An Initial Comment on *Prometheus*: The Irrelevance of Intangibility[1]

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BACKGROUND: THE MACHINE-OR-TRANSFORMATION TEST OF *BILSKI*

Last fall, the Federal Circuit articulated the "machine-or-transformation" test for patent eligibility in its landmark case *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (*en banc*). It held that a method is eligible for patent protection only if it is either (a) limited to a "particular machine" or (b) responsible for transforming a "particular article" into a different state or thing. *Id.* at 954. Additionally, in a classic example of language that adds judicial wiggle room, the machine or transformation that satisfies either of these prongs "must impose *meaningful* limits on the claim's scope," it "must be *central* to the purpose of the claimed process," and it must not be part of "*insignificant* extra-solution activity" or a "*mere* data-gathering step." *Id.* at 961–62 (emphases added).

The Supreme Court has accepted certiorari in *Bilski*, but the impending Supreme Court opinion has not stopped the Federal Circuit from issuing what is perhaps its most important case to date applying the machine-or-transformation test: *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*. There have been two distinct types of claims that have taken center stage in recent debates over the section 101 doctrine of patent eligibility: "business methods"

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and what I will call "determine-and-infer methods." The claim at issue in *Bilski* describes a classic business method. In contrast, *Prometheus* involves a determine-and-infer method. The Federal Circuit's opinion in *Prometheus* opens a new window into the import of the machine-or-transformation test. Regardless of one's views of the soundness of Federal Circuit's reasoning in *Prometheus*, herein lies one of the opinion's greatest virtues. By issuing *Prometheus* before the Court's oral arguments in *Bilski*, the Federal Circuit has helped to clarify the stakes of the Court's decision to sanction, reformulate, or reject the machine-or-transformation test.

DETERMINE-AND-INFER CLAIMS AND *PROMETHEUS*

Employed most frequently today in the medical arts, determine-and-infer claims follow a standard template. They initially recite prior-art steps that identify or measure a real-world phenomenon (the "determining" step), and they conclude with a newly invented mental step in which the identifier infers useful information about a distinct real-world phenomenon from the measured phenomenon (the "inferring" step). The Supreme Court's truncated proceedings in *Laboratory Corp. v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006), involved a determine-and-infer claim: (a) determine the amount of one chemical in a bodily fluid and (b) infer information about the amount of another chemical in the bodily fluid. The claim in *Prometheus* follows this template, too, adding only a slight twist. It includes as a limitation an initial step that creates the phenomenon that is subsequently measured: (a) administer a drug to a patient, (b) determine the concentration of the drug's metabolite in the patient's body, and (c) infer information about the optimality of the amount of the drug administered to the patient. *Prometheus*, slip. op. at 3. (Some of the *Prometheus* claims, however, lack the administering step and are classic determine-and-infer claims. *Id.* at 16.) Determine-and-infer claims are nonobvious advances over the prior art because the inventor discovers a previously unknown relationship or correlation among real-world phenomena and employs that relationship as a premise in the act of logical reasoning that constitutes the mental

inference.[2] The patent applicant in *Laboratory Corp.* discovered the relationship between chemical A and chemical B in bodily fluids and invented the mental process of inferring information about the unmeasured chemical B from the measurement of chemical A. The patent applicant in *Prometheus* discovered the relationship between the concentration of a drug's metabolite in a patient and the optimality of the dose of the drug that the patient is currently taking.

In *Prometheus*, the Federal Circuit upheld the claims at issue as patent eligible subject matter under the transformation prong of *Bilksi*'s machine-or-transformation test. While acknowledging that the inference step was a mental step that did not affect a transformation, *id.* at 19, it concluded that both the administering and determining steps were steps that transformed articles into different states or things. The administering step transforms "the human body," and the determining step manipulates the "bodily sample" taken to measure the metabolite because the metabolite "levels cannot be determined by mere inspection" but must rather be physically manipulated through a process such as high pressure liquid chromatography. *Id.* at 14–17. Furthermore, the Federal Circuit asserted—as it had to in order to support its finding of patent eligibility—that the transformations in the administering and determining steps were central to the purpose of the claims and thus were not mere data-gathering steps. *Id.* at 18–19, 20–21.

