NEUROBIOLOGY AND PATENTING THOUGHT

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I. INTRODUCTION

In 2004, Professor Henry T. Greely offered several predictions about how neuroscience might affect "owning thoughts."[1] His predictions included the prospect that patents on human neural processes could trigger controversy similar to that caused by the earlier patenting of human gene sequences.[2] Since then, there has indeed been a proliferation of patents claiming aspects of human neural processes and human neural networks.[3] However, there has been another, unforeseen, development at the intersection of patent law and neurobiology. A flowering of cases involving alleged infringement of patents claiming thought—traditionally referred to in patent law as "mental steps"—has revived interest in an old, neglected, but apparently not entirely abandoned principle of patent law called "Mental Steps Doctrine."

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1 Henry T. Greely, *Prediction, Litigation, Privacy, and Property*, *in* NEUROSCIENCE AND THE LAW: BRAIN, MIND, AND THE SCALES OF JUSTICE 114, 152–54 (Brent Garland ed., 2004).

2 *Id.* at 152–53.

3 *See, e.g.*, U.S. Patent No. 6,876,989 (filed Feb. 13, 2002); U.S. Patent No. 7,082,419 (filed Feb. 1, 2000); U.S. Patent No. 6,625,588 (filed Mar. 23, 1998).

This article reviews the history of the Mental Steps Doctrine and the renewed interest that courts, including, most notably, the United States Supreme Court, have shown in patents claiming thoughts or aspects thereof. Furthermore, it suggests several implications that neurobiology may hold for setting coherent and defensible boundaries on the patenting of "thought." In particular, this article explores the implications for patent law of (1) thought that is significantly subject to "executive control," and (2) reflexive "default" thought, not significantly subject to executive control. Finally, it makes the novel suggestion that, if any category of thought is to constitute patentable subject matter, insights from neurobiology would favor the patentability of thought subject to executive control more strongly than the patentability of default thought not subject to executive control.

Many have argued that thought should constitute *per se* unpatentable subject matter, and that any patent claim that includes a mental step should lie outside patentability.[4] However, courts have long disagreed with such a draconian rule, and have instead upheld myriad patents with claims that include mental steps. For example, the United States Court of Appeals for the Federal Circuit ("Federal Circuit") has upheld—and the United States Supreme Court ("Supreme Court") has declined to reverse—a patent whose claims include mental steps as simple as making a correlation between two variables.[5] However, courts have increasingly struggled to decide where to draw the line between patentable and unpatentable "thought patents." Insights from neurobiology about how to differentiate categories of thought can offer useful criteria for deciding between patentable and unpatentable mental steps. In particular, this article argues that thoughts subject to "executive control" should be situated more towards the patentable end of the spectrum, whereas "default thoughts" should be situated closer to the unpatentable end of the spectrum. This schema represents somewhat of a departure from the traditional view that First Amendment interests should privilege sophisticated, expressive thought, as well as diversity of thought, by protecting it from patentability. Nevertheless, it accords well with Thirteenth Amendment interests, privileging thoughts that cannot be avoided by protecting them from patentability, and thus preventing the iniquity of involuntary patent servitude.

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4 Obviously, if thought, and patents claiming mental steps, simply constituted unpatentable subject matter, any taxonomy of thought (e.g., thought under executive control versus default thought) would have little relevance for patent law.

5 *See* Metabolite Labs., Inc., v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1368 (Fed. Cir. 2004), *cert. dismissed*, 548 U.S. 124 (2006).

II. THE RISE AND FALL OF THE MENTAL STEPS DOCTRINE

Thought has long been difficult to claim in a patent. In 1874, the Supreme Court declared that "an idea of itself is not patentable."[6] During the middle of the 20th Century the courts and the United States Patent and Trademark Office ("USPTO") developed a legal doctrine governing the patentability of claims involving mental steps.[7] As part of an enumeration of unpatentable categories of subject matter, the Supreme Court noted that "mental processes . . . are not patentable."[8] In a famous statement on this rule, the Court of Customs and Patent Appeals declared, in *In re Abrams*,[9] that "[i]t is self-evident that thought is not patentable."[10]

There are a number of rationales that can help to explain why patent law might consider, and often has considered, thought to constitute unpatentable subject matter. The Supreme Court has stated that natural phenomena, such as "laws of nature, physical phenomena, and abstract ideas have been held not patentable."[11] This exclusion accords with the view that patent law should reward the invention of new phenomena rather than the mere discovery of existing, "natural," phenomena. Here, thought might be construed as falling within, or overlapping, the category of "abstract ideas."[12] Whether the conceptual overlap between thoughts and abstract ideas is tight enough to justify synonymy, or even significant overlap, depends on what precise meanings are attributed to both concepts. Since the scope of the word "idea" is logically greater than that of "abstract idea," there is a possibility that non-abstract ideas might still be patentable. Furthermore, because the mapping of thought onto abstract ideas is imperfect, the logical possibility exists that at least some thoughts might constitute patentable subject matter.

From the perspective of neurobiology, thought almost certainly implicates neurons, neural circuits and networks, and neurophysiological processes involving both electrochemical and molecular signaling. This neurobiological conception of "thought" might qualify for inclusion within a second enumerated category of unpatentable subject matter, namely "physical phenomena." Patent

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6 Rubber-Tip Pencil Co. v. Howard, 87 U.S. 498, 507 (1874).

7 1 DONALD S. CHISUM, CHISUM ON PATENTS, § 1.03[6], at 1-169 (Matthew Bender & Co., Inc. 2009).

8 Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

9 188 F.2d 165 (C.C.P.A. 1951).

10 *Id.* at 168.

