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An Initial Comment on *King Pharmaceuticals*: The Printed Matter Doctrine as a Structural Doctrine and Its Implications for *Prometheus Laboratories*[1]

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On August 2, 2010, the Federal Circuit affirmed the district court's summary judgment of patent invalidity in *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*[3] *King Pharmaceuticals* is most notable for its extension of the printed matter doctrine from objects claims that recite written texts as limitations to method claims that recite speech acts as limitations.

This Essay proceeds in three parts. Part I summarizes the *King Pharmaceuticals* opinion. Part II argues that the opinion was correctly decided, and it offers an original thesis about the role that the printed matter doctrine should play to enforce patentees' disclosure obligations and preserve the deep structure of the Patent Act. Assuming that *King Pharmaceuticals* was correctly decided, Part III addresses the necessary next step in the continuing refinement of the printed matter doctrine. The Federal Circuit must explain why claims like the claim at issue in *Prometheus Laboratories v. Mayo Collaborative Services* are novel.[4]

I. Summary of *King Pharmaceuticals*

The discovery that underlies the patent claims at issue in *King Pharmaceuticals* was "the unexpected finding that administration of metaxalone [a known, already-used

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[3] 2010 WL 3001333 (Fed. Cir. Aug. 2, 2010).

[4] 581 F.3d 1336 (Fed. Cir. 2009), *vacated and remanded by* 2010 WL 2571881 (U.S. Jun. 29, 2010) (requiring reconsideration in light of *Bilski v. Kappos*).

drug] with food increases both the rate and extent of absorption" of the drug.[5] Brushing aside many of the details, King wound up with two types of patent claims. First, there were claims to administering metaxalone to a patient with food.[6] Second, there were claims to administering metaxalone to a patient and "informing" the patient that taking metaxalone with food increases the drug's bioavailability.[7] Variants of the second claim-type also included claims with limitations that required the drug to be given to patients in bottles with labels "advising" the patient that taking metaxalone with food increases the drug's bioavailability.[8] With respect to the first set of claims, the Federal Circuit affirmed the district court's judgment of anticipation based on the inherency doctrine—a holding that will receive no further comment here.[9] It is the Federal Circuit's treatment of the second set of claims under the printed matter doctrine of section 102 that provides food for thought.[10]

In its historical form, the printed matter doctrine is a long-standing, yet often opaque doctrine that restricts the set of patentable things, and it is often described as a doctrine that more specifically restricts the set of things that constitute novel advances over the prior art under section 102.[11] The gist of the doctrine is that the knowledge conveyed by printed matter to a human reader—i.e., the "content" of the printed matter—cannot be considered by a patent examiner or a court that is determining whether a claimed invention is novel.[12] A paradigmatic application of the printed matter doctrine is that a technical text or diagram that represents the patented advance to a human reader cannot be patented, as the difference between the text/diagram and the prior art resides only in the content of the print. Similarly, a kit of prior-art chemicals claimed in conjunction with printed instructions conveying a newly discovered method of using those chemicals is new as a purely

[5] *King Pharms.*, 2010 WL 30001333, at *2.

[6] *Id.*

[7] *Id.* at *2–*3.

[8] *Id.*

[9] *Id.* at *6–*8.

[10] The district court also rejected these claims as patent-ineligible under section 101. *Id.* at *4–*5. The Federal Circuit, however, expressly declined to review this aspect of the district court's reasoning. *Id.* at *10.

[11] For a more detailed exposition of the doctrinal and statutory quirks of the printed matter doctrine, see Kevin Emerson Collins, *Semiotics 101: Taking the Printed Matter Doctrine Seriously*, 85 Ind. L.J. 1379, 1386–1403 (2010). The printed matter doctrine also affects nonobviousness, but this Essay discusses only novelty for simplicity.

[12] The emphasis on human-readable texts was reaffirmed in *In re Lowry*, 32 F.3d 1579 (Fed. Cir. 1994).

factual matter but, thanks to the printed matter doctrine, old as a legal matter.[13] A well established exception to the printed matter doctrine is that the content of printed matter can distinguish a claimed invention from the prior art if the printed matter is "functionally related" to the substrate on which it is printed.[14] However, the historical case law on the functional-relation exception is difficult to explain with any single, coherent narrative.[15]

