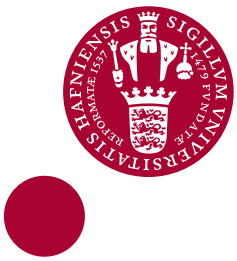

One year after Vanda, are diagnostics patents transforming into methods of treatment to overcome Mayo-based rejections?

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One year after *Vanda*, are diagnostics patents transforming into methods of treatment to overcome *Mayo*-based rejections?

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On the first anniversary of Vanda, 1) to what extent have legal arguments and claim amendments based on Vanda been effective in overcoming 35 USC 101 Mayo-based rejections?; and 2) How are applicants transforming diagnostic patent claims into method of treatment claims to overcome Mayo-based subject matter eligibility rejections?

In 2012, the US Supreme Court issued its much anticipated decision in the case of *Mayo Collaborative Services v. Prometheus Laboratories, Inc* (*Mayo*). The Court concluded that a claim directed to a method of optimizing drug dosage for treatment of a disorder was patent-ineligible for being directed to a law of nature, namely "the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages".[1] This decision had a significant impact on the threshold of patentability for life sciences inventions, in particular those involving methods of detection, diagnosis, and treatment.[2]

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One of the outcomes of the *Mayo* ruling was a vaguely outlined two-step enquiry for determining patent subject matter eligibility. It came to be known as the *Mayo/Alice* test after it was refined in the subsequent US Supreme Court decision *Alice Corp v. CLS Bank (Alice)*. The test assesses eligibility by i) determining whether the claim is "directed to" a law of nature (Step A), and ii) if so, identifying whether there are additional non-routine or non-conventional elements so that the claim amounts to "significantly more" than the natural law (Step B). Far from settling the controversy surrounding patent subject matter eligibility, the application of the *Mayo/Alice* test has remained unclear and its results unpredictable.[2]

In an attempt to promote consistent patent examination practices, the USPTO issued several examination guidance documents, providing instructions on the application of this test[3]. This guidance included a list of subject matter eligibility examples in the life sciences. Example 29 set out the USPTO's interpretation of the *Mayo/Alice* test for methods of detection, diagnosis, and treatment, using a set of illustrative claims directed to the detection, diagnosis, and treatment of a fictitious disease called "Julitis". The guidance then explained how each of the illustrative claims fared against the *Mayo/Alice* test. The claim in Example 29 directed to a *method of detection* of the disease was considered eligible at Step A (not "directed to" a *law of nature*). In contrast, other claims directed to methods of diagnosis and treatment were deemed to be directed to natural laws, and were eligible or ineligible based on whether or not they satisfied Step B, the "significantly more" inquiry.[3]

It was against this background that, on April 13, 2018, the US Court of Appeals for the Federal Circuit decided V*anda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals (Vanda)*[4] The court held the claims at issue were not "directed to" a judicial exception, and therefore were patent eligible under 35 USC 101. The claims recited a method of

treatment of schizophrenia with iloperidone, where the drug dosage is adjusted based on the patient's genotype in order to lower the risk of side effects. Following this decision, on June 7, 2018, the Deputy Commissioner for Patent Examination Policy at the USPTO issued a memo to the Patent Examining Corps updating its guidance on how to evaluate the patent eligibility of method of treatment claims in light of *Vanda*.[5] The memo emphasized the Federal Circuit's conclusion that "the [*Vanda*] claim was not "directed to" the recited natural relationship between the patient's genotype and the risk of QTc prolongation," but to an application of that relationship. The memo stated that "methods of treatment" such as the one claimed in *Vanda* "apply" natural relationships, and are not "directed to" them. The key difference identified in the memo between the claim at issue in *Mayo* and the one in *Vanda* was that the *Mayo* claim focussed on a diagnostic test and simply involved a dosage adjustment as part of performing the diagnosis, whereas the *Vanda* claim recited the additional "administration step" of adjusted dosage as part of a direction to treat a particular disease. The memo also conceded that in light of the *Vanda* decision, the two-step *Mayo/Alice* test should have been applied differently in Example 29 (Julitis) of the USPTO guidance, but would nonetheless eventually yield the same eligibility results. More specifically, the method of treatment claims should have been considered patent eligible under Step A of the *Mayo/Alice* test.

Taken at face value, such developments could seem just a slight shift. But on closer inspection, the *Vanda* decision had the potential to be a significant development in the evolving domain of patent subject matter eligibility. Not only did it unequivocally clarify that methods of treatment could be patent eligible under 35 USC 101, but it made this determination at Step A of the *Mayo/Alice* test, thus meaning there was no need to conduct a Step B analysis, and, accordingly, no need to show non-routine or non-conventional steps in the treatment.

Seen in this light, the shift opened a new door for life sciences inventions affected by *Mayo*. But what lay across the threshold? We hypothesised in a recent empirical study examining the impact of the *Mayo* decision that, after *Vanda*, patent applicants with a rejection for a claim directed to a method of diagnosis might seek to amend the claim during prosecution into a method of treatment claim.[2] This could be done, for example, by including a drug administration step based on the results gathered from the diagnostic test.

To date, the empirical reality has not yet been investigated. As some have pointed out, such claims might create unattractive enforcement difficulties for diagnostic companies which generally do not administer drugs to patients[6]. There is also persistent legal uncertainty - will the view of the Federal Circuit in *Vanda* be upheld by the Supreme Court?

Box 1 Methods

- **Step 1: Search Strategy**
  - Description: A search of the PAIR system was conducted to identify USPTO correspondence citing *Mayo*
  - Search Terms: "*Mayo*" and "*Vanda*" and "*West-Ward and Pharmaceuticals*"
  - Classes: All Classes
  - Technology Centers: TC 1600 (Biotechnology)
- **Step 2: Analysis of Office Actions & Responses**
  - Office Actions vs. Response Citations
- **Step 3: Analysis of Patented, Abandoned & Pending**
  - No. of cases resulting in a *Notice of Allowance* (Patented) vs. Abandonment, Pendency Analysis
- **Step 4: Analysis of Prosecution Statistics & Art Units**
  - No. of Office Actions, RCEs, Prosecution Time
- **Step 5: Analysis of *Mayo* Rejections & *Vanda* Responses**
  - Selection of Examples: Illustrative examples of claim amendments (changes from application to patent grant)

Research Questions

In this paper we examine the effect of *Vanda* on patent prosecution. Specifically, we address the following research questions:

1) One year after *Vanda*, to what extent have legal arguments and claim amendments based on *Vanda* been effective in overcoming 35 USC 101 *Mayo*-based rejections?; and 2) How are applicants transforming diagnostic patent claims into method of treatment claims to overcome *Mayo*-based subject matter eligibility rejections?

These are significant and open questions for practice and law reform efforts. Their answers shed light into the joint impact of *Mayo* and *Vanda* for applicants attempting to obtain patent protection for inventions involving methods of diagnosis and methods of treatment.

The method to answer these questions (**Box 1**) is derived from similar methods used to analyze the impact of *Mayo* and *Myriad*.[2,7,8,9]

Results & Examples

We identified 407 patent cases where applicants cited *Vanda* in their response to a USPTO office action containing a 35 USC 101 rejection citing *Mayo*.

One year after Vanda, to what extent have legal arguments and claim amendments based on Vanda been effective in overcoming 35 USC 101 Mayo-based rejections?

At the one year anniversary of the *Vanda* decision, there were 19 patent applications for which there was a final disposition: 16 applications were allowed and issued as granted patents, and 3 were abandoned.

This represents an allowance rate of 84.2% for patent applications with a rejection citing *Mayo* where the applicant responded to the office action with arguments and amendments based on *Vanda,* and for which there is a final disposition. This figure is substantially higher than the allowance rate previously estimated for applications with a 35 USC 101 rejection citing *Mayo* (35.9%).[2] Additionally, in one of the three abandoned cases, the *Vanda* argument was successful in overcoming the *Mayo* rejection.

Accordingly, this strategy has been effective in overcoming the 35 USC 101 rejection in 89.5% of the cases for which there is a final disposition (granted patent issued or final abandonment). This sample was then manually reviewed to determine the nature of the legal arguments and claim amendments.

How are applicants transforming diagnostic patent claims into method of treatment claims to overcome Mayo-based subject matter eligibility rejections?

In order to answer this research question, a manual and expert review of the relevant USPTO file wrappers was conducted. In particular, the prosecution history for each of the granted patent applications was downloaded using the USPTO PAIR (Patent Application Information Retrieval) System. Each application was then analyzed and classified with reference to the first claim receiving the 35 USC 101 rejection citing *Mayo* as either: A) a method of diagnosis (and other related claims that are not methods of treatment) or B) a method of treatment. **Fig. 1** shows the results of the classification of the original patent applications (Fig. 1.a) and the issued patents. (Fig.1.b). We found that 80% of the claims in the patent application sample were A-type (i.e., methods of diagnosis or related).

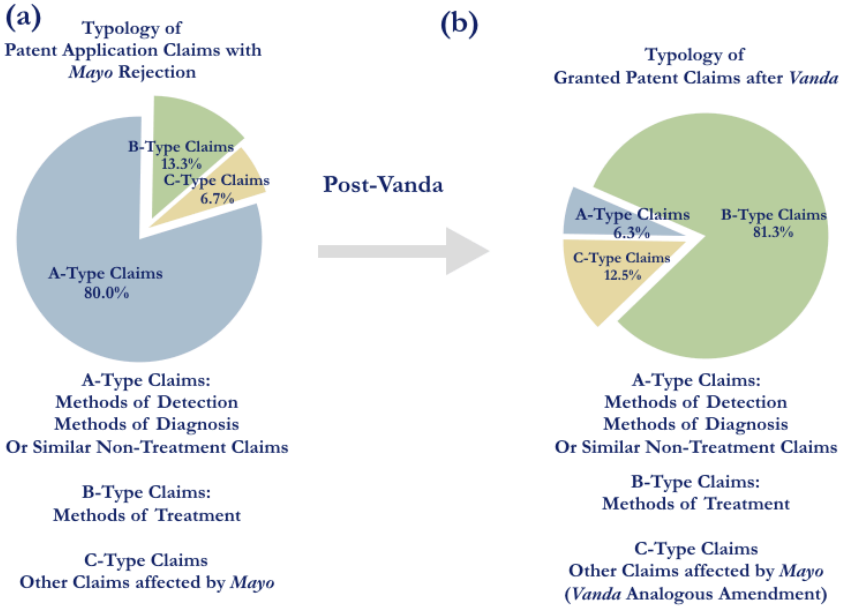

Figure 1 Study results. (**a**) Typology of patent applications claims with *Mayo* rejections. (**b**) Typology of granted patent claims after *Vanda*. The results indicate that a large proportion of diagnostic related claims are being amended to method of treatment claims to overcome *Mayo*-based rejections following the *Vanda* decision and corresponding USPTO examination guidance.

Next we used the prosecution histories to follow the fate of the central claim that sorted groups A and B. The majority of the claims in group A (diagnostic-related methods receiving a *Mayo*-based rejection) subsequently transformed into method of treatment claims in the final issued patent. In fact, in 81.3% of the granted/issued patents the claims were directed to methods of treatment (**Fig. 1**). The original claims in the patent applications, the corresponding claims in the granted patents, and our classification and prosecution notes are included in the **Supplementary Information**.

Notably, in all 16 cases, modifying claim language and citing the *Vanda* decision resulted in a reversal of the existing 35 USC 101 rejection (including a *Mayo* citation), with a *Notice of Allowance* in the following communication. Furthermore, in several of these cases, as shown in the prosecution notes (Supplementary Information), the applicants had already tried several times to persuade the examiner, but were unsuccessful until *Vanda* was cited in support of legal arguments and proposed claim amendments. With rather simple amendments that mirrored claim language in *Vanda*, the applicants finally found a way to effectively overcome the 35 USC 101 subject-matter eligibility rejection, where previously they had been unsuccessful.

Reviewing the applicants' arguments and claim language in the patent file wrappers, we observed three types of successful claim transformations. These included: (1) transforming non-method of treatment claims (e.g., diagnostics claims) to method

of treatment claims, (2) altering non-method of treatment claims to claims analogous to methods of treatment, and (3) modifying original method of treatment claims using *Vanda* to guide the claim drafting.

The first type of transformation (i.e., diagnostic-related claims transforming into method of treatment claims) was the most common, comprising 11 of the 16 analyzed granted patents.

For example, one applicant transformed the claimed invention from a "method for determining, in a patient presenting with hematuria, the level of risk for having urothelial cancer" to a "method for treating a patient for urothelial carcinonma" (case 4, Supplementary Information). In this case, while the examiner initially rejected the claimed invention based on *Mayo/Alice*, the simple amendment from a method of determining cancer risk to a method of treatment made the claim allowable based on *Vanda*.

In another example the applicant changed the claim language from a "method for diagnosing Systemic Lupus Erythematosus (SLE)" to a "method of treating Systemic Lupus Erythematosus (SLE) in a human subject identified as negative for SLE" (case 7, Supplementary Information). The initial *Mayo*-based rejection (i.e. that identifying SLE disease risk based on various antibody levels is merely a naturally occurring correlation) was overcome by transforming the diagnosis claim into a treatment one, in accordance with the USPTO *Vanda* guidance. Notably, previous arguments and amendments were unsuccessful in several previous responses to office actions.

Finally, while some granted applications did not explicitly mention a "method of treatment," they included an "administration step" following the *Vanda* memo, which passed Step A of the two-step eligibility test. For example, an applicant changed a three-step method of diagnosing a subject with a certain disorder to a six-step method of determining prognosis in a subject diagnosed with the disorder, in which the fifth step comprised "administering to the subject with an indication of unfavorable prognosis a treatment" (case 11, Supplementary Information). The examiner was persuaded that this active administration of treatment step appropriately applied a law of nature/natural phenomenon, and was therefore patent eligible under *Vanda* (despite being recited at a high level of generality).

There were three examples of the second type of transformation (i.e., altering non-method of treatment claims to claims analogous to methods of treatment). These demonstrated that some examiners were open to claims that were analogous to method of treatment claims. For instance, an applicant modified a "method of identifying a soybean plant that comprises a genotype associated with an stem canker resistance phenotype" to a "method of producing a population of soybean plants that comprises a genotype associated with a stem canker resistance phenotype" through the crossing of selected soybean plants (case 12, Supplementary Information). The examiner found the analogy between the "crossing step" and a *Vanda*-type "administration step" persuasive, and allowed the patent on these grounds.

In another case, an applicant altered a method for diagnosing propensity to CCLR in a dog to a method for breeding a dog, in which the "breeding step" to reduce injury propensity was found to mirror the administration of treatment step in *Vanda* (case 14, Supplementary Information).

The third type of transformation (i.e., modifying original method of treatment claims using *Vanda* to guide the claim drafting) was illustrated by two granted patents. In these prosecution files, the original claims referred to methods of treatment, but the applications were not allowed until after the *Vanda* ruling. An applicant in one example repeatedly modified a method of treating Dengue Hemorrhagic Fever to further increase specificity (narrowing the scope of the claim), but the patent was only allowed after the applicant supplied arguments written after the *Vanda* decision (case 15, Supplementary Information). In these examples, it is possible that the claims in their original form would have been found eligible if the claims and related legal arguments had been made after the *Vanda* guidance.

In summary, in the cohort of 16 patents that we manually reviewed (patent applications with a rejection citing *Mayo* where the applicant responded to the office action with arguments and amendments based on *Vanda,* and for which there is a final disposition), there was clear evidence that most applicants had actively changed their claim type and language in response to *Vanda* to make their patents allowable. It was also evident that examiners had not been ready to accept these arguments prior to *Vanda,* but clearly became receptive to them after the USPTO *Vanda Examination Memo*.

Pending Applications

From the 407 patent cases we found where applicants cited *Vanda* in their response to a USPTO office action containing a 35 USC 101 *Mayo*-based rejection, we analyzed 19 following inclusion criteria that required the patent application to have been issued or abandoned by the 1 year anniversary of the *Vanda* decision. Accordingly, there is a sizeable number of applications (n=388)

where applicants cited *Vanda* in response to a *Mayo*-rejection that are still patent pending. This is to be expected given standard patent prosecution timelines (e.g., up to 6 months between office actions and applicant responses; additional time for examiner to consider arguments and issue the next communication; and 3-6 months from Notice of Allowance to patent issuance).

Within the pending applications sample, we identified 35 patent applications that had already received a *Notice of Allowance* (NOAs) one year post-*Vanda* (but had not yet issued). Of these, 33 can be classified using the same claim transformation typology as the original sample: 17 transformed to method of treatment claims from diagnostics or other non-treatment types (Type 1 transformation), 13 were originally methods of treatment which were allowed after *Vanda* (Type 3 transformations), and 3 transformed from other types of non-treatment claims to claims analogous to a method of treatment claim based on *Vanda* (Type 2 transformations).

Discussion

Vanda*'s impact on patent prosecution*

This research confirms our earlier hypothesis. Following the Federal Circuit's decision in *Vanda*, as interpreted by the USPTO, patent applicants with rejected methods of diagnosis have sought to transform these into patent eligible claims via claim amendments – without having to satisfy Step B in the *Mayo/Alice* test (showing that the claim amounts to *significantly more* than a natural law). Averaging more than one per month in the year since *Vanda*, rather than claim a method of diagnosis, patent drafters are amending to method of treatment (or analogous) claims to avoid or overcome *Mayo*-based rejections. This mercurial change, particularly its strikingly positive and immediate impact on patent examiners, has an aura of legal 'magic' about it.

This has provoked considerable controversy and debates about whether *Vanda* was a good decision. Parties on both sides of the debate claim that the *Vanda* decision stands to affect "untold numbers of future patents"[10] hinting at the idea that large numbers of patentees could be affected with major socio-economic ramifications. Our research identified 16 patents in 12 months that were issued pursuant to *Vanda* but which otherwise might have been rejected pursuant to *Mayo* (and 35 additional allowed applications). If *Vanda* is overruled, these sorts of claims (method of diagnosis and method of treatment claims) would be unenforceable unless the claim includes 'significantly more' (Step B *Mayo/Alice*). At this point, we do not think this is a large number of patentees. Nevertheless, there are important policy issues at stake.

Diagnostic Companies and Divided Infringement

Holman argued that the *Vanda* solution is inadequate for diagnostic companies facing *Mayo/Alice* rejections, because *Vanda*-type claims (for example drafted as a method of medical treatment claim or including a drug administration step) may be difficult for them to enforce[6] against a defendant diagnostic company that solely provides a diagnostic test and leaves drug administration to other parties[11]. If the method of treatment or administration step cannot be attributed to the defendant diagnostic company, then the company will not have performed all the steps in the patented method and thus is not liable for infringement. This type of scenario is commonly known as divided infringement. Holman argues that challenges remain for diagnostic companies dealing with divided infringement even after the en banc US Federal Circuit reformulated the test of divided infringement law in *Akamai*[12]. We agree that arguably the *Mayo/Alice* precedent, even post-*Vanda*, overly hampers diagnostic companies with business models devoted to diagnostic testing. A substantial number of companies operate in the molecular and tissue testing diagnostics space rather than selling drugs with companion diagnostic tests. But in our view, the legal position is not necessarily as bleak as Holman suggests, and our results in relation to *Vanda* are consistent with this.

