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

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 12/554,497 | 09/04/2009 | John A. MCINTYRE | 20415-135721-US | 8660 |

42798 7590 06/10/2020

FITCH, EVEN, TABIN & FLANNERY, LLP
120 South LaSalle Street, Suite 2100
Chicago, IL 60603-3406

| EXAMINER |
|---|
| EMCH, GREGORY S |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1699 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 06/10/2020 | PAPER |

**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.

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

*Ex parte* JOHN A. MCINTYRE[1]

---

Appeal 2020-000157
Application 12/554,497
Technology Center 1600

---

Before DONALD E. ADAMS, ERIC B. GRIMES, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* GRIMES.

Opinion Dissenting filed by *Administrative Patent Judge* FREDMAN.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method of diagnosing Alzheimer's disease, which have been rejected as being ineligible for patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

---

[1] Appellant identifies the real party in interest as REDOX-REACTIVE REAGENTS, LLC. Appeal Br. 1. We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a).

STATEMENT OF THE CASE

The Specification describes "autoantibodies that are produced when they undergo an oxidation-reduction reaction, nam[ed] . . . redox-reactive autoantibodies (R-RAA)." Spec. 20:1–3. "These antibodies display no autoantibody reactivity in their native state. However, in the laboratory, these antibodies can undergo a redox reaction wherein they lose an electron(s) to an oxidizing agent such as hemin. When this happens, the antibodies are 'unmasked' to behave *in vitro* as autoantibodies." *Id.* at 20:6–10. The Specification discloses that "redox-reactive autoantibodies can act as biomarkers to enable the improved understanding, diagnosis, and treatment of . . . neurodegenerative diseases such as Alzheimer's disease." *Id.* at 20:16–18.

Claims 1–7 and 20–25 are on appeal. Claims 1 and 25, reproduced below, are the independent claims:

> 1. A method for diagnosing, monitoring and/or staging Alzheimer's disease which comprises:
>
> providing a blood sample from a human subject;
>
> oxidizing the blood sample from a human subject *in vitro*; and then
>
> conducting a blood test for determining a level of at least one redox-reactive autoantibody in the blood sample;
>
> comparing the level of the at least one redox-reactive autoantibody to a predetermined value; and
>
> diagnosing, monitoring and/or staging Alzheimer's disease based on the comparison between the level of the at least one redox-reactive autoantibody and the predetermined value.

25. A method for treating Alzheimer's disease which comprises:

providing a blood sample from a human subject;

oxidizing the blood sample from a human subject *in vitro*; and then

conducting a blood test for determining a level of at least one redox-reactive autoantibody in the blood sample;

comparing the level of the at least one redox-reactive autoantibody to a predetermined value;

diagnosing, monitoring and/or staging Alzheimer's disease based on the comparison between the level of the at least one redox-reactive autoantibody and the predetermined value; and

when the patient is diagnosed with Alzheimer's disease, treating the human subject based on the diagnosing, monitoring and/or staging.

OPINION

Claims 1–7 and 20–25 stand rejected under 35 U.S.C. § 101 on the basis that they are "directed to the natural correlation between natural redox-reactive autoantibodies and Alzheimer's disease state," without significantly more. Final Action[2] 2–3. The Examiner states that "[t]he rationale for this determination has been explained previously and will not be reiterated herein." *Id.* at 3.

As we understand it, the Examiner relies on the explanation of the rejection provided most recently in the Examiner's Answer for the previous appeal of this application (Appeal 2017-000477, decided June 28, 2018). In that appeal, the Examiner found that the claims "are directed to the natural correlation between natural redox-reactive autoantibodies and a disease

[2] Office Action mailed Oct. 25, 2018.

state" and "there are no features in addition to the exception that are more than purely conventional or routine in the art." Previous Ans.[3] 2. More specifically, the Examiner found that "the comparing and diagnosing steps can be mental processes and are simply drawn to the observance of nature." *Id.* at 3. The Examiner also found that "[t]he element of oxidizing the sample is well-understood in the art and is simply mirroring that which occurs naturally." *Id.* at 3–4 (citing McIntyre '541[4] and McIntyre '681[5]). "That is, McIntyre ['541] and McIntyre ['681] both teach oxidizing bloods samples *in vitro* with oxidizing agents, such as hemin." Final Action 3.[6]

Appellant argues, among other things, that the claims are "eligible under . . . the *Alice/Mayo* analysis because the additional elements recited in the claims provide 'significantly more' than the recited judicial exception (e.g., because the additional elements are unconventional in combination)." Appeal Br. 8. Specifically, Appellant argues that "oxidizing a blood sample from a human subject *in vitro* . . . was not was [sic] well-understood, routine, and conventional." *Id.* at 9.