THE IRRELEVANCE OF INTANGIBILITY

There is no rational reason to use the tangibility of the transformation affected by the determining steps in a determine-and-infer claim as a peg on which to hang patent eligibility. There are, of course, administrative difficulties entailed in distinguishing patent-eligible transformations of articles from worldly changes that are insufficient to amount to

[2] For an in-depth analysis of a determine-and-infer claim, see Kevin Emerson Collins, *Propertizing Thought*, 60 S.M.U. L. REV. 317, 323–42 (2007).

patent-eligible transformations. Does simply drawing blood count as a transformative process, in and of itself? Reasoning by analogy, is the breaking of a chair a transformation, but not the shuffling of chairs from one room to another? The point to be made here is that the transformation of an article is dependent on the level of generality at which one defines the relevant "article." Rooms are physically transformed by the shuffling of chairs, but the individual chairs may appear not to be. Bodies and circulatory systems are physically transformed by the drawing of blood (they have less mass after the procedure than they did before), but the individual blood cells may appear not to be.[3]

Yet, however daunting the task may initially seem, the difficulty inherent in line-drawing is not a reason in and of itself categorically to avoid drawing lines. Sometimes the lines are important, and the cost of line-drawing is often an acceptable cost that is outweighed by the benefit of having the line in place. In the context of determine-and-infer claims, the crux of the issue is that the line between tangible and intangible determining steps is not important. The intangibility of the determining steps is irrelevant to the policy concerns that underlie the doctrine of patent eligibility. To underline this fact, consider two determine-and-infer claims in which the determining step is accomplished through different technologies. One determining step requires cell membranes to be broken and chemical reactions to alter molecules, whereas the other simply requires the analysis of the spectrum of the light that a blood sample absorbs. Why should the former claim be patent eligible, but not the latter?

[3] The author discusses this concept—namely the importance of the level of generality at which a conceptual thing-type is framed—in much greater depth in Kevin Emerson Collins, *The Reach of Literal Claim Scope into After-Arising Technology: On Thing Construction and the Meaning of Meaning*, 41 CONN. L. REV. 493, 514–36 (2008) (explaining how "thing construction" is important when determining the reach of an enabled claim into after-arising technology).

THE REAL STAKES

What is actually at stake in the debate over the patent eligibility of determine-and-infer claims is the nature of the property rights that can result from the invention of an act of logical, human reasoning. As explained above, "inferring" steps are acts of human reasoning that are enabled by the inventor's disclosure in the specification of a previously unknown factual relationship among real-world phenomena. There is a widespread consensus that inferring steps in isolation are not eligible for patent protection: the act of thinking about the information disclosed in the specification *per se* is not patent eligible. *See, e.g.*, *Bilski* at 965 (nothing that the "application of [only] human intelligence to the solution of problems" is not patentable subject matter). However, when newly invented inferring steps are combined with prior-art, extra-mental steps to create determine-and-infer claims, the consensus disappears, and the controversial issue addressed in *Prometheus* appears.

To be clear, the issue is not an easy one. There are weighty concerns on each side. The proponents of determine-and-infer claims argue that the incentives generated by these claims will speed up the development of personalized medicine, and that patent incentives will be insufficient in their absence. Incentive arguments lie at the heart of the justification of the patent regime, and they should not be lightly tossed aside. On the other side, however, is *inter alia* a concern about the dynamic costs of patents that privatize "the basic tools of technological and scientific work." *Gottschalk v. Benson*, 409 U.S. 64, 67 (1972). The determine-and-infer claims in *Metabolite* and *Prometheus* arguably describe methods consumed by the end-users of medical advances: they describe methods through which doctors can diagnose sick patients or increase the safety and efficacy of patients' drug regimens. However, the determine-and-infer claim establishes a template that can readily be used to generate property rights in most, if not all, basic scientific advances. For example, assume that a researcher discovers that a particular mutation in a gene leads to a malformed protein that in turn leads to an

increase in the likelihood of a particular type of cancer. Following the determine-and-infer template, the researcher could claim a right to exclude others from (a) determining whether a cell contains either the genetic mutation or the malformed protein and (b) correlating the presence of the mutation/malformation to an increased likelihood of cancer. This claim—which may be just as useful, novel, and nonobvious as the *Prometheus* claim—effectively privatizes future research involving the metabolic pathway through which the genetic mutation leads to an increased likelihood of cancer. Furthermore, the determining step is just as transformative as the determining step in *Prometheus*.

THE PATENT-ELIGIBILITY OF HUMAN INFERENCE

There are basically three rational approaches to the doctrine that governs the patent eligibility of determine-and-infer claims. First, determine-and-infer claims could be categorically eligible for patent protection. Perhaps the incentives are sorely needed, and perhaps the concerns about dynamic costs will be mitigated by under-enforcement of patent rights in academic laboratories.

Second, determine-and-infer claims could be categorically ineligible for patent protection if, when such claims are considered as a class, the balancing of costs and benefits tilts strongly in the other direction. The Federal Circuit, however, has shown no interest in this approach as a doctrinal matter. It would require a rule that resembles the now-defunct mental steps doctrine and that prohibits the patenting of any claim in which the advance over the prior art resides in an act of human cognition enabled by the information disclosed in the patent specification. The Federal Circuit has repeatedly insisted that the Supreme Court's articulation in *Diamond v. Diehr* of a "claim as a whole" approach to patent eligibility for "laws of nature, natural phenomena, and abstract ideas" also governs the patent eligibility of mental processes. *See, e.g.*, *Bilski*, 545 at 958. This interpretation of *Diehr* rules out an approach modeled on the mental steps doctrine that inquires whether an act of human

cognition is the claim's point of novelty. If determine-and-infer claims are to be categorically ineligible for patent protection, it looks like the Supreme Court will need to cabin the Federal Circuit's interpretation of *Diehr*. Given that the Supreme Court has not yet addressed a claim that literally encompasses an act of human cognition, however, a clarification that the claim as a whole approach to patent eligibility was never meant to apply to mental processes is a reasonable possibility in either *Bilski* or a future case.

Third, determine-and-infer claims could be screened on a case-by-case basis to sort the wheat from the chaff. To address the "basic tools" concern, one possibility is that claims could be differentiated on the basis of whether they are used principally by end-users or by the practioners of basic science. However, this is a delicate, policy-intensive undertaking without many clear-cut factual distinctions onto which courts and PTO examiners can grasp. If one is concerned about line drawing, this would seem to be one of the most difficult lines to draw, and one would likely find the categorical treatments of determine-and-infer claims considered above to be preferable.

Yet, in the end, this policy-intensive line may be precisely the line that the Federal Circuit has set itself up to police—in a behind-the-rhetoric manner, of course—with its *Prometheus* decision. Assume that the Federal Circuit concludes that the vast majority of determining steps transform articles into different states or things. Or, more modestly, assume that most determining steps can be re-drafted to encompass only processes that transform articles into different states or things without an economically meaningful loss of scope. If this assumption holds, then the patentability of determine-and-infer claims will hinge on whether the administering and determining steps are central to the purpose of the claims (i.e., are not mere data-gathering steps). The discussion of the centrality of the administering and determining steps is the least-satisfying line of reasoning in the Federal Circuit's *Prometheus* opinion. It simply asserts that these steps "are part of the treatment protocol." *Id.* at 18-19. This characterization of the claims provides no basis to

distinguish *Prometheus* from past cases in which claims to mental processes were held to be ineligible for patent protection because they recited mental steps in combination with mere data-gathering determining steps. *Id.* (attempting to distinguish *In re Grams*). It is tautological to argue that data-gathering steps are part of the overall claimed method. The reasoning must be result-driven: the administering and determining steps are central to the purpose of the claim because the panel believed that claims to methods for optimizing the treatment of patients should be eligible for patent protection. One of the most persuasive reasons for viewing the *Prometheus* claim as patent eligible is that it describes a method that is most commonly performed to directly benefit the identifiable end-users of health care, namely individual patients. Inversely, perhaps future courts will be more likely to identify the determining steps as mere data-gathering steps when the claims are likely to be employed in basic scientific research. In other words, perhaps it will be the distinction between claims that are treatment protocols and those that are research protocols that guides whether determine-and-infer claims are eligible for patent protection under the machine-or-transformation test. If this is the end result, there might be something to applaud. However, if this is the case, the Federal Circuit should openly admit the irrelevance of intangibility.