Some optimism comes from *Akamai* since the alleged infringer can be liable if a step in a method claim is performed by another actor when the alleged infringer 'conditions … receipt of a benefit upon performance of a step…of a patented method and establishes the manner or timing of that performance.' Potentially a *Vanda*-type claim could be enforced against a defendant diagnostic company (when another actor performs the drug administration step) when the manifest purpose of the diagnostic test is to determine if a drug should be administered. The defendant company arguably creates an *Akamai* scenario where it conditions receipt of a benefit of the test (the effect of the administered drug for the patient) on a third party administering the drug. Arguably, the defendant diagnostic company also establishes the timing of the administration (after receiving the test results), and perhaps even the manner of the administration, if, for instance, dosage is also determined by the test.

Our research is consistent with a degree of optimism. Notwithstanding on-going debates about enforcing *Vanda*-type claims in situations of divided infringement, a significant number of organizations that choose to use the *Vanda* prosecution strategy are

diagnostic companies whose competitors are likely to be other diagnostic companies. It remains an open question what proportion of diagnostic companies do not use *Vanda*, perhaps for the reasons identified by Holman. This is not necessarily highly problematic. They could instead seek to draft claims that meet Step B. In this regard it is important to recall empirical studies that indicate that *Mayo* did not sound the death knell for sustainable business models for diagnostics. Patent prosecution is more drawn out and uncertain in the absence of a *Vanda* "administration step," and tends to result in narrower patents with potential reduced value, but method of diagnosis patents are still issued (when they pass Step B) and diagnostic companies have continued to invest in and develop diagnostic tests.

Legal Uncertainty

An issue for the future is the legal uncertainty surrounding *Vanda*, and indeed the future of the *Mayo/Alice* test. Will these legal tests remain the cornerstone of patent eligiblity? Three sources of unpredictability include the Supreme Court certiorari proceedings currently under way, review of §101 also afoot within the US Congress and Senate, and future refinement of the *Vanda* approach by lower courts or the USPTO. For example, in the recent *INO Therapeutics v. Praxair Distrib. Inc.*, 2018-1019 (Fed. Cir. Aug. 27, 2019) (Nonprecedential), the Majority held that the *INO* claimed method of treatment was ineligible under 35 USC 101. It differentiated the *INO* claims with those in *Vanda* because in this case *iNO* treatment *is withheld* if the patient is identified as subject to the increased risk (i.e., the invention involves the *non-administration* of the treatment). Judge Newman (the most senior judged on the CAFC) dissented.

The US Supreme Court has been asked to overrule the Federal Circuit's approach in *Vanda*. It may decide the matter purely with reference to the meaning it thinks should be ascribed to the words "directed to" within the prevailing *Mayo/Alice* tests. On the other hand, now constituted by justices different from Chief Justice Breyer's court in *Mayo*, it might take a bolder approach and revisit *Mayo*, perhaps recasting it so that the *Mayo/Alice* test is significantly changed, perhaps even abandoned.

There is considerable debate whether - assuming the law is unsatisfactory - the root of the problem is *Mayo/Alice*, or the legal refinements in cases such as *Vanda*. A view put forward in the certiorari proceedings is that the problem rests with *Vanda* because it introduces an unsatisfactory gloss on the *Mayo* exception. According to Counsel for Hikma, and Professor Sarnoff et al (Amici) a method of medical treatment claim is no different from a claim that claims a law of nature with general instructions "to apply it" unless the claim includes non-conventional steps in addition to the newly discovered medical correlation[10].