In *King Pharmaceuticals*, the Federal Circuit invalidated the "advising" and "informing" claims for lack of novelty under the printed matter doctrine.[16] This holding is noteworthy because it is the first extension of the printed matter doctrine to method claims that recite speech acts.[17] Just as the content of printed texts cannot differentiate claimed objects from the prior art, the content of the messages conveyed through speech acts—whether spoken or written—now cannot differentiate claimed methods from the prior art. Thus, the claims were held to lack novelty under section 102 because the act of administering metaxalone to patients was old in the art and the "advising" or "informing" steps, while new as a factual matter, could not render the claims novel as a legal matter. To reach this conclusion, the Federal Circuit also rejected King's argument that the "advising" and "informing" steps are functionally related to the other steps recited in the claim.[18]

II. Why the Printed Matter Doctrine Is Important and Why *King Pharmaceuticals* Was Correctly Decided

After *King Pharmaceuticals*, the printed matter doctrine isn't just about object claims and printed matter anymore.[19] *King Pharmaceuticals* points the way to a reconceptualization of the printed matter doctrine as a doctrine that protects the overall structure of the Patent Act.[20] It restricts patentable inventions in order to

[13] *In re Nagi*, 367 F.3d 1336 (Fed. Cir. 2004).

[14] *See, e.g.*, *In re Gulack*, 703 F.2d 1381 (Fed. Cir. 1983).

[15] Collins, *supra* note 11, at 1392–96.

[16] *King Pharms*, 2010 WL 30001333, at *9–*13.

[17] *Id.* at * 11.

[18] *Id.*

[19] Therefore, the doctrine is due to be renamed, but this Essay continues to call it the printed matter doctrine in order to avoid unnecessary confusion.

[20] I describe this structural theory of the printed matter doctrine at length elsewhere. Collins, *supra* note 11, at 1427–30. *See also* Kevin Emerson Collins, *Claims to Information qua Information and a Structural Theory of Section 101*, 4 I/S: A J. OF L. AND POL'Y FOR THE INFO. SOC'Y 11, 22–26 (2008), *reprinted in* PATENT CLAIMS: JUDICIAL INTERPRETATION AND ANALYSIS (2009) (discussing a structural interpretation of section 101). In these earlier writings, I have

ensure that patentees comply with their statutory disclosure obligations.

One of the deepest structural principles of the Patent Act is its "duality of claiming and disclosing."[21] Congress did not unilaterally bestow benefits upon inventors who generate technological progress. Rather, it structured the patent regime as a "bargain" in which inventors and the public exchange valuable rights.[22] The public, via the state, grants an inventor limited rights to exclude others from making the claimed embodiments of an invention. As the "quid pro quo of the right to exclude," the inventor discloses newly discovered knowledge that she otherwise could have kept secret.[23] These disclosures serve two distinct functions. First, they enable the public to make and use the claimed technology after the patent expires.[24] Second, they are "additions to the general store of knowledge" that must be free for all to use *qua* knowledge immediately upon publication and during the patent's term so as to "stimulate ideas and the eventual development of further significant advances in the art."[25] It is only because of the public's ability to use the disclosure *qua* knowledge during the term of a patent—to think about the knowledge revealed in a patent disclosure, convey it to others, and discuss its implications with others—that the concepts of improvement on and "design around" of patented technologies during the term of a patent are commonplace.

What is frequently overlooked in the theory and doctrine of the disclosure is that the public's privilege to use the disclosure *qua* knowledge during the term of a patent is not a natural or inevitable feature of all possible patent regimes. The public privilege is sure to exist only if patent doctrine is crafted so as to shelter it from the privatizing effect of patent claims. At least when knowledge is in a form

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characterized the printed matter doctrine as an artifact of section 101 rather than section 102, but I have also noted that that statutory locus is not critical given that the theory derives from an interpretation of the structure of the Patent Act as a whole. Collins, *supra* note 11, at 1429–30. One advantage of lodging the printed matter doctrine in section 102 rather than section 101 is that it nips in the bud any potential conflict between the "patentable weight" approach to validity that inheres in the printed matter doctrine and the "claim as a whole" approach to validity that governs contemporary patent-eligibility doctrine. *See id.* at 1402–03 & 1430–31 (discussing this potential conflict but arguing that is not actually a conflict at all).

[21] Graeme B. Dinwoodie & Rochelle Cooper Dreyfuss, *Patenting Science: Protecting the Domain of Accessible Knowledge*, *in* THE FUTURE OF THE PUBLIC DOMAIN: IDENTIFYING THE COMMONS IN INFORMATION LAW 191, 193 n.4 (2006) (Lucie Guibault & P. Bernt Hugenholtz, eds.).

[22] Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150–51 (1989).

[23] Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974).

[24] Grant v. Raymond, 31 U.S. (6 Pet.) 218, 247 (1832).

[25] *Id.* at 481.

that is useful to humans, knowledge is not an ethereal, immaterial entity. It is a phenomenon rooted in both the electro-chemical states of our brains and the worldly things that our minds understand to be meaningful. Because of the worldly, material bases of knowledge, the disclosure side of the duality of claiming and disclosing is in jeopardy of being curtailed or eliminated unless there are doctrinal restrictions on the patentability of the worldly resources that constitute knowledge built into patent law. Unless the scope of the set of things that can be patented is restricted, patentees can dress up knowledge itself as a patentable invention.[26] They can describe in a claim, and thus purport to privatize, the resources that they should be obligated to publicize. Unless there is patent doctrine to prevent them from doing so, patentees can claim printed documents (including printed copies of specifications), speech (including the acts of reading a specification or conveying the ideas communicated therein in one's own words), and thought (including the act of understanding the contents of the specification). Thus, patent disclosures are guaranteed to produce a public domain of knowledge, rather than privatized knowledge, only if there are doctrinally enforced limits on the nature of the claims to which inventors are entitled.

As extended in *King Pharmaceuticals*, the printed matter doctrine is nothing more than the doctrine that is needed to enforce the patentee's statutory disclosure obligations. Under the disclosure side of the patent bargain, the public should have an unfettered right to convey the newly discovered knowledge revealed in a patent specification before the expiration of the patent and, furthermore, to do so in conjunction with the practice of any prior-art technology that the public has a pre-existing right to use. The historical printed matter doctrine protects this public domain of the disclosure by invalidating any object claim in which novelty resides solely in the knowledge conveyed by a tangible document. It is because of the printed matter doctrine that an inventor cannot claim the combination of old chemicals and the specification of a patent disclosing a new method of using those chemicals. The extension of the printed matter doctrine formulated in *King Pharmaceuticals* simply brings the same rule to bear on acts of speaking and reading. If the *King Pharmaceuticals* claims were novel, then a doctor could run afoul of patent law by handing a copy of the patent to a patient—or reading it to a patient—to whom she has prescribed metaxalone. If the public's side of the patent bargain is to have any substance at all prior to patent expiration, this conduct cannot constitute a patentable method that falls under the exclusive control of a patentee.[27]

One practical advantage of construing the printed matter doctrine in this structural

[26] This issue is not about patent scope. The potential problem is not overbroad patents—patents that sweepingly encompass too many distinct things. It is patents that claim the wrong kind of thing—patents that claim a thing that is new as a factual matter but that should not be recognized as new for the purposes of the section 102 novelty inquiry.

[27] The public could, in theory, be held vicariously liable in part because they distribute patent specifications with the intent to cause others to commit infringement.

manner is that it provides the doctrine with its otherwise absent statutory grounding. The Federal Circuit has repeatedly stated that "[a] 'printed matter rejection' . . . stands on questionable legal and logical footing" because there is no express mention of the printed matter doctrine anywhere in the Patent Act.[28] When reconceptualized as the enforcer of the public's side of the patent bargain, however, the structural canon of statutory interpretation resolves the statutory mystery. Structural statutory interpretation requires courts to look to "the structure and purpose of the Act" as a whole when construing statutory language.[29] When section 102 is viewed in the context of the Patent Act as a whole, and the disclosure obligations of section 112 in particular, it is clear that there is one category of claims that Congress did not intend to sanction as patentably novel: claims like those at issue in *King Pharmaceuticals* that interfere with the public's ability to access, understand, and convey "the general store of knowledge" to which patent disclosures make their contributions as soon as they are published.[30]

III. Next Question: Are the Claims at Issue in *Prometheus Laboratories* Novel?

Assuming that *King Pharmaceuticals* correctly extended the printed matter doctrine into method claims, the remand from the Supreme Court that is currently pending before the Federal Circuit in *Prometheus Laboratories* should force the Federal Circuit to clarify the scope of its holding in *King Pharmaceuticals* almost immediately.[31] Given that the *King Pharmaceuticals* "advising" claims lack novelty, then why don't the claims at issue in *Prometheus Laboratories* lack novelty as well?

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[28] *In re* Lowry, 32 F.3d 1579, 1583 (Fed. Cir. 1994) (quoting *In re* Gulack, 703 F.2d 1381, 1385 n.5 (Fed. Cir. 1983)).

[29] N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995).