11 Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

12 *Id.*

law already appears to restrict the patentability of involuntary physiological phenomena that occur with the human body. This Physiological Steps Doctrine seems to preclude patents claiming products of *in vivo* conversion, and suggests that courts tend not to allow or enforce patents that claim involuntary physiological processes of the human body.[13] Physiological Steps Doctrine may preclude the patenting of default thoughts due to their involuntary nature.[14] Most obvious is the Supreme Court's prohibition on patenting "mental processes . . . as they are [included among] the basic tools of scientific and technological work."[15]

Mental Steps Doctrine reached its zenith in the late 1960s before rapidly waning into obscurity. In 1970, the United States Court of Customs and Patent Appeals ("CCPA"), in *In re Musgrave*,[16] derided the Mental Steps Doctrine as "something of a morass."[17] Judge Rich went on to repudiate the doctrine: "As may be seen from the statutory language, it contains nothing whatever which would either include or exclude claims containing 'mental steps' and whatever law there may be on the subject cannot be attributed to Congress."[18]

As late as 1978, the Supreme Court, in *Parker v. Flook*,[19] declared that "mental processes, and abstract intellectual concepts are not patentable . . . ."[20] However, in 1981, the Supreme Court decision in *Diamond v. Diehr*[21] upheld the patentability of claims involving the use of a mathematical algorithm (that

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13 Andrew W. Torrance, *Physiological Steps Doctrine*, 23 Berkeley Tech. L.J. 1471, 1472–1505 (2008). On nearly a dozen separate occasions federal courts have considered whether human products of "in vivo conversion" (that is, the conversion of a first chemical species into a distinctly different second chemical species by the body's own physiological processes) constitute patentable subject matter that can be protected from infringement by valid and enforceable patent claims. These cases all consider whether human administration of an unpatented "prodrug" (or drug precursor) that is subsequently converted within the human body into a different, therapeutically active, and patented, drug can trigger patent infringement. Although well-settled principles of patent law mandate that infringers are strictly liable for making or using a claimed invention, remarkably no court has finally found infringement for the in vivo production of a patented drug within the human body. *Id.*

14 *Id.* at 1502.

15 Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

16 431 F.2d 882 (C.C.P.A. 1970).

17 *Id.* at 890.

18 *Id.*

19 437 U.S. 584 (1978).

20 *Id.* at 589.

21 450 U.S. 175 (1981).

is, the Arrhenius equation) for shaping and curing synthetic rubber in a mold.[22] Although this algorithm was well known at the time the relevant patent application was filed, and capable of calculation in the mind of a human, the inventor claimed using a computer to apply the Arrhenius equation to the curing of rubber.[23]

In 1998, in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*,[24] the Federal Circuit appeared to widen recognition of mental steps as patentable subject matter by affirming the validity of claims to methods of doing business.[25] In that case, claims of U.S. Patent No. 5,193,056, entitled "Data Processing System for Hub and Spoke Financial Services Configuration," involved a multi-tiered funding complex modeled on a "hub and spoke," wherein mutual funds pool their assets into an investment portfolio organized as a partnership, thus providing the administrator of the mutual fund with the combination of economies of scale in administering investments and the tax advantages of a partnership configuration.[26] The decision in *State Street* appeared to open the floodgates to patents claiming thought because the USPTO subsequently issued a significantly greater number of patents claiming methods—especially business methods—based largely, and sometimes entirely, on mental steps.[27]

III. MENTAL STEPS DOCTRINE RESURGENT

In 2006, the odd disposition of a case appealed to the Supreme Court appeared to clear the way to patents claiming methods that involve human mental processes. In *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*,[28] the Supreme Court first granted certiorari; but then, rather than decide the case, it dismissed the writ of certiorari as improvidently

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22 *Id.* at 192–93. The claims, as issued by the USPTO, avoided the possibility that a human could infringe them by carrying out calculations in her mind by specifically requiring (in claim 1) "the aid of a digital computer." *Id.* at 179 n.5.

23 *Id.* at 187–88.

24 149 F.3d 1368 (Fed. Cir. 1998), *abrogated by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc).

25 *Id.* at 1377.

26 *Id.* at 1370.

27 *See, e.g.*, Wade M. Chumney, David L. Baumer & Roby B. Sawyers, 46 AM. BUS. L.J. 343, 356 (2009) ("Business method patent filings have been rapidly proliferating. In 2006, over 10,000 applications were filed for business method patents (categorized as Class 705) by the PTO, and there have been at least 7,500 patents filed in this category every year since 2000.").

28 548 U.S. 124 (2006).

granted.[29] Justice Breyer dissented, joined by Justices Stevens and Souter.[30] Breyer's vigorous dissent outlines the facts of the case, then suggests how the case should have been disposed of, had the writ of certiorari not been dismissed.[31]

Respondent Metabolite Laboratories was the licensee of a patent claiming "new methods for testing homocysteine levels using gas chromatography and mass spectrometry" developed by researchers in the 1980s.[32] Laboratory Corporation used these patented methods under a royalty-bearing license from Metabolite Laboratories until 1998, when the former started using a superior test created by Abbott Laboratories.[33] Laboratory Corporation decided to discontinue paying royalties after concluding that the Abbott test was not covered by the Metabolite Laboratories patent.[34] Metabolite Laboratories sued Laboratory Corporation for both patent infringement and breach of the patent license agreement.[35]

At issue was claim 13, which claims:

> A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
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> assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.[36]

The parties agreed that "assaying a body fluid" referred to any test that detects an elevated level of total homocysteine.[37] At trial, the inventors testified that "correlating" in this context simply refers to a doctor recognizing an elevated level of homocysteine, which "would occur automatically in the mind of any competent physician."[38] In the district court, a jury found Laboratory Corporation liable, under 35 U.S.C. § 271(b), for actively inducing doctors to infringe Metabolite's patent.[39]

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29 *Id.* at 125.

30 *Id.* (Breyer, J., dissenting).

31 *Id.* at 125, 138.

32 *Id.* at 128.

33 *Id.*

34 Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 129 (2006) (Breyer, J., dissenting).

35 *Id.*

36 *Id.*

37 *Id.*

38 *Id.* at 129–30.

39 *Id.* at 130.

On appeal, the Federal Circuit rejected Laboratory Corporation's argument that the claims were construed too broadly, and did not address its alternative argument that, "*if so construed*, claim 13 must be struck down as an improper effort to obtain patent protection for a law of nature."[40]

The Supreme Court granted Laboratory Corporation's petition for certiorari, but limited the appeal to a single question: "Whether a method patent . . . directing a party simply to 'correlate' test results can validly claim a monopoly over a basic scientific relationship . . . such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result."[41]

However, the Supreme Court then declined to decide the case on the grounds that the writ of certiorari had been improvidently granted.[42] In a vigorous dissent, Justice Breyer proceeded to list reasons why the Court should have proceeded to decide the case.[43] Breyer then turned to the merits of the dispute, characterizing the issue as follows: The researchers who obtained the present patent found that an elevated level of homocysteine in a warm blooded animal is correlated with folate and cobalamin deficiencies. As construed by the Federal Circuit, claim 13 provides those researchers with control over doctors' efforts to use that correlation to diagnose vitamin deficiencies in a patient. Does the law permit such protection or does claim 13, in the circumstances, amount to an invalid effort to patent a "phenomenon of nature"?[44]

Breyer conceded "that the category of non patentable '[p]henomena of nature,' like the categories of 'mental processes' and 'abstract intellectual concepts,' is not easy to define."[45] For Breyer, the issue on which the Supreme Court had granted certiorari was easy to decide because he considered the "correlation" between homocysteine and vitamin deficiency to be a "natural phenomenon."[46] Metabolite argued that its invention should constitute patentable subject matter for three reasons: (1) because it was an "*application* of a law of nature" (citing *Diamond v. Diehr*), (2) because it entails a physical transformation of blood samples (citing *Cochrane v. Deener* and *Gottschalk v. Benson*), and (3)

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40 Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 131 (2006) (Breyer, J., dissenting).

41 *Id.* at 132.

42 *Id.* at 125.

43 *Id.* at 132–34.

44 *Id.* at 134.

45 *Id.* (citing Parker v. Flook, 437 U.S. 584, 589 (1978)) (alteration in original).

46 Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 135 (2006) (Breyer, J., dissenting).

because it produces a "useful, concrete, and tangible result" (citing *State Street*).[47] Breyer addressed these arguments by noting that even if he were to assume that the invention met some requirements of process patentability, Metabolite would also have to meet the natural phenomenon requirement.[48]

However, despite Breyer's dissent, the actual disposition of the case left the contested claim of Metabolite's patent—a claim potentially infringed by human thought—intact, valid, and infringed by Laboratory Corporation.

After the Supreme Court declined to decide Laboratory Corporation's appeal, the Federal Circuit and the Board of Patent Appeals and Interferences ("BPAI") experienced an increase in patent litigation involving patent claims encompassing human thought. These included *In re Nuijten*,[49] *Ex parte Jakobsson*,[50] *Ex parte Gutta*,[51] *Ex parte Glenner*,[52] and *Classen Immunotherapies, Inc. v. Biogen IDEC*.[53] Two cases were accorded special importance by the Federal Circuit, which ultimately considered them en banc: *In re Comiskey*[54] and *In re Bilski*.[55]

In *Comiskey*, the claimed invention at issue involved "a method and system for mandatory arbitration involving legal documents, such as wills or contracts."[56] The parties agreed that the claims did not require the use of a computer, but could be performed using human thought.[57] The USPTO Examiner

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47 *Id.* at 135; *see also* Diamond v. Diehr, 450 U.S. 175, 187 (1981); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780, 788 (1877); State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998), *abrogated by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc).

48 *Lab. Corp.*, 548 U.S. at 137 (Breyer, J., dissenting) (citing *Flook*, 437 U.S. at 588 n.9).

49 500 F.3d 1346 (Fed. Cir. 2007).

50 84 U.S.P.Q.2d 1511 (B.P.A.I. 2007).

51 84 U.S.P.Q.2d 1536 (B.P.A.I. 2007).

52 No. 2007-1089, 2007 WL 1874818 (B.P.A.I. June 28, 2007).

53 Civ. No. WDQ-04-2607, 2006 U.S. Dist. LEXIS 98106 (D. Md. Aug. 16, 2006).

54 554 F.3d 967 (Fed. Cir. 2009) (en banc). On January 13, 2009, acting en banc, the Federal Circuit vacated its previous panel decision of September 20, 2007, and withdrew the opinion of that panel. *In re* Comiskey, 499 F.3d 1365 (Fed. Cir. 2007), *vacated* 554 F.3d 967 (Fed. Cir. 2009) (en banc). Although the panel opinion was revised at the order of the en banc Federal Circuit, largely to remove confusing linkages the panel had made between non-obviousness (35 U.S.C. § 103) and patentable subject matter (35 U.S.C. § 101), the panel's original conclusions regarding the patentability of inventions involving mental processes remained unchanged in the en banc opinion.

55 545 F.3d 943 (Fed. Cir. 2008) (en banc), *cert. granted sub nom.* Bilski v. Doll, 129 S. Ct. 2735 (2009) (No. 08-964) (argued Nov. 9, 2009).

56 554 F.3d at 970.

57 *Id.*

had rejected this method on grounds of obviousness.[58] The inventor, Comiskey, appealed to the BPAI, which sustained the Examiner's rejections.[59]

Upon appeal, the Federal Circuit affirmed the conclusion of the BPAI, but on statutory subject matter grounds and without reaching the issue of obviousness.[60] First, the Federal Circuit evaluated whether it could address the statutory subject matter question.[61] In the second part of the opinion, the court considered the substance of the statutory subject matter question.[62] The Federal Circuit characterized the patent application at issue as a business method patent and said that, while *State Street* allows the patentability of business methods, claims to such inventions must still meet the other requirements of patentability, including the requirements of 35 U.S.C. § 101.[63]

The court then reviewed the history of the prohibition on the patenting of abstract ideas.[64] The Federal Circuit found that abstract ideas are not patentable unless they have practical application (citing *AT&T* and *State Street*).[65] The court reasoned that even if the invention does have a practical application, it must either (1) be tied to a particular apparatus, or (2) change materials to a different state or thing (citing *Flook* and *Diehr*, among other sources).[66]

Next, the court described the Mental Steps Doctrine:

> Following the lead of the Supreme Court, this court and our predecessor court have refused to find processes patentable when they merely claimed a mental process standing alone and untied to another category of statutory subject matter even when a practical application was claimed. . . .
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> . . . .
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> It is thus clear that the present statute does not allow patents to be issued on particular business systems—such as a particular type of arbitration—that depend entirely on the use of mental processes. In other words, the patent statute does not allow patents on particular systems that depend for their opera-

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58 *Id.* at 969.

59 *Id.*

60 *Id.*

61 *Id.* at 973–75.

62 *In re* Comiskey, 554 F.3d 967, 976–82 (Fed. Cir. 2009) (en banc).

63 *Id.* at 975–76 (quoting State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1375 (Fed. Cir. 1998), *abrogated by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc)).

64 *Id.* at 978.

65 *Id.* (citing AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352, 1355 (Fed. Cir. 1999); *State St.*, 149 F.3d at 1373)).

66 *Id.* (citing Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Diamond v. Diehr, 450 U.S. 175, 184 (1981)).

> tion on human intelligence alone, a field of endeavor that both the framers and Congress intended to be beyond the reach of patentable subject matter. Thus, it is established that the application of human intelligence to the solution of practical problems is not in and of itself patentable.[67]

Applying this rule to the specific patent claims at issue, the Federal Circuit found that many of the claims violated the rule because they did not require the use of a machine, but could have been carried out by the human mind.[68]

Even so, the Federal Circuit did find that two sets of claims potentially constituted patentable subject matter because, under a broad interpretation, they could have required the use of a computer.[69] The Federal Circuit then remanded the case to the USPTO for a determination of whether those potentially patentable claims, with the addition of computer-use, satisfied § 101.[70]

Almost simultaneously with *Comiskey*, in *In re Bilski*[71] the Federal Circuit reviewed a decision of the BPAI[72] regarding the patentability of methods encompassing human mental processes. The Federal Circuit, sitting en banc, considered "[w]hether the claimed subject matter is not patent-eligible because it constitutes an abstract idea or mental process; when does a claim that contains both mental and physical steps create patent-eligible subject matter?"[73] The claimed invention was "a method practiced by a commodity provider for managing (i.e., hedging) the consumption risks associated with a commodity sold at a fixed price."[74] The examiner had rejected claims 1–11 of the application, finding the invention to be merely an "abstract idea" not within the "technological arts" under *In re Musgrave*.[75] The BPAI characterized the patent as claiming "non-machine-implemented" methods, and stated that "the claims do not recite how the steps are implemented and are broad enough to read on performing the steps without any machine or apparatus."[76] The Federal Circuit thus characterized the issue as whether the invention, involving human thought potentially unfettered from the use of a computer, constituted patentable subject matter.

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67 *Id.* at 980.

68 *In re* Comiskey, 554 F.3d 967, 981 (Fed. Cir. 2009) (en banc).

69 *Id.*

70 *Id.* at 981–82.

71 545 F.3d 943 (Fed. Cir. 2008) (en banc).

72 *Ex parte* Bilski, No. 2002-2257, 2006 WL 4080055 (B.P.A.I. Mar. 8, 2006).

73 *In re* Bilski, 264 F. App'x 896, 897 (Fed. Cir. 2008).

74 *Ex parte Bilski*, 2006 WL 4080055, at *1.

75 *Id.*

76 *Id.* at *2.

The BPAI began its analysis by incorporating by reference the legal analysis of statutory subject matter in *Ex parte Lundgren*,[77] and presented a detailed summary of that analysis.[78] The BPAI then briefly discussed the *Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility* (Nov. 22, 2005), giving several reasons why these guidelines are only of limited assistance.[79] The BPAI cited *Lundgren*, and rejected the proposition that there exists a separate "technological arts" test.[80] Instead, the BPAI applied three different tests:

> (1) a "transformation test," whereby an invention is a statutory process if it transforms something to a different physical state of that thing;[81]
>
> (2) an "abstract idea test", which relates to that judicially recognized category of unpatentable subject matter; and[82]
>
> (3) a "practical application"/"concrete and tangible result" test, derived from *State Street*.[83]

Under all three tests, as well as under the Interim Guidelines, the BPAI decided that the invention did not constitute statutory subject matter, and sustained the examiner's rejections.[84]

The Federal Circuit affirmed the decision of the BPAI. It agreed that the claimed invention of hedging commodities trading risks is unpatentable subject matter under 35 U.S.C. § 101.[85] The Federal Circuit also articulated a new "machine-or-transformation" test for determining whether or not a claimed process constitutes patentable subject matter.[86] The Federal Circuit stated that:

> The Supreme Court . . . has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the prin-

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77 76 U.S.P.Q.2d 1385 (B.P.A.I. 2005).

78 *Ex parte Bilski*, 2006 WL 4080055, at *4–15.

79 *Id.* at *15–18.

80 *Id.* at *18 (citing *Ex parte Lundgren*, 76 U.S.P.Q.2d at 1388).

81 *Id.* at *6 (summarizing *Lundgren's* interpretation of Supreme Court precedent).

82 *Id.* at *20–21.

83 *Id.* at *21.

84 *Ex parte* Bilski, No. 2002-2257, 2006 WL 4080055, at *18–23 (B.P.A.I. Mar. 8, 2006).

85 *In re* Bilski, 545 F.3d 943, 949 (Fed. Cir. 2008) (en banc), *cert. granted sub nom.* Bilski v. Doll, 129 S. Ct. 2735 (2009) (No. 08-964) (argued Nov. 9, 2009).

86 *Id.* at 956.

> ciple itself. A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.[87]

The Federal Circuit held the claims to be unpatentable subject matter because the invention neither was necessarily "tied to a particular machine or apparatus"[88] since it could be performed by human thought, nor "transforms a particular article into a different state or thing."[89] The Federal Circuit specifically prohibited the patentability of any invention capable of being performed entirely by thought:

> Of course, a claimed process wherein all of the process steps may be performed entirely in the human mind is obviously not tied to any machine and does not transform any article into a different state or thing. As a result, it would not be patent-eligible under § 101.[90]

On June 1, 2009, the Supreme Court granted certiorari for *In re Bilski*,[91] having come under considerable pressure to do so in order to clarify the patentability of inventions involving human thought, especially in light of its failure to provide such guidance in *Laboratory Corporation*.

Comiskey and *Bilski* have important implications for medical diagnostic patents. Citing *Bilski*, in December 2008 the Federal Circuit in *Classen Immunotherapies, Inc. v. Biogen IDEC*[92] affirmed a lower court's decision to invalidate patent claims on "evaluating and improving the safety of immunization schedules."[93] The lower court found that "the correlation between vaccination schedules and the incidence of immune mediated disorders that Dr. Classen claims to have discovered is a natural phenomenon."[94]

More recently, the Federal Circuit reversed an appeal of *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*,[95] in which a lower court held that patent claims directed to methods of optimizing treatment of Crohn's dis-

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87 *Id.* at 954.

88 *Id.* at 962, 1003–04.

89 *Id.* at 954, 963–64.

90 *Id.* at 961 n.26.

91 *In re* Bilski, 545 F.3d 943, 949 (Fed. Cir. 2008) (en banc), *cert. granted sub nom.* Bilski v. Doll, 129 S. Ct. 2735 (2009) (No. 08-964) (argued Nov. 9, 2009).

92 304 F. App'x 866 (Fed. Cir. 2008).

93 *Id.* at 866.

94 Classen Immunotherapies, Inc. v. Biogen Idec, Civ. No. WDQ-04-2607, 2006 WL 6161856, at *5 (D. Md. Aug. 16, 2006).

95 581 F.3d 1336 (Fed. Cir. 2009), *petition for cert. filed*, 78 U.S.L.W. 3254 (U.S. Oct. 22, 2009) (No. 09-490).

ease were unpatentable subject matter.[96] Here, the claims involved three major steps: (1) administration of thiopurine to a patient, (2) measuring the amount of thiopurine in the patient, and (3) using the measured amount of thiopurine to fine-tune the administration to the patient of subsequent drug doses.[97] The Federal Circuit recognized the third step as a "mental step" because it is largely based upon human thought.[98] However, the court pointed out that "[a] subsequent mental step does not, by itself, negate the transformative nature of prior steps."[99] The court then held that the claimed methods of treatment do constitute patentable subject matter because, in accordance with the court's *Bilski* test, they "'transform an article into a different state or thing,' and this transformation is 'central to the purpose of the claimed process.'"[100] The Supreme Court is currently considering whether to grant certiorari in this case.[101] Given the complementariness of the issues raised in both *Bilski* and *Prometheus*, it would not be surprising if the Supreme Court granted certiorari in order to decide both cases together.

If the Supreme Court proceeds further in the appeal of *Bilski* than it did in the abortive *Laboratory Corporation* case, and actually issues a decision, it is likely the decision will help to define for a generation the patentability of inventions implicating human thought. Given the importance this judicial decision is likely to have on the patentability of thought, it is vitally important that the Supreme Court consider not simply issues of patent law doctrine, but also the scientific understanding of thought itself as revealed by neurobiology.

IV. NEUROBIOLOGY AND PATENTING THOUGHT

Patent infringement tends to be a strict liability offense. Beyond a few exceptions, such as the ability of physicians to perform patented medical procedures,[102] the monopoly right to exclude others that a patent confers on its owner can generally be exercised regardless of whether infringement is deliberate or

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96 *Id.* at 1339.

97 *Id.*

98 *Id.* at 1348.

99 *Id.*

100 *Id.* at 1345 (quoting *In re* Bilski, 545 F.3d 943, 962 (Fed. Cir. 2008) (en banc)).

101 Mayo Collaborative Servs. v. Prometheus Labs., Inc., 78 U.S.L.W. 3254 (U.S. Oct. 22, 2009) (No. 09-490).

102 35 U.S.C. § 287(c)(1) (2006).

not.[103] In other words, if all forms of thought were patentable, then both thoughts about light perception and thoughts about data correlation could equally infringe if they were elements in a patent claim. However, the strict liability rule of patent law infringement seems absurd if applied to a patented invention, the infringement of which could be triggered by uncontrollable or inevitable thought. In such a case, the thinker would be powerless to prevent infringement. For example, if one element of a patent claim were perception of light, it would be possible that a person not wishing to infringe a patent claim might do so anyway, simply by having a light shone in his eyes. This outcome seems much harsher—and much more difficult to justify—than would a similar outcome triggered by a thought that involved an avoidable correlation of data with a disease state, such as was at issue in *Laboratory Corporation*.

Many reasons have been offered to justify why thoughts should constitute unpatentable subject matter. For example, Professor Dan Burk suggests that "there would seem to be profound First Amendment implications to the concept of infringement by 'thinking patented thoughts.'"[104] Kevin Collins has offered a different rubric for denying patentability to thoughts, suggesting that the correlation step in *Laboratory Corporation* should be unpatentable because it is essentially "involuntary," unavoidable, and unfairly susceptible to patent infringement due to "insufficient thought control."[105] Regardless of rationale, unless the Supreme Court surprisingly reverses the long-standing repudiation of the Mental Steps Doctrine, then at least some categories of human thought will continue to be patentable.

Thoughts *per se* are difficult to study with specificity and precision. First, they cannot yet be neuroimaged.[106] Part of the reason for this is that "[t]hought is a composite of cognitive functions involving information processing, individual dispositions to information, and individual methods of integrating information into an internal schema and responding to it."[107] Marc

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103 Though beyond the scope of this article, enforcement of patents claiming thought may be challenging if direct evidence is required in order to demonstrate that a mental step has actually been performed by a human mind.

104 Dan L. Burk, *Patenting Speech*, 79 TEX. L. REV. 99, 140 (2000).

105 Kevin Emerson Collins, *Constructive Nonvolition in Patent Law and the Problem of Insufficient Thought Control*, 2007 WIS. L. REV. 759, 760, 792, 796–97 (2007). As noted in detail below, neurobiology might disagree with Collins' conclusions regarding voluntary and involuntary thoughts, and would likely categorize the correlation step he discusses as subject to executive control and, thus, deliberate and avoidable.

106 July Illes, *Empirical Neuroethics: Can Brain Imaging Visualize Human Thought? Why Is Neuroethics Interested in Such a Possibility?*, 8 EMBO REPORTS, S57, S58 (2007).

107 *Id.*

Hauser has subdivided "thinking" into "a set of mental tools for solving ecological and social problems . . . [including] a basic capacity to recognize objects, count, and navigate."[108] Some of these tools are specific to humans, while others, such as "folk mathematics,"[109] "folk psychology,"[110] the ability to make "inferences about other individuals' intentions and goals by evaluating their actions in relation to the constraints imposed by the environment,"[111] and even the ability to "learn simple rules and apply them to new situations,"[112] we share with other mammals.

There is significant and meaningful diversity in the categories of thoughts that humans experience. Some thoughts, such as those generated in the cerebellum, leave no subjective record in the brain of a local computation.[113] Other thoughts, such as those generated in the cerebral cortex, may leave enough of a subjective record of a local computation that the brain may later reconstruct them.[114] Still other thoughts are determined almost entirely by the input stimulus that causes them to be perceived in the brain.[115] For instance, visible-light photons hit the specialized receptor cells in the eyes, stimulating the optic nerve, and triggering electrochemical signals that are neuronally transmitted into the primary visual area of the cortex for to be perceived as "light."[116] Whether or not one wishes to perceive light, once it hits the eye, unless blind, one cannot prevent the formation of a thought involving the perception of light.

At a very gross anatomical level, differences between the cerebral cortex and the cerebellum may be instructive in understanding differences between thought that can be deliberately controlled and thought that is less controllable and more reflexive. In the cortex,

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108 MARC D. HAUSER, WILD MINDS: WHAT ANIMALS REALLY THINK xv (First Owl Books ed. 2001) (2000).

109 Marc D. Hauser, *Our Chimpanzee Mind*, 437 NATURE 60, 60–61 (2005).

110 *Id.* at 61–62.

111 Justin N. Wood et al., *The Perception of Rational, Goal-Directed Action in Nonhuman Primates*, 317 SCIENCE 1402, 1402 (2007).

112 Robin A. Murphy et al., *Rule Learning by Rats*, 319 SCIENCE 1849, 1849 (2008).

113 György Buzsáki, *The Structure of Consciousness: Subjective Awareness May Depend on Neural Networks in the Brain Supporting Complex Wiring Schemes and Dynamic Patterns of Activity*, 446 NATURE 267, 267 (2007).

114 *See id.*

115 *See* JOHN E. DOWLING, THE GREAT BRAIN DEBATE: NATURE OR NURTURE? 40 (Princeton Univ. Press 2007).

116 *See id.*

> [n]eural firing patterns are . . . controlled not only by the external sensory environment but also by the internally generated and perpetually changing state of cortical networks.
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> . . . .
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> . . . If [environmental inputs] manage to perturb ongoing activity for a sufficiently long time in a big enough population of neurons, their effect will be noticed; that is, we will become conscious of them. In contrast, the locally organized cerebellar cortex, used largely for sensorimotor integration, does not give rise to self-generated or spontaneous activity, and its response to input remains local and non-persistent.[117]

The cerebellum and cerebral cortex appear to play different, though cooperative and to a minor extent overlapping, roles in the brain. For many years,

> the cerebellum has been considered an important center for initiation, coordination, learning, and execution of all bodily movements, as well as for the control of posture of the head, limbs, and trunk. In order to regulate these functions, this organ receives information from sensory and motor systems. Information arrives from muscle and joint receptors, the viscera, the skin, and the sense organs—visual, auditory, vestibular—and from all the movement-related centers of the brain. These regulations are mostly automatic and not under conscious control.[118]

The cerebral cortex plays a very different role in the brain. It is "the seat of higher mental functions, including perception, memory, judgment, and reasoning."[119] Understanding these broad functional divisions between the cerebral cortex and the cerebellum in generating thought has facilitated a more detailed understanding of executive control and default thought.

As explained below, unlike default thoughts over which a person cannot exercise significant control, a method of correlating data with a diagnosis—such as that claimed in *Laboratory Corporation*—involves more deliberate thought than does light perception. Consequently, the person performing the correlation can exercise executive control over whether or not to have a thought that carries out a correlation. With this in mind, perhaps neurobiology may suggest why some forms of thought, such as executive control thought, should be viewed as more defensibly patentable, while others, such as default thought, are more difficult to justify as patentable.

It has been well demonstrated that, under certain circumstances, a person may deliberately exercise significant control over aspects of cognition. In

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117 Buzsáki, *supra* note 113, at 267.

118 Jan Voogd & Enrico Mugnaini, *Cerebellum*, *in* ENCYCLOPEDIA OF NEUROSCIENCE (George Adelman & Barry H. Smith eds., 3d ed. 2004).