Responding to the view that *Mayo*, *Alice* and *Myriad* are the source of the problem, a group of senators, headed by Sen. Thom Tillis (R-NC) and Sen. Chris Coons (D-Del.), announced a draft bill in May 2019 which would bypass the judicially created exceptions to subject matter eligibility including the Supreme Court decisions in *Mayo*, *Myriad* and *Alice*. The bill has received mixed reactions ranging from strong support to harsh criticism, as evidenced by the June hearings of the US Senate Judiciary Subcommittee on Intellectual Property. Most recently, at the end of July, a group of law professors, former chief judges of the US Federal Circuit, and former heads of the USPTO sent a letter to the IP Committee in support of the bill. In contrast, the American Civil Liberties Union (ACLU) and other medical, health, and civil rights organizations have expressed vehement opposition.

Comparison with Europe

Vanda focuses legal minds on the meaning of the words "directed to" in the *Mayo/Alice* test. Is a patent claim "directed to" a law of nature (Step A) if it claims an application of the natural law in the format of "a method of medical treatment." Is this a genuinely 'practical application' such that the patent claim is no longer "directed to" a law of nature but actually "directed to" a patent-eligible invention by integrating the laws of nature into an inventive concept? The claim still recites a law of nature, but is it "directed to" that law? What about situations where the claim includes nothing additional apart from well-understood, routine, conventional activity?

This sort of analysis has a sense of hair-splitting. The European approach avoids the semantic meaning of the words "directed to", and might therefore hold some appeal. However, it too has become mired in controversial micro-analysis of words. Under the European Patent Convention claims shall not be granted to "discoveries or scientific theories …as such"[13]. The qualifier 'as such' is open to multiple meanings - just like the qualifier 'directed to'. Not without controversy, EPC case law has taken the route that excludes claims only if they pertain *solely* to a discovery or scientific theory. Claims with a 'technical' element or technical application included in the claim are eligible even when the core leap forward was the scientific discovery or theory.

This can seem more cut-and-dry, less demanding, and helpful for legal certainty. But the European approach has its own controversies

and additional considerations. For example, defining the metes and bounds of technicality, technical effect, technical character and their relation to other patentability criteria remains one of the most disputed issues in European patent law[14]. The current situation is that it is relatively easy for competent draftspersons to draft a token technical element. Some think this is sensible because the key issue then becomes whether the claim is novel and inventive. Others think the European approach fails to protect the proper spirit of the EPC exclusion and allows claims which are, in essence, natural correlations.

According to EPO case law, if the claim includes any kind of technical contribution it is elevated from a claim that claims a discovery or scientific theory as such to a claim that is patent eligible. In other words, the 'as such' element means that if the claim pertains to *no more* than a *discovery* or s*cientific theory* it is patent ineligible. This is less demanding than Step B of the *Mayo/Alice* test, and less semantic than the words 'directed to'. In Europe, the technical element – which shifts the claim from an ineligible discovery to eligible subject matter– can include the process of diagnosis if the process includes collection of physical specimens, kits or platforms. This is quite unlike *Mayo/Alice* and *Vanda*, where the process of diagnosis is considered a mere instruction to apply a natural phenomenon (so the claim is still 'directed to' the natural phenomenon) and insufficient to change a patent ineligible claim to an eligible one. In Europe, the technical element can also be achieved by focusing on a new use of a drug, akin to a method of medical treatment and analogous to *Vanda*. For completeness, it is important to add that in Europe, methods of treatment and diagnostic methods practiced "on" the human body are excluded from European patent protection by a separate provision of patent law, but this provision does not apply to in vitro diagnosis nor products, in particular substances or compositions, for use in any of these methods (EPC Art 53(c)).

Conclusion

These and other issues show there is much to be considered in the future. In the short term, if *Vanda* is upheld, and *certiorari* denied, patent attorneys with pending patent applications receiving *Mayo* rejections would do well to consider whether amendment to a method of medical treatment claim might assist their client. In doing so, our research indicates they are likely to have more and/or swifter success persuading examiners if they link their arguments to the USPTO Examination guidance rather than case law alone. Meanwhile patent law scholars might like to ponder whether *Vanda* is another example of the pre-eminence of draftsmanship notwithstanding repeated calls from the Supreme Court to avoid this.[15]

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