---

[3] Examiner's Answer mailed Aug. 8, 2016.
[4] McIntyre, US 2006/0141541 A1, published June 29, 2006.
[5] McIntyre, US 2005/0260681 A1, published Nov. 24, 2005.
[6] The Examiner also reasons that, "[b]ecause all of the claims are drawn to the same invention that was considered by the Board and this rejection was affirmed by the Board, the rejection is affirmed herein on the ground of *res judicata*." Final Action 4. However, we agree with Appellant (Appeal Br. 10–11) that *res judicata* does not apply here, because the claims have been amended and the evidentiary record is different from what was considered in the previous appeal. *See* MPEP § 706.03(w) (citing cases in which *res judicata* rejections were reversed because of differences in the claims or new evidence).

"In support of its position that oxidizing a blood sample from a human subject *in vitro* was not was [sic] well-understood, routine, and conventional, appellant notes the Declaration of Paul A. Hyslop Under 37 CFR §1.132 submitted August 28, 2018." *Id.* Appellant points out that,

> [f]or the reasons set forth in his declaration, Dr. Hyslop concludes that the steps of oxidizing the blood sample from a human subject *in vitro*, and then conducting a blood test for determining a level of at least one redox-reactive autoantibody in the blood sample were not, as of the effective filing date of the invention . . . , well-understood, routine, and conventional.

*Id.* at 10.

*Principles of Law*

*A. Section 101*

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 U.S. 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).

In determining whether a claim falls within an excluded category, we are guided by the Court's two-part framework, described in *Mayo* and *Alice*. *Alice*, 573 U.S. 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.").

If the claim is "directed to" a judicial exception—a law of nature, a natural phenomenon, or 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). "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." *Mayo*, 566 U.S. at 77.

*B. USPTO Section 101 Guidance*

In January 2019, the U.S. Patent and Trademark Office (USPTO) published revised guidance on the application of § 101. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019) ("2019 Revised Guidance").[7] "All USPTO personnel are, as a matter of internal agency management, expected to follow the guidance." *Id.* at 51; *see also* October 2019 Update at 1.

[7] In response to received public comments, the Office issued further guidance on October 17, 2019, clarifying the 2019 Revised Guidance. USPTO, *October 2019 Update: Subject Matter Eligibility* (the "October 2019 Update") (available at https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf).

Under the 2019 Revised Guidance and the October 2019 Update, 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 activity such as a fundamental economic practice, or mental processes) ("Step 2A, Prong One"); and
>
> (2) additional elements that integrate the judicial exception into a practical application (*see* MPEP § 2106.05(a)–(c), (e)–(h) (9th ed. Rev. 08.2017, Jan. 2018)) ("Step 2A, Prong Two").[8]

2019 Revised Guidance, 84 Fed. Reg. at 52–55.

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look, under Step 2B, to whether the claim:

> (3) adds a specific limitation beyond the judicial exception that is 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.

2019 Revised Guidance, 84 Fed. Reg. at 52–56.

*Revised Guidance Step 2A, Prong 1*

Following the Revised Guidance, we first consider whether claims 1 and 25 recite a judicial exception. Claims 1 and 25 both recite the steps of

[8] This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. *See* 2019 Revised Guidance - Section III(A)(2), 84 Fed. Reg. at 54–55.

"conducting a blood test for determining a level of at least one redox-reactive autoantibody in [a] blood sample," "comparing the level of the at least one redox-reactive autoantibody to a predetermined value," and "diagnosing, monitoring and/or staging Alzheimer's disease based on the comparison between the level of the at least one redox-reactive autoantibody and the predetermined value."

The Revised Guidance identifies "a law of nature, or a natural phenomenon" as being among the judicial exceptions to patentability. 84 Fed. Reg. at 54.

