited a mathematical formula, but the Supreme Court held that “[a] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula.” *Diehr*, 450 U.S. at 176; *see also id.* at 191 (“We view respondents’ claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula.”). Having

Appeal 2018-007658
Application 12/949,420

said that, the Supreme Court also indicated that a claim “seeking patent protection for that formula in the abstract . . . is not accorded the protection of our patent laws, . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.” *Id.* (citing *Benson* and *Flook*); *see, e.g., id.* at 187 (“It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”).

If the claim is “directed to” an abstract idea, we turn to the second step of the *Alice* and *Mayo* framework, where “we must examine the elements of the claim to determine whether it contains an ‘inventive concept’ sufficient to ‘transform’ the claimed abstract idea into a patent-eligible application.” *Alice*, 573 U.S. at 221 (quotation marks omitted). “A claim that recites an abstract idea must include ‘additional features’ to ensure ‘that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].’” *Id.* (alterations in original) (quoting *Mayo*, 566 U.S. at 77). “[M]erely requir[ing] generic computer implementation[] fail[s] to transform that abstract idea into a patent-eligible invention.” *Id.*

The PTO recently published revised guidance on the application of § 101. USPTO’s January 7, 2019 Memorandum, *2019 Revised Patent Subject Matter Eligibility Guidance* (“2019 Revised Guidance”). Under that guidance, we first look to whether the claim recites:

- (1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, certain methods of organizing human interactions such as a fundamental economic practice, or mental processes); and

Appeal 2018-007658
Application 12/949,420

(2) additional elements that integrate the judicial exception into a practical application (*see* MPEP § 2106.05(a)–(c), (e)–(h)).

See 84 Fed. Reg. at 54–55. Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look to whether the claim:

(3) adds a specific limitation beyond the judicial exception that are not “well-understood, routine, conventional” in the field (*see* MPEP § 2106.05(d)); or

(4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.

See 2019 Revised guidance.

As discussed more fully below, we have considered the positions of the Examiner and Appellant and conclude that the claims, as drafted are directed to a natural phenomenon without anything significantly more. We, therefore, agree with the Examiner that the claims are not patent eligible.

Step 1

As the Examiner correctly found, the claims are directed to a kit which is an article of manufacture. Thus, the claims are directed to patent eligible subject matter unless one of the exceptions applies.

Step 2A

Having found that the claims are directed to an article of manufacture, we must then determine if one of the exceptions applies. Here the kit comprises at least three sets of antibodies – capturing antibodies for YLK-40, capturing antibodies for MASP2 and detecting antibodies. Resp. to Non-Compliant Br. 2. As the Examiner points out, the claims as drafted embrace naturally occurring antibodies. Final Act. 7; Ans. 6. While Appellant

contends that the claims are directed to antibodies produced in vitro, there is nothing in the present claims which limits the antibodies to those produced in vitro. *See* Resp. to Non-Complaint Br. 2. As claimed, the antibodies in the kit possess the same characteristics as naturally occurring antibodies. Final Act. 7. Thus, the claims are directed to a natural phenomenon.

We also find that the three sets of antibodies is similar to the combination of known rhizobium bacterial inoculant components found ineligible in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). *Funk Brothers* explained that the “combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility.” *Id.* at 131. Appellant presents no evidence that the combination of the antibodies, which may be naturally occurring polyclonal antibodies (*see* Spec. ¶ 39), result in any change in the antibodies themselves or enlargement in the range of their utility as protein binding components.

We next ask if the claims comprise additional elements which integrate the exception into a practical application. Here the antibodies are incorporated into a diagnostic kit, however the claims do not include any other meaningful limitation other than the presence of the antibodies. The section of the claim discussing the levels of antibodies being indicative of cancer do not render the claims patentable as the section merely recites a natural phenomenon – that high antigen levels are indicative of cancer.

Step 2B

We now look to see if the claims recited a limitation that not well-know, routine or conventional. Appellant contends that the fact that the use of the three sets of antibodies together results in faster and more accurate

Appeal 2018-007658
Application 12/949,420

diagnosis rendering the claims patent eligible. Appeal Br. 6. We are not persuaded by this argument.

As shown in the Specification, the capturing and detecting antibodies were known, were commercially available, were purchased, and were used to diagnose cancer. *See* Spec. ¶¶ 54 and 58 (“A YKL-40 kit produced by Quidel Company” and “a MASP2 kit produced by Dutch Hycult Biotechnology Company” were used for the examples) Moreover, as the Examiner points out, Clark also teaches the use of YKL-40 or MASP2 antibodies to detect cancer. Ans. 6–7. Appellant’s invention is to use the two kits together to diagnose cancer. *See* Spec. ¶¶ 62–65. The combination of two commercially available or well known antibodies into a single kit diagnostic kits is conventional and well know. Thus, the claim does not recite an element which renders the invention as claimed patent eligible.

CONCLUSION

For the reasons stated above, the Examiner’s rejection is affirmed

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
10 and 11	101	Patent eligibility	10 and 11	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED