

**WHAT IS AN INVENTION?  
A REVIEW OF THE LITERATURE ON PATENTABLE SUBJECT  
MATTER**

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INTRODUCTION

[1] This work is a critical review of the literature on patentable subject matter. It examines the central feature of modern patent law—the “invention”—at an international and comparative level. As with most codified terms intended to have wide-ranging, prospective applicability, it is usually left undefined, or if defined, is usually drafted broadly and permissively. Despite the hallmarks of patentability (namely, novelty, inventiveness, and industrial applicability), some courts<sup>1</sup> and academic

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<sup>1</sup> See *Biogen Inc. v. Medeva Plc*, 112 R.P.C. 25 (1995) (U.K.); *Genentech Inc.'s Patent*, 106 R.P.C. 147 (1989) (U.K.). *But see* *Biogen Inc. v. Medeva Plc*, 114 R.P.C. 1 (1997) (U.K.).

commentators<sup>2</sup> have questioned whether there still needs to be an invention in the first place, before one even considers its patentability.

[2] The following sections have been structured as follows. Parts I and II provide an overview and early history of patentable subject matter. Part III examines various subject matter which seem immune to patentability – laws of nature, natural phenomena and abstract ideas. Part IV addresses the tools of basic research. Within this section, there appears to be a long-standing reluctance against the monopolization of these types of subject matter. I have folded some of my discussions regarding biotechnological innovations into this subsection, since some advances in biotechnology can reasonably be viewed as involving or uncovering the tools of basic research.

[3] Part V illustrates the internationalization of “invention” and patent-eligible subject matter through the standard-setting agenda of TRIPS.<sup>3</sup> Indeed, the literature in this field is generally divided between authors who look at the concept of invention from an international perspective under TRIPS, rather than an Americentric point of view. TRIPS has become the focal point for many Commonwealth<sup>4</sup> scholars since it is administered by the WTO and sets out minimum standards for most forms of intellectual property, and ratification of it is therefore a mandatory requirement for membership in the World Trade Organization (“WTO”) “game” (at least as of 1994, following the Uruguay Round of the General Agreement on Tariffs and Trade).<sup>5</sup>

[4] The remaining sections, Parts VI, VII, and VIII, deal with patenting intangible inventions (business methods, software, signals, and even sporting techniques), and the role (if any) that policy and ethics ought to

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<sup>2</sup> See *infra* notes 77-79 and accompanying text (arguing that TRIPS has articulated a subject matter threshold followed by the aforementioned hallmarks of patentability).

<sup>3</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter TRIPS].

<sup>4</sup> The Commonwealth is an intergovernmental, multilateral organization of countries with historical constitutional links to Britain. See Foreign Affairs and International Trade Canada, Canada and the Commonwealth, <http://www.dfait-maeci.gc.ca/commonwealth/index.aspx> (last visited Oct. 26, 2008).

<sup>5</sup> TRIPS, *supra* note 3.

play in determining subject matter eligibility. The problems that biotechnological advances present to the concept of “invention” resurface in the section on ethics and subject matter eligibility, especially in relation to human-animal chimeras, and life forms that are genetically approximate to humans.

#### I. OVERVIEW & ASSUMPTIONS ON PATENTABLE SUBJECT MATTER

[5] Professor Vaver provides an overview of how the notion of invention is presently interpreted under Commonwealth patent laws, by using TRIPS as his starting point.<sup>6</sup> Article 27.1 of TRIPS provides that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application,”<sup>7</sup> with little more as to what qualifies as an invention. Indeed, the only exceptions to patentability under TRIPS are those necessary to protect any of the following: ordre public or morality; diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animals other than microorganisms, and in essence biological processes for the production of plants or animals other than non-biological and microbiological processes.<sup>8</sup> These exceptions, however, are neither absolute nor required; TRIPS states that Member States “may” exclude these from patentability, but they are not required to do so.<sup>9</sup>

[6] Vaver rightly notes that WTO trade panels have become a major vehicle used to control the meaning of “invention” at an international level. Signatories to TRIPS, although permitted to expand their “range of items for which patents are granted,” may not “through legislation or judicial decision, restrict the meaning of invention . . . [As] the WTO may, through its dispute resolution procedures, require the offender to discard any unacceptably narrow meaning of invention or any unacceptably broad interpretation of a permissible exception.”<sup>10</sup>

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<sup>6</sup> David Vaver, *Invention in Patent Law: A Review and a Modest Proposal*, 11 INT’L J.L. & INFO. TECH. 286, 289-90 (2003).

<sup>7</sup> TRIPS, *supra* note 3, art. 27.1.

<sup>8</sup> Vaver, *supra* note 6, at 290.

<sup>9</sup> *Id.* at 301.

<sup>10</sup> *Id.*

Furthermore, Vaver remarks that there seems to be a trend towards the reduction of the exceptions to patentability.<sup>11</sup> Aside from common law trends, Vaver notes that many bilateral treaties (concluded either in response to, or to augment, existing obligations under TRIPS – so-called “TRIPS-plus” treaties) have the effect of further relaxing restrictions to patentability to the benefit of one of the parties to that treaty. This relaxation of restrictions may in turn “have multilateral effects because TRIPS requires any advantage extended by one WTO member to another to be extended to all.”<sup>12</sup>

[7] Although I agree with Vaver’s views on the use of TRIPS to globalize and control the meaning of “invention,” he does proffer some controversial (and certainly, far from modest)<sup>13</sup> claims and suggestions for reform. Vaver writes that:

Patents should work manifestly in the public benefit – the ultimate justification for the system. The public pays a high price for patents. . . . Therefore the legislation should be amended to exclude inventions that it would not be in the public interest to patent – in effect, a return to the principle of excluding “generally inconvenient” patents, but one where the issue of “convenience” or “public interest” is seriously weighed and considered.<sup>14</sup>

Vaver even argues that special ethics and public interest panels be established, independent of the patent offices around the world, to decide whether a particular invention qualifies as patentable subject matter.<sup>15</sup> Perhaps this is where Vaver’s suggestions may have gone too far. In

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<sup>11</sup> *Id.*

<sup>12</sup> TRIPS represents a relaxation of the patentability restrictions, however, “TRIPS-plus” treaties narrow requirements even further. *See* TRIPS, *supra* note 3, art. 4; Vaver, *supra* note 6, at 302 (emphasis omitted).

<sup>13</sup> Although, it is likely that Vaver was making a guised reference to Jonathan Swift’s book. *See generally* JOHN SWIFT, A MODEST PROPOSAL: FOR PREVENTING THE CHILDREN OF POOR PEOPLE IN IRELAND FROM BEING A BURDEN TO THEIR PARENTS OR THE COUNTRY, AND FOR MAKING THEM BENEFICIAL TO THE PUBLIC (1729) (suggesting that poor Irish children be sold to the gentry as food).

<sup>14</sup> Vaver, *supra* note 6, at 305.

<sup>15</sup> *Id.* at 306-07.

particular, his suggestion that patents should work to the public's benefit appears inconsistent with the nature of a patent as a negative right. His suggestion to establish an "Ethics and Public Interest Panel,"<sup>16</sup> which would be independent from the patent offices, neither defines patentable subject matter nor helps one to find relevant examples of inventions that qualify. Independent panels are often anything but independent. The "public interest" (assuming that patents ought to serve the public interest in the first place) becomes the "panel's interest," it reflects the vested interests and influences of the panel. The introduction of a special "Ethics and Public Interest Panel" would likely add another layer of complexity and uncertainty to the patent race.

[8] Indeed, Richard Gold has recently written on many of the assumptions upon which the patent system is built – namely, patents as ethically neutral, negative rights which encourage research and dissemination of knowledge.<sup>17</sup> Gold, perhaps intentionally, challenges the Americentric, capitalist view that patents are necessary to promote and encourage research and economic growth.<sup>18</sup> He systematically demonstrates that patents are neither necessary to provide an incentive to innovate, nor are they the optimal policy tool for stimulating and sustaining research and development.<sup>19</sup>

[9] Gold also deals with the assumption that patents are ethically neutral. He argues that the ethical neutrality of patents is "assumed by the literature and jurisprudence."<sup>20</sup> He characterizes the assumption as follows:

Were ethical review a necessary criterion for patentability  
(as opposed to an ancillary regulatory concern), so this

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<sup>16</sup> *Id.* at 306.

<sup>17</sup> See generally E. Richard Gold, et al., *The Unexamined Assumptions of Intellectual Property: Adopting an Evaluative Approach to Patenting Biotechnological Innovation* (European Univ. Inst. Working Paper RSCAS No. 2004/45, 2004), available at [http://www.iue.it/RSCAS/WP-Texts/04\\_45.pdf](http://www.iue.it/RSCAS/WP-Texts/04_45.pdf) (highlighting the assumptions upon which intellectual property issues are structured).

<sup>18</sup> *Id.* at 23.

<sup>19</sup> See *id.* at 2-10.

<sup>20</sup> *Id.* at 14.

argument goes, it would jeopardize the ostensible neutrality of the patent system which otherwise coordinates the simultaneous and contradictory objectives of achieving maximum levels of innovation and access to the products of innovation.<sup>21</sup>

Gold acknowledges that this assumption is somewhat tenuous, especially in considering that property is power and that control over significant biotechnological resources is being delegated to the private sector on an ad hoc, first-come, first-served basis; control is disbursed one patent at a time.<sup>22</sup> Gold sums up these assumptions neatly:

Together, they lead to a policy of relying on the patent system to encourage most research. But as the patent system provides a reward for commercial products and processes and not for the acquisition of basic knowledge, the combination of these assumptions leads to an over-emphasis on applied, as opposed to basic, research. Although such an approach may be economically favourable in the short term, it threatens longer-term sustainability and economic competitiveness.<sup>23</sup>

[10] Later in his work (after constructing a solid and uncontroversial framework, like Vaver), Gold proposes what he labels a “compelling alternative,” namely, the evaluation of intellectual property (patents in particular) through the use of transdisciplinary probes.<sup>24</sup> His proposal is weakened by the ambitious goal of replacing one paradigm of how patents are granted and construed with another (similar to Vaver’s suggestions for reform). Gold’s transdisciplinary probes also assume that the involvement of other fields of inquiry into the patenting process would somehow *alleviate* administrative burden, and indeed, it assumes some level of congruence and agreement among those “transdisciplines.” Ironically, Gold’s transdisciplinary probes need their own assumptions examined.

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<sup>21</sup> *Id.*

<sup>22</sup> *Id.* at 15.

<sup>23</sup> *Id.* at 19.

<sup>24</sup> *Id.* at 20-31.

## II. HISTORICAL VIEWS ON PATENTABLE SUBJECT MATTER

[11] While the previous section provided a brief overview of patentable subject matter as it stands today, the following section provides an overview of how patentable subject matter has been cast historically. The statutory basis for modern patent law originated in Italy under the Venetian Statute of 1474.<sup>25</sup> English patent law did not find a statutory basis until the *Statute of Monopolies* in 1623.<sup>26</sup>

[12] Many scholars have examined the early jurisprudence following the enactment of the Statute of Monopolies to distil how earlier Courts had viewed patentability and patentable subject matter. Justine Pila however, provides a new twist on these views. She provides a historical account of how inherently patentable subject matter was viewed by the Courts *before* the *Statute of Monopolies* (which again, gave rise to the modern patent system in so far as it is used throughout the Commonwealth).<sup>27</sup> Pila notes that:

[there] has been a tendency to treat the *Statute of Monopolies* as having given rise to a new body of law, rather than given legislative form to an existing jurisprudence. This tendency—first recognised by E Wyndham Hulme in 1896—continues to be particularly problematic in countries (such as Australia and New Zealand) in which the meaning of “invention” still derives expressly from the *Statute of Monopolies*, and in other common law countries that continue to rely on

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<sup>25</sup> See Ikechi Mgbeoji, *The Juridical Origins of the International Patent System: Towards a Historiography of the Role of Patents in Industrialization*, 5 J. Hist. Int'l L. 403, 413 (2003). The statutory basis for modern patent law can be traced to Italy, this is not to say that patent ‘systems’ themselves have strictly Italian roots). Mgbeoji, for instance, has traced patents systems to the Andaman Islanders, the Kai, the Koryak and the Plains Indians. *Id.* at 406.

<sup>26</sup> Justine Pila, *The Common Law Invention in Its Original Form* 8-9 (Univ. of Melbourne Pub. Law & Legal Theory, Working Paper No. 18, 2001), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=270909](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=270909).

<sup>27</sup> *Id.* at 2-9.

jurisprudence said to originate with the *Statute of Monopolies* to explicate their own patent legislation.<sup>28</sup>

[13] The *Statute of Monopolies* was merely the legislative response to an existing body of jurisprudence and royal prerogative concerning the grant of letters patent.<sup>29</sup> It was not until 1601 that the Crown lost its exclusive jurisdiction over letters patent, allowing the common law courts to weigh in on the matter for the first time.<sup>30</sup>

[14] In *Darcy v. Allin*, the Court of the King's Bench held that Her Majesty's 1598 grant of a monopoly over the manufacture, sale, and import of playing cards was invalid, since it amounted to granting a monopoly over an *existing* trade, as opposed to a new trade (or invention).<sup>31</sup> Likewise in the *Clothworkers of Ipswich* case,<sup>32</sup> the Court held that:

[I]f a man hath brought in a *new invention and a new trade* within the kingdom . . . or if a man hath made a new discovery of any thing . . . [the King] may grant by charter unto him, that he only shall use such a trade or trafique for a certain time . . . but when that patent is expired, the King cannot make a new grant thereof: for when the trade is become common, and others have been bound apprentices in the same trade, there is no reason that such should be forbidden to use it.<sup>33</sup>

[15] Pila therefore notes that the only subject matter which generally qualified for patentability were entire trades or devices.<sup>34</sup> The mere addition to a trade or device, or anything derivative of such trades or

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<sup>28</sup> *Id.* at 1.

<sup>29</sup> *Id.* at 7 n.64 (“The 1601 debate in Parliament focused on a bill entitled ‘An Act for the Explanation of the Common Law in Certain Cases of Letters Patent’ which clarified the common law limits of the Crown’s power to grant monopolies.”).

<sup>30</sup> *Id.* at 7-8.

<sup>31</sup> (1603) 74 Eng. Rep. 1131 (K.B.).

<sup>32</sup> (1615) 78 Eng. Rep. 147 (K.B.).

<sup>33</sup> *Id.* at 148.

<sup>34</sup> Pila, *supra* note 26, at 10.



devices, would not qualify as patentable subject matter.<sup>35</sup> Although Pila's observations are insightful from a historical perspective, the *Statute of Monopolies* no longer forms the basis for the Patent Acts of Canada, nor for the U.S., nor the U.K. (the latter being harmonized with the European Patent Convention). So while Pila's observations might be pertinent to New Zealand or Australian patent law, they lie beyond the bounds of this work. Furthermore, early jurisprudence often reflects the priorities and interests of the Courts at those times; it does not necessarily tell us how a statute is to be read or interpreted in today's world. Patentable subject matter may have been restricted to new inventions or new trades "as a whole" because of the relative scarcity or unavailability of information as to true novelty or rightful ownership. A pragmatic scheme was devised which would only grant patents for such macro-categories.

[16] In other writings, however, Pila notes that much of the excluded subject matter from American jurisprudence (namely, laws of nature, natural phenomena and abstract ideas)<sup>36</sup> are actually mirrored within the Commonwealth's exclusions to patentability as well.<sup>37</sup> Such underlying similarities suggest an international coherence in patent law existed well before the standard-setting agenda of TRIPS. It is this "unholy" and unpatentable trinity of excluded subject matter that form the bulk of the American writings on patent-eligible subject matter.

### III. THE UNHOLY AND UNPATENTABLE TRINITY – LAWS OF NATURE, NATURAL PHENOMENA AND ABSTRACT IDEAS<sup>38</sup>

[17] Michael Meehan notes that despite the expansive wording of the U.S. Patent Statute, it has nonetheless been "well established" in jurisprudence that mathematical algorithms, laws of nature, natural phenomena, and

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<sup>35</sup> See *id.* at 11.

<sup>36</sup> See Justine Pila, *Inherent Patentability in Anglo-Australian Law: A History*, 14 AUSTL. INTELL. PROP. J. 109, 140-41, 163 (2003), available at <http://users.ox.ac.uk/~lawf0169/papers/inhpathistory.pdf>

<sup>37</sup> See generally *id.* at 109 (discussing the evolution of judicial constructions of inherent patentability).

<sup>38</sup> Throughout this work, I shall refer to laws of nature, natural phenomena and abstract ideas as either the "unholy trinity," or the "unholy and unpatentable trinity."

abstract ideas cannot be patented.<sup>39</sup> He notes that the U.S. Supreme Court has consistently held that such discoveries “are not the kind of ‘discoveries’ that the statute was enacted to protect.”<sup>40</sup>

[18] Meehan raises an interesting point, which he argues against vigorously later in his paper, that perhaps,

One might argue that the limited monopoly provided by the patent system should reward those who discover useful new mathematical algorithms, unknown laws of nature, new scientific facts, and novel abstract ideas. Perhaps one should be given the reward (*ex post*) or incentive (*ex ante*) of a patent monopoly in exchange for the effort involved.<sup>41</sup>

Meehan raises this argument in the context of examining the Federal Circuit’s appellate decision in *Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings*.<sup>42</sup> That case involved the licensing of a patented method of testing homocysteine levels in body fluids, while the patent at issue specifically sought to protect the scientific connection between homocysteine levels and vitamin deficiency.<sup>43</sup> From 1992 to 1998, Metabolite sublicensed this patent to Laboratory Corp. (“LabCorp”) in exchange for a royalty stream. After 1998, however, LabCorp began using another test developed by Abbott Laboratories and discontinued royalty payments to Metabolite.<sup>44</sup> At the district court level, the trial jury found that LabCorp breached its contract with Metabolite, and that the

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<sup>39</sup> Michael Meehan, *The Handiwork of Nature: Patentable Subject Matter and Laboratory Corporation v. Metabolite Labs*, 16 ALB. L.J. SCI. & TECH. 311, 312 (2006).

<sup>40</sup> *Id.* at 312-13 (citing *Parker v. Flook*, 437 U.S. 584, 593 (1978)).

<sup>41</sup> *Id.* at 313.

<sup>42</sup> 370 F.3d 1354 (2004).

<sup>43</sup> B vitamins facilitate the metabolism of homocysteine, an amino acid. The patent licensed to Metabolite explains a two-step method for testing for homocysteine (an amino acid); and then correlating the level with the B vitamin levels in the body. Duke Law, Supreme Court Online, <http://www.law.duke.edu/publiclaw/supremecourtonline/labvmet.html> (last visited Oct. 24, 2008).

<sup>44</sup> *Metabolite*, 370 F.3d at 1359.

patent claim in question was valid.<sup>45</sup> The jury awarded damages of \$3,652,724.61 to Metabolite for Labcorp's breach of contract and \$1,019,365.01 for its indirect infringement.<sup>46</sup> The district court granted a permanent injunction, and doubled the infringement award because Labcorp wilfully infringed the patent in question.<sup>47</sup>

[19] Meehan argues that the patent licensed to Metabolite should have been declared invalid by the U.S. Supreme Court, since it was either a law of nature, or merely the discovery of "the Handiwork of Nature."<sup>48</sup> Although Meehan's demarcation here is not entirely clear, or sound, he argues that the patentees merely patented a method of correlating two events – a correlation which already existed, independent of, and unimproved by, their "mere" discovery of it.<sup>49</sup>

[20] Unfortunately for Meehan, after he published his piece, the Supreme Court, in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, dismissed the writ of certiorari in *Metabolite* as being improvidently granted (and hence, did not address the merits of the case).<sup>50</sup> Interestingly though, Justice Breyer (joined by Justice Stevens and Justice Souter) offered a strong dissenting opinion as to why the Court should not have dismissed the writ.<sup>51</sup> Perhaps something of a vindication to Meehan, the dissent takes the view that the claim in question was indeed invalid, since it amounted to a monopoly on a scientific correlation – nothing more than a law of nature, or at the very least, a natural phenomenon.<sup>52</sup> The dissent expressly adopted and reinforced the notion that the unpatentability of the unholy trinity – laws of nature, natural phenomena, and abstract ideas – is a "given"; that is, the dissent assumed the soundness of excluding these from patent eligibility. Although Justice Breyer admitted that these categories were and are often not easy to

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<sup>45</sup> *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, No. 99-CV-870, 2001 WL 34778749, at \*1 (D. Colo. Dec. 3, 2001).

<sup>46</sup> *Id.*

<sup>47</sup> *Metabolite*, 370 F.3d at 1358.

<sup>48</sup> Meehan, *supra* note 39, at 313. Only claim 13 was at issue. *Id.* at 315.

<sup>49</sup> *Id.*

<sup>50</sup> 548 U.S. 124, 124 (2006).

<sup>51</sup> *Id.* at 124 (Breyer, J., dissenting).

<sup>52</sup> *Id.* at 132, 135.

define, his dissent clarified that this case was “not at the boundary ... claim 13 is invalid no matter how narrowly one reasonably interprets that doctrine.”<sup>53</sup> Meehan agrees with Justice Breyer’s dissent in *Metabolite*; both posit that patents relating to basic scientific relationships and methods ought to be declared invalid because they are given for ineligible subject matter, irrespective of how guised the claim drafting may be.<sup>54</sup>

[21] In its most basic formulation, the exclusion of laws of nature, natural phenomena, and abstract ideas from patentability underscores the very powerful argument that these are things which either exist independently of humans (irrespective of how useful or difficult its discovery may have been). This exclusion from patentability also emphasizes that these are items to which one may not ascribe property rights; to do so would be inappropriate, unenforceable, or impractical. Now, if we consider laws of nature, natural phenomena, and abstract ideas to be the most fundamental, raw, or ethereal subject matter in the natural world, then, conceptually, the tools and methods employed by scientists in discovering them are one layer above that.

#### IV. MONOPOLIZING THE TOOLS OF BASIC RESEARCH

[22] There are a growing number of scholars (primarily American) who contend that the *basic* tools or elements of scientific research ought to continue to be excluded from patentability. Eileen Kane is one of these writers.<sup>55</sup> Though she concedes that the “rationales for the exclusion of laws of nature, natural phenomena and abstract ideas cannot be described with precision,”<sup>56</sup> she also writes that “[t]he absence of extensive justifications by the Court may speak for itself.”<sup>57</sup> This thought is perhaps as equivocal a statement as is permissible in scholarship, since the absence of extensive justification may indicate that the Court is being arbitrary or circumventive. It is precisely this reason – that there is little coherent

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<sup>53</sup> *Id.* at 135.

<sup>54</sup> *Id.* at 135-38; Meehan, *supra* note 39, at 312-13.

<sup>55</sup> Eileen Kane, *Patent Ineligibility: Maintaining a Scientific Public Domain*, 80 ST. JOHN’S L. REV. 519 (2006).

<sup>56</sup> *Id.* at 545 (citing ROBERT S. MERGES & JOHN F. DUFFY, J. PATENT LAW AND POLICY 151 (3d ed. 2002)).

<sup>57</sup> *Id.*

rationale to exclude either these basic tools of research, or the unholy trinity – which forms the basis for my view that exceptions to patentability ought not to be as widely drawn as much of the jurisprudence and writings in the Commonwealth and America suggest.