Here, we agree with the Examiner that the correlation between the level of certain redox-reactive antibodies and Alzheimer's disease is a natural phenomenon. *See* Spec. 26 ("A simple rule based classifier . . . would be: Either an OD value of hemin treated IgG PE BSA greater than 0.28 or an OD value of hemin treated IgG PE BSA less than 0.28 combined with an OD value of hemin treated IgM PE ABP less than 0.13 indicates a non AD patient.").

In *Mayo*, the Court held that "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." 566 U.S. at 77. Similarly here, Appellant's claims set forth laws of nature—namely, relationships between the levels of certain redox-reactive antibodies and the likelihood that a patient suffers from Alzheimer's disease. Appellant's claims recite a judicial exception to patentability.

*Revised Guidance Step 2A, Prong 2*

Even though claims 1 and 25 recite a natural phenomenon, they would still be patent-eligible if "the claim as a whole integrates the recited judicial exception into a practical application of the exception." 2019 Revised Guidance, 84 Fed. Reg. at 54. "A claim that integrates a recited judicial exception into a practical application will apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception." *Id.*

The analysis of determining whether the claim integrates the judicial exception into a practical application includes "[i]dentifying whether there are any additional elements recited in the claim beyond the judicial exception(s)" and "evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application." *Id.* at 54–55.

Here, claims 1 and 25 both recite the steps of "providing a blood sample from a human subject" and "oxidizing the blood sample from a human subject *in vitro*." The "examples in which a judicial exception has not been integrated into a practical application" include "an additional element [that] adds insignificant extra-solution activity," such as mere data-gathering, to the judicial exception. 2019 Revised Guidance, 84 Fed. Reg. at 55.

In this case, the steps of providing a blood sample and oxidizing the blood sample *in vitro* amount to steps required to gather the data that is

needed in order to apply the natural phenomenon recited in the claims. *Cf. Mayo*, 566 U.S. at 79:

> Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.
>
> The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations.

Similarly here, anyone who want to make use of the natural correlation between Alzheimer's disease and the level of certain redox-reactive antibodies in a patient's blood must collect and oxidize a blood sample—which necessarily be done *in vitro*, since it is done with a blood sample rather than with a patient. Thus, the steps of providing a blood sample and oxidizing it are mere data gathering and do not integrate the recited judicial exception into a practical application.

Claim 25 also adds the step of, "when the patient is diagnosed with Alzheimer's disease, treating the human subject based on the diagnosing, monitoring and/or staging." The "exemplary considerations are indicative that an additional element . . . may have integrated the exception into a practical application" include "an additional element that applies or uses a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition." 2019 Revised Guidance, 84 Fed. Reg. at 55.

However, "[t]he treatment or prophylaxis limitation must be 'particular,' i.e., specifically identified so that it does not encompass all applications of the judicial exception(s)." October 2019 Update at 14. For example, a claim to identifying a genotype associated with poor metabolism

of beta blocker medications, followed by administering a suitable medication does not add a *particular* administration step, "and is instead merely instructions to 'apply' the exception in a generic way." *Id.*

Here, the treatment step recited in claim 25 does not require any particular treatment, but encompasses any treatment that is administered based on the diagnosis of Alzheimer's disease, which itself is based on the natural correlation between Alzheimer's disease and the level of certain redox-reactive antibodies in a patient's blood. Thus, the treatment step of claim 25 amounts merely to instructions to "apply" the recited judicial exception.

We conclude that claims 1 and 25 are directed to a natural phenomenon.

*Revised Guidance Step 2B*

Finally, the Revised Guidance directs us to consider whether claim 1 includes "additional elements . . . [that] provide[] 'significantly more' than the recited judicial exception." 84 Fed. Reg. at 56. The Revised Guidance states that an additional element that "simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception, . . . is indicative that an inventive concept may not be present." *Id.*

However, an additional element that "[a]dds a specific limitation or combination of limitations that are not well-understood, routine, conventional activity in the field, . . . is indicative that an inventive concept may be present." *Id*. The Revised Guidance also states that if, for example, an additional element was found to be insignificant extra-solution activity

under revised Step 2A, that conclusion should be reevaluated in Step 2B: "If such reevaluation indicates that the element is unconventional or otherwise more than what is well-understood, routine, conventional activity in the field, this finding may indicate that an inventive concept is present and that the claim is thus eligible." *Id.*

"The question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018). "Whether a particular technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art. The mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional." *Id.* at 1369.

"In rejecting an application, factual determinations by the PTO must be based on a preponderance of the evidence." *In re Oetiker*, 977 F.2d 1443, 1449 (Fed. Cir. 1992) (J. Plager, concurring). In this case, the Examiner cites two of the present inventor's own published patent applications as evidence that "oxidizing bloods samples *in vitro* with oxidizing agents, such as hemin" is "routine and conventional in the art." Final Action 3.

In response, Appellant has provided the Hyslop Declaration. Appellant argues that "the Declaration of Paul A. Hyslop Under 37 CFR §1.132 demonstrates that oxidizing a blood sample from a human subject *in vitro* was not was [sic] well-understood, routine, and conventional." Appeal Br. 10.

We agree with Appellant that the Examiner has not shown, by a preponderance of the evidence, that oxidizing a blood sample from a human subject *in vitro* and conducting a blood test to determine the level of redox-reactive autoantibody in the blood sample, as recited in both independent claims on appeal, was well-understood, routine, and conventional.

We find that Dr. Hyslop is well-qualified, by education and experience, to provide an opinion on whether the assay method recited in the claims was well-understood, routine, and conventional. Dr. Hyslop states that he "performed extensive literature surveys to establish that only the inventor and his associates published scientific papers between 2004–2007 using the inventor's technology." Hyslop Decl. 1[9] (footnotes omitted). Dr. Hyslop also states that his "extensive literature surveys found only two other laboratories published publications, which relate to modification of purified IgG . . . that pre-date the filing of the provisional." *Id.* at 2.[10] Dr. Hyslop states that, in both cases, the publications describe oxidation of purified IgG, rather than blood samples. *Id.*

Dr. Hyslop "conclude[s] that the steps of oxidizing the blood sample from a human subject *in vitro*, and then conducting a blood test for determining a level of at least one redox-reactive autoantibody in the blood sample were not, as of the effective filing date of the invention . . . , well-understood, routine, and conventional." *Id*. at 2–3.

---

[9] The first page of the declaration in not numbered, so the second page of the declaration is numbered "1" and the following pages are numbered sequentially from there.

[10] The instant application claims the benefit of provisional application 61/094,167, filed Sept. 4, 2008. Spec. 1.

We conclude that the Examiner's position is not supported by a preponderance of the evidence. As noted above, the Examiner relies solely on evidence that the inventor himself practiced the recited assay steps prior to the effective filing date of the instant application. The fact that the *inventor* may have described the assay in published patent applications is not sufficient evidence that the assay was well-understood, routine, and conventional. *See Berkheimer*, 881 F.3d at 1369 ("Whether a particular technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art. The mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.").

This is particularly true where, as here, Appellant has submitted declaratory evidence to show that prior to the effective filing date, only two other laboratories had published related assay methods, and even those examples used purified IgG rather than a blood sample, as required by the claims.

The Examiner responds that, in the previous appeal of this application, the Board concluded that "it was known and conventional in the art to unmask autoantibodies with an oxidizing agent." Ans. 4–5. The conclusion, however, was made based on a different evidentiary record. "After evidence or argument is submitted by the applicant in response [to a rejection], patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). As discussed above, we

conclude that the rejection on appeal is not supported by a preponderance of the evidence now in the record.

The Examiner also concludes that "[t]he declaration is merely offering an opinion on the ultimate legal conclusion at issue and the declaration does not provide any compelling evidence, facts or data consistent with applicant's conclusion." Ans. 5. This reasoning, however, does not take into account the entire Hyslop Declaration, which provides not only Dr. Hyslop's opinion but also the evidentiary basis for that opinion: the limited examples of similar assay methods described in the scientific literature that were carried out by laboratories other than the inventor's. The Examiner has not provided evidence that contradicts the evidence cited by Dr. Hyslop.

In summary, we conclude that "additional elements recited in the claims provide[] 'significantly more' than the recited judicial exception (e.g., because the additional elements [a]re unconventional in combination)." 2019 Revised Guidance, 84 Fed. Reg. at 56. We therefore reverse the rejection of claims 1–7 and 20–25 under 35 U.S.C. § 101.

## DECISION SUMMARY

In summary:

| Claims Rejected | 35 U.S.C. § | Reference(s)/Basis | Affirmed | Reversed |
|---|---|---|---|---|
| 1–7, 20–25 | 101 | Eligibility | | 1–7, 20–25 |

REVERSED

FREDMAN, *Administrative Patent Judge, dissenting.*

I respectfully dissent from the Majority's opinion and would affirm the Examiner's rejection under 35 U.S.C. § 101.

The Majority finds, under the Revised Guidance, Step 2A, Prong 1, that the claims encompass a correlation that is a natural phenomenon and therefore a judicial exception to patentability. The Majority finds, under the Revised Guidance, Step 2A, Prong 2, that "the steps of providing a blood sample and oxidizing it are mere data gathering and do not integrate the recited judicial exception into a practical application." Dec. *supra*.

However, under the Revised Guidance, Step 2B, citing *Berkheimer*, and based in part on the Hyslop Declaration, the Majority finds that the evidence fails to establish that "oxidizing a blood sample from a human subject *in vitro* and conducting a blood test to determine the level of redox-reactive autoantibody in the blood sample, as recited in both independent claims on appeal, was well-understood, routine, and conventional." Dec. *supra*.

I dissent both as to the meaning of "well-understood, routine, and conventional" and as to the application of that test to the instant facts. *Berkheimer* states that "whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018). As the Majority pointed out, *Berkheimer* also states that the "mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional." *Id.* at 1369. However, "[e]vidence of the state of the art . . . consists of proof

of what was old and in general use at the time of the alleged invention. It is received . . . to show what was then old, [and] to distinguish what was new." *Brown v. Piper*, 91 U.S. 37, 41 (1875). Thus, while disclosure in a single piece of prior art might not, in some cases, be sufficient to satisfy the "well-understood, routine, and conventional," I would find that disclosure in multiple prior art references and review articles reasonably demonstrates that an element is "well-understood, routine, and conventional."

In this case, even Appellant's Declarant Dr. Hyslop acknowledges that the technology was being performed in three different laboratories and was published in 9 separate journal articles prior to the filing date of the instant application (*see* Hyslop Decl. 1–2). Dr. Hyslop failed to further note that two additional publications, the McIntyre '541[11] and McIntyre '681[12] patents were both published prior to the filing date of the instant application.

Dr. Hyslop also failed to particularly address the teachings of these references,[13] specifically the disclosure in McIntyre et al., *Redox-reactive autoantibodies: detection and physiological relevance*, 5 Autoimmunity Reviews 76–83 (2006)[14] that "we made concerted efforts to enlist the help of other investigators who have proven and documented proficiencies in testing for specified autoantibodies to analyze our redox-reacted and control serum/plasma samples" (McIntyre 77, col. 1). "Other laboratories, selected

[11] McIntyre, US 2006/0141541 A1, published June 29, 2006.
[12] McIntyre, US 2005/0260681 A1, published Nov. 24, 2005.
[13] I note that consideration of rebuttal evidence cited for its persuasive power does not constitute a New Ground of Rejection. *See ICOS Corp. v. Actelion Pharm. Ltd*, 726 F. App'x 812, 817 (Fed. Cir. 2018).
[14] This reference is identified in footnote #4 of the Hyslop Declaration.

by us for their respective expertise, have studied our redox-reacted and control serum and/or antibody preparations and have found an expanding array of autoantibody specificities" (McIntyre 76, abstract). Thus, the asserted inventive technology was not limited to Dr. McIntyre's laboratory, but was made well-known to other investigators. McIntyre further notes, relevant to the instant claims, that "[i]t will be interesting to study the concentrations of these masked and unmasked antibodies to phospholipids in CSF of patients with diseases of the central nervous system, such as Alzheimer's disease." (McIntyre 80, col. 1).

Therefore, based both on Dr. Hyslop's statement that multiple labs were aware of the technology and the disclosure in the McIntyre Autoimmunity Reviews paper that a number of labs were enlisted and disclosed the claimed technology, I conclude that the technology is "well-understood, routine, and conventional." I would therefore affirm the Examiner's rejection under 35 U.S.C. § 101.