119 DOWLING, *supra* note 115, at 13.

one remarkable example, "individuals can gain voluntary control over activation in a specific brain region, [learning how to develop some] control over pain perception."[120] Even a patient in a persistent vegetative state may control whether or not she imagines playing tennis or touring her home with "a clear act of intention."[121] Surely, if those examples of cognitive control are possible, exercising control over whether to think about an abstract mathematical process, like the correlation of data, would also be possible. In fact, evidence from cognitive neuroscience strongly suggests that, by virtue of executive control, one may choose to think, or not think, a variety of thoughts. Executive control could be exerted by a person to prevent herself from mathematically correlating data with a disease state.

Executive control has been defined as "[t]he cognitive function associated with altering thought and behavior in a goal-directed, context-dependent, and flexible manner."[122] Functionally, executive control involves control processes that "are important for overcoming behaviors that would otherwise be carried out more or less automatically."[123] In the absence of executive control "behavior is determined by a default mode of brain operation [in which] responses are made more or less reflexively to a stimulus or series of stimuli."[124] Instead of executive control, the default mode "predominate[s] in animals with limited prefrontal cortices, in human infants with immature frontal lobes, and in adults with prefrontal damage."[125] Executive control may be understood as an evolutionary adaptation "[t]o overcome the limitations of the default mode, we and many other animals have evolved executive control processes that allow more flexible and dynamic relationships between stimuli and behaviors."[126] Although there is certainly some overlap between them, executive control thoughts and default thoughts generally represent two functionally distinct categories of mental processes.

Beyond function, there is a significant degree of anatomical localization of executive control within the brain. "[S]everal brain structures are especially

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120 R. Christopher deCharms et al., *Control Over Brain Activation and Pain Learned by Using Real-Time Functional MRI*, 102 PNAS 18626, 18626 (2005).

121 Adrian M. Owen et al., *Detecting Awareness in the Vegetative State*, 313 SCIENCE 1402, 1402 (2006).

122 DALE PURVES ET AL., PRINCIPLES OF COGNITIVE NEUROSCIENCE G-8 (2008).

123 *Id.* at 579–80.

124 *Id.* at 580.

125 *Id.*

126 *Id.*

important for mediating . . . aspects of executive control."[127] Within the cortex, four structures play especially important roles: the dorsolateral prefrontal cortex, the ventromedial prefrontal cortex, the anterior cingulate cortex, and the posterior parietal cortex.[128] The basal ganglia of the subcortex also plays an important role in executive control.[129] In addition to individual, localized brain structures, executive control also relies on "broad interconnectivity" between these structures for its functionality.[130]

Thoughts subject to executive control and default thoughts exhibit differences with potential salience to the issue of patent infringement via thought. As discussed above, many courts and scholars have advocated against the patentability of any invention the practice of which requires mental steps. Under the extreme version of this view, human thought should never trigger patent infringement. However, since 1970 at least, patent law has allowed the patenting of such inventions and, by extension, infringement via thought. Recent court decisions *Comiskey*, *Bilski*, *Prometheus*, and others, not to mention the Supreme Court non-decision *Laboratory Corporation*, have focused renewed attention on where to draw the boundaries between patentable and unpatentable thought. Moreover, the Supreme Court's grant of certiorari in *Bilski* (and, potentially, in *Prometheus*) represents an opportunity to improve the coherence, objectivity, and defensibility of these boundaries. Here, neurobiology offers valuable insight.

If thought is to be patentable at all, then neurobiology offers a scientific criterion for parsing patentable thought from unpatentable thought. Consider a spectrum with thoughts subject to executive control situated at one end and default thoughts situated at the other end. Patentability of inventions involving mental steps should increase towards the executive control end of the spectrum and decrease towards the default end of the spectrum. To allow the patentability of default thoughts is to contemplate a form of involuntary patent infringement in which people possess little or no control over whether a significant subset of their thoughts could potentially infringe patents owned by others. By contrast, allowing patents whose claims include thoughts subject to executive control provides potential infringers with an opportunity to avoid infringement, limiting patent infringement to deliberate thoughts. In general, society and the law judge human behaviors differently depending upon whether or not their author is ca-

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127 *Id.* at 584.

128 PURVES ET AL., *supra* note 122, at 584.

129 *Id.*

130 *Id.* at 586.

pable of controlling such behaviors. As Elkhonen Goldberg, a Clinical Professor of Neurology at New York University School of Medicine, has explained:

> Society holds an individual responsible for certain actions but not for others. The scope of our responsibilities is defined by the scope of our volitional control. Vomiting in public by a drunk will be punished, but vomiting following a heat stroke will be excused. A traffic accident caused by speeding will be punished, but an accident caused by a driver's heart attack will be excused. Profanities spouted publicly in anger will be punished, but the same profanities uttered involuntarily by a coprolalic Tourette's patient might be excused. Bodily harm inflicted in assault will be punished, but bodily harm inflicted by a seizure patient who fell on a child will be excused.
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> Society draws a legal and moral distinction between the consequences of actions presumed to be under the individual's volitional control and those presumed to be outside such control. Drunkenness, speeding, rudeness, and aggression are usually presumed to be under volitional control, thus avoidable and punishable. The effects of seizures, tics, fainting spells, and heart attacks, by contrast, cannot be controlled by the patient at the time of their happening and thus will not be punishable by law.
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> Volitional control implies more than conscious awareness. It implies the ability to anticipate the consequences of one's action, the ability to decide whether the action should be taken, and the ability to choose between action and inaction. A Tourette's patient and a hapless heatstroke-stricken vacationer may be fully aware of what is happening to them, but they cannot control it.
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> It appears that, at a cognitive level, the capacity for volitional behavior depends on the functional integrity of the frontal lobes. The capacity for restraint in particular [that is, executive control] depends on the orbitofrontal cortex.[131]

Restricting liability for patent infringement to acts under executive control is consistent with the tendency to restrict liability—both normative and legal—to volitional behavior.