[30] *Kewanee Oil*, 416 U.S. at 481. There are other structural arguments supporting the printed matter doctrine—including its extension to method claims reciting speech acts in *King Pharmaceuticals*—as well, but space limitations prevent their full inclusion in this Essay. Perhaps most pressingly, there are close to insurmountable difficulties establishing both the scope of a claim that turns on the content of knowledge conveyed and the prior art against which to measure the novelty and nonobviousness of such a claim. In other words, the disclosure argument presented in the text is only one arrow in a quiver of possible structural arguments. In the author's opinion, however, it is one of the strongest arguments.

[31] Prometheus Labs. v. Mayo Collaborative Servs., 581 F.3d 1336 (Fed. Cir. 2009), *vacated and remanded by* 2010 WL 2571881 (U.S. Jun. 29, 2010). Because the remand requests that the Federal Circuit reconsider its holding in light of the Supreme Court's recent interpretation of section 101 in *Bilski v. Kappos*, the Federal Circuit may restrict itself to the section 101 issue in its impending opinion. Nonetheless, whether for the purposes of the pending appeal or for future cases, it is important to investigate the impact that *King Pharmaceuticals* will have on the novelty of claims like those at issue in *Prometheus Laboratories*.

The clinical research that gave rise to the claims at issue in *Prometheus Laboratories* quantified a previously unknown correlation between the amount of the metabolite of a drug in the blood of a patient ingesting the drug and the acceptable clinical-outcome risks for that patient. More specifically, the research revealed both the upper-bound safety limit and a lower-bound efficacy limit on the concentration of the metabolite.[32] Based on this discovery, the broadest claim that Prometheus Laboratories obtained was, roughly summarized, a two-step method claim to (a) "determining" the amount of metabolite in the blood of a patient who is taking the drug and (b) inferring a "need" to increase or decrease the amount of the drug administered to the patient if the amount of the metabolite fell beyond the limits.[33]

The first step of the *Prometheus Laboratories* claim is old in the art, as doctors had been testing for the metabolite of the particular drug at issue before the discovery of the optimal upper and lower bounds on the metabolite concentration. The factual novelty of the method, therefore, resides only in the second, inferring step. The question raised by *King Pharmaceuticals* is whether the factual novelty of the inferring step can make the claim novel as a legal matter, or whether the novelty of this step must be overlooked under the extension of the printed matter doctrine to method claims. The latter option seems reasonable at first glance given at the inferring step is simply a mental step that involves thinking about the content of the patent specification, namely the correlation between the metabolite concentration and the optimal clinical outcomes.

An initial attempt to distinguish *King Pharmaceuticals* might rely on the fact that the *King Pharmaceuticals* claim ignored the factual novelty of an act of communicating knowledge whereas the *Prometheus Laboratories* claim recites a purely mental act of thinking about knowledge. To infringe the *Prometheus Laboratories* claim, the doctor need not give any advice to a patient. She need not convey any knowledge to anyone. All she needs to do is to mentally reach a conclusion about the need *vel non* to increase or decrease the amount of the drug administered. This distinction between extroverted and introverted mental acts, however, is an unpersuasive reason to distinguish *Prometheus Laboratories* from *King Pharmaceuticals* for two reasons. First, as a practical matter, the doctor is likely to advise her patients of any need to change the amount of the drug administered. Second, and more to the point, the extension of the printed matter doctrine to method claims in *King Pharmaceuticals* should also extend to steps reciting the purely internal mental process of "understanding" the knowledge conveyed in the specification. As a hypothetical, assume that King had obtained a two-step method claim describing a

[32] *Prometheus Labs.*, 581 F.3d at 1339.

[33] *Id.* at 1340, 1347. Many of the claims also recited an initial step of "administering" the drug to the patient. *Id.* at 1340. The text of claims does not include the word "inferring," but the "wherein" clause of the actual claims describes an act of logical inference. Kevin Emerson Collins, *An Initial Comment on Prometheus: The Irrelevance of Intangibility*, PATENTLYO, http://www.patentlyo.com/patent/2009/09/an-initial-comment-on-prometheus-the-irrelevance-ofintangibility-1.html (September 17, 2009) (explaining why the claim is a "determine-and-infer" claim).

patient (a) taking metaxalone and (b) understanding that the consumption of metaxalone with food increases the bioavailability of the drug. Surely this claim, too, would be rendered legally anticipated under the printed matter doctrine. Therefore, *King Pharmaceuticals* must extend the printed matter doctrine not only to speech acts but also to the purely mental act of understanding the knowledge disclosed in a patent specification.

The key to possibly distinguishing *Prometheus Laboratories* from *King Pharmaceuticals* is to develop a taxonomy of mental acts that allows the acts of understanding and inferring to be distinguished. An act of understanding is nothing more than the mental process of comprehending the knowledge disclosed in a patent specification. If a variant of the *Prometheus Laboratories* claim were to describe the two-step method of (a) determining the metabolite concentration and (b) understanding that there are specific upper and lower bounds on the optimal window of metabolite concentration, then the claim would not recite a legally novel invention under *King Pharmaceuticals*. However, the act of inference described in the second step is more complex than a simple act of understanding. As I've demonstrated at length elsewhere, the inferring step describes a particular type of deductive reasoning.[34] The doctor performing the mental act is presumed to understand two facts. First, because she performed the first "determining" step, she knows the amount of the drug metabolite in the blood in her particular patient. For simplicity, say it is 5. Second, because she reads the patent specification (or learns the knowledge disclosed therein through any other channel), she knows that, in general, patients with metabolite levels beyond the upper bound—again for simplicity, say 4—are exposed to unnecessary safety risks. With these two facts in her mind, the doctor deduces a third fact: the fact that her patient in particular has an unsafe level of the metabolite, which in turn implies a "need" to decrease the amount of drug administered. Schematically presented, the logical argument—a syllogism—looks like this:

Premise 1:	My particular patient has a metabolite level of 5.
Premise 2:	Patients with metabolite levels of 5 suffer from unacceptable safety risks.
Inferred conclusion:	My particular patient suffers from an unacceptable safety risk.

This syllogistic act of inferring goes beyond the act of simply understanding the knowledge disclosed in the patent specification. It is an act of reasoning that employs the knowledge disclosed in the specification as a premise (Premise 2) and that yields a new fact (the Conclusion) that was not itself disclosed in the specification or necessarily otherwise known at all.

In sum, there is a way to reconcile the unpatentability of the claim in *King Pharmaceuticals* and the patentability of the claim in *Prometheus Laboratories*. Simple mental acts of understanding facts disclosed in specifications clearly cannot

[34] Kevin Emerson Collins, *Propertizing Thought*, 60 SMU L. Rev. 317, 335–42 (2007) (explaining the reasoning involved in a statistical syllogism).

be used to differentiate claims from the prior art under *King Pharmaceuticals*, but perhaps the novelty of mental acts of inferring that employ facts disclosed in the specification as premises can differentiate claims from the prior art. One doctrinal means of achieving this end result is to reinterpret (yet again, as has been done many times in the past) the "functional relation" exception to the printed matter doctrine.[35] Unlike the simple act of understanding, perhaps the act of inferring is functionally related to the act of "determining" in the first step because the fact determined in the first step (Premise 1) is required to perform the claimed inference.

To be clear, whether the Federal Circuit *should* as a normative matter use the distinction between understanding and inferring as a peg on which to hang the legal novelty of the *Prometheus Laboratories* claims raises an issue that is far beyond the scope of this Essay. The point made here is far more limited. In order for the Federal Circuit to even consider whether to uphold the section 102 novelty of the *Prometheus Laboratories* claims in light of *King Pharmaceuticals*, the Federal Circuit must develop a taxonomy of mental processes that distinguishes the inferring process at issue in *Prometheus Laboratories* from the understanding step in the hypothetical variant of the *King Pharmaceuticals* claims. This would be new terrain for the Federal Circuit. To date, the Federal Circuit has addressed the patentability of mental steps only under the section 101 doctrine of patent eligibility, and it has assumed that all mental steps are equally abstract.[36] To address the novelty of the *Prometheus Laboratories* claim and sanction any patent claims in which novelty resides only in a mental step, the Federal Circuit must enter an Orwellian world in which some mental steps are more equal than others when it comes to property rights in human thought.

[35] *See supra* text accompanying notes 14–15 & 18.

[36] *See, e.g.*, *In re* Comiskey, 554 F.3d 967, 979 (Fed. Cir. 2009). Similarly, the now-defunct (or at least dormant) mental steps doctrine of Section 101 never differentiated between different types of mental steps. *In re* Abrams, 188 F.2d 165, 168 (C.C.P.A. 1951) (articulating the mental steps doctrine); *In re* Musgrave, 431 F.2d 882 (C.C.P.A. 1970) (criticizing and abandoning the mental steps doctrine).