[23] Nonetheless, Kane agrees with the Court’s view in *Gottschalk v. Benson*<sup>58</sup> that “[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”<sup>59</sup> For instance, she argues that the genetic code, which defines the relationship between DNA and protein, is a law of nature and anything that attempts to replace this law of nature erodes the legitimacy of gene patents.<sup>60</sup> Kane states that advances in nanotechnology also present subject-matter-eligibility problems on the level of an atomic or subatomic structure, since these are either natural phenomena or governed by laws of nature.<sup>61</sup>

[24] In addressing precisely these two concerns, Jason Williams considers the challenges that proteomics (a branch of biotechnology dealing with the structure and function of proteins) poses to patent law.<sup>62</sup> Williams’ approach is similar to Kane’s. He stresses that there ought to be an available scientific commons in which the basic tools of scientific research and advancement are available to the scientific community, without the fear of infringement and litigation.<sup>63</sup>

[25] Williams traces the development and inclusion of biotechnological advances into the realm of patentable subject matter, and acknowledges that “[c]onventional patent theory completely supports a strong protection regime for fields that need incentives for private research and development.”<sup>64</sup> He disputes that biotechnology as a whole and

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<sup>58</sup> 409 U.S. 63, 67 (1972).

<sup>59</sup> *Id.* at 67.

<sup>60</sup> Kane, *supra* note 55, at 552.

<sup>61</sup> *Id.* at 552-53.

<sup>62</sup> J. Jason Williams, *Protecting the Frontiers of Biotechnology Beyond the Genome: The Limits of Patent Law in the Face of the Proteomics Revolution*, 58 VAND. L. REV. 955, 958 (2005).

<sup>63</sup> *See id.* at 958.

<sup>64</sup> *Id.* at 985 (accepting this justification for the granting of patents without questioning it further, while being careful to use the phrase “conventional patent theory”).

proteomics in particular are unlike other areas of technology and therefore they defy many comparisons.<sup>65</sup> Although such claims can be made about any new scientific (or other) paradigm – indeed, the same was said about Internet “law” barely a decade ago.

[26] Although his demarcation needs to be developed a bit further (e.g. that biotechnology is not technology, then but it is, then but it is not), Williams postulates that, much like the *Orphan Drug Act*<sup>66</sup> and the (derelict) *Semiconductor Chip Protection Act*,<sup>67</sup> a sui generis statutory scheme for biotechnology would better enhance research, innovation, and (presumably) the common good.<sup>68</sup> Williams fails to consider how advances in biotechnology could be separated, either by definition or in practice, from other technological advances; he fails to provide a definition of biotechnology at all. The expansiveness of the term becomes apparent if we adopt the definition of biotechnology from the United Nations Convention on Biological Diversity: “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.”<sup>69</sup> Indeed, there is no bright line here for Williams to draw.

[27] Yet in other writings, less radical means have been suggested as ways to deal with biotechnological innovations. Burton Ong, for instance, argues that organic innovations in particular ought to be protected by process patents, rather than product patents.<sup>70</sup> He argues that if one were to accept a desert-based approach to patent entitlements, then patents ought to never be granted for organic inventions (*per se*), since the only contribution that the inventor can claim is the process through which the inventor realized that organic matter.<sup>71</sup> Hence, the process ought to be

<sup>65</sup> *Id.* at 985-86.

<sup>66</sup> 21 U.S.C. §§ 360aa-ee (1998).

<sup>67</sup> 17 U.S.C. §§ 901-914 (1988).

<sup>68</sup> *Cf.* Williams, *supra* note 62, at 992 (allowing the existing patent system to remain intact while providing for the requisite elements of biological molecule patents).

<sup>69</sup> Conference on Environment and Development: Convention on Biological Diversity, art. 2, *opened for signature*, June 5, 1992, 31 I.L.M 818 (1992).

<sup>70</sup> Burton T. Ong, *Patenting the Biological Bounty of Nature: Re-Examining the Status of Organic Inventions as Patentable Subject Matter*, 8 MARQ. INTELL. PROP. L. REV. 1, 8-9 (2004).

<sup>71</sup> *See id.* at 28.

patentable, but not the actual organic product since that contribution only extends to the means, not the ends, and this is the limit of his or her “desert.”<sup>72</sup> Although Ong’s position is inviting, it still confines the processes, methods, and means