If any thought is to constitute patentable subject matter, the arguments in favor of patentability are especially strong for thoughts subject to executive control. Thoughts in this functional category are deliberate and avoidable, rather than involuntary and unavoidable. If a mental step subject to executive control is an element of a patent claim, a potential infringer has the capacity deliberately to perform or deliberately to avoid performing that mental step; that is, a potential infringer may avoid infringement. This deliberation is crucial because patent infringement is subject to strict liability. In this case, providing that a potential infringer is aware of the claims of a patent, the notice function of

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131 ELKHONON GOLDBERG, THE NEW EXECUTIVE BRAIN: FRONTAL LOBES IN A COMPLEX WORLD 173 (2009).

patents can be successful because notice can lead to deliberate avoidance of infringement. Using claim 13 from *Laboratory Corporation* as an illustration, and providing a physician had actual or constructive notice of the patent in suit, a physician could avoid performing the mental step "correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate" by exercising executive control.[132] Thus, deliberate avoidance of this mental step allows deliberate avoidance of patent infringement via thought. In this light, the decision of the Federal Circuit not to invalidate a claim like claim 13 can be justified by the fact that claim 13 is subject to neurobiological executive control.

Neurobiology does not justify default thought as patentable subject matter. Default thought tends to be reflexive and involuntary. Given the strict liability standard by which patent infringement is judged, to allow the patentability of mental steps consisting of default thought would lead to the unpalatable circumstance of unavoidable patent infringement. Even with notice of a patent claim, whether actual or constructive, a default thought, being reflexive in nature, cannot be deliberately avoided, thus leading to a failure in the notice function of patents. In contrast to situations of potential infringement involving mental steps subject to executive control, in which a potential infringer may deliberately avoid an infringing thought, the patentability of default thought leads to a situation of humans *qua* machines because potential infringers cannot deliberately avoid performing default mental steps. In fact, allowing the patentability of default thoughts could invite abuse by patent owners who could create situations in which a potential infringer had no choice but to infringe a patent claim by thinking a claimed default thought.

Insights from neurobiology of thought reveal an irony in how different categories of thought have traditionally been privileged by the law. The First Amendment freedom of expression in the U.S. Constitution is one of the most revered—and litigated—parts of the Bill of Rights. Dan Burk has argued that "there would seem to be profound First Amendment implications to the concept of infringement by 'thinking patented thoughts.'"[133] And, the sorts of thoughts that have traditionally been celebrated and litigated under the protections of the First Amendment—thoughts rich in intellectual, political, philosophical, and expressive content—have tended to be exactly those sorts of thoughts that are subject to executive control. Consequently, First Amendment concerns moti-

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132 *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 129 (2006) (Breyer, J., dissenting).

133 Burk, *supra* note 104, at 140.

vate many arguments in favor of privileging thoughts subject to executive control from legal encumbrances, including patents.

Despite the traditional primacy of First Amendment concerns in the debate over patenting thought, a distinctly different part of the Constitution argues against the patentability of default thoughts: the Thirteenth Amendment. As discussed above, to allow the patenting of claims that include default mental steps is to invite the possibility of involuntary infringement. Because a potential infringer may not be able to deliberately avoid infringement of such a claim, reflexive thought coupled with the strict liability of patent infringement, even where the potential infringer has sufficient notice, could lead inexorably to unavoidable infringement. In fact, clever (or unscrupulous) patent owners could create situations in which unsuspecting people were forced into patent infringement. Such risks implicate the Thirteenth Amendment's prohibition against involuntary servitude—in this case, involuntary patent servitude. Thirteenth Amendment interests would militate against patentability for default thought.

Claim 13 from *Laboratory Corporation* can again be used to illustrate. This correlation step is precisely the sort of thought that is subject to executive control. Thus, by means of executive control, a physician can deliberately avoid "correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate."[134] Interestingly, Kevin Collins has specifically argued that the correlation step in *Laboratory Corporation* should be unpatentable because it is essentially "involuntary," unavoidable, and unfairly susceptible to patent infringement due to "insufficient thought control."[135] But neurobiology of executive control suggests otherwise. The fact that this correlation mental step is subject to executive control vitiates arguments regarding involuntary patent infringement. Thus, the outcomes of *Laboratory Corporation* and *Prometheus*—that is, to recognize correlation claims as patentable subject matter—are more consistent with Thirteenth Amendment interests because the mental steps involved in both cases are subject to executive control, though less consistent with First Amendment interests as traditionally applied to patent law.

V. CONCLUSION

Many reasons have been offered to justify why thoughts should constitute patentable or unpatentable subject matter. For example, Dan Burk has argued that "there would seem to be profound First Amendment implications to

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134 *See Lab. Corp.*, 548 U..S. at 129.

135 Collins, *supra* note 105, at 759, 760, 783–85.

the concept of infringement by 'thinking patented thoughts,'"[136] and Kevin Collins has suggested that thoughts such as the correlation step in *Laboratory Corporation* should be unpatentable because they are subject to "insufficient thought control."[137] These and other perspectives will be available to the Supreme Court as it considers how to set rules for the patentability of thought in *Bilski*. Neurobiology offers the Supreme Court a singularly valuable source of insight into what thought is, and where to draw the boundaries between patentable and unpatentable thoughts. For example, neurobiology suggests that thoughts subject to executive control tend to be relatively more deliberate and avoidable in nature while, by contrast, default thoughts tend to be more reflexive and unavoidable in nature. If any category of thought should constitute patentable subject matter, the arguments in favor of patentability are stronger for thoughts subject to executive control than for default thoughts not subject to executive control. Although First Amendment arguments have traditionally privileged the kind of thoughts subject to executive control, Thirteenth Amendment interests militate strongly against allowing the patenting of default thoughts to prevent unavoidable infringement that might result in a sort of involuntary patent servitude. In other words, neurobiology offers reasons why default thoughts that could result in involuntary or unavoidable infringement should not be patentable. By contrast, neurobiology offers few impediments to the patenting of thoughts subject to executive control, such as the correlation mental steps involved in *Laboratory Corporation* and *Prometheus*.

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136 Burk, *supra* note 104, at 140.

137 Collins, *supra* note 105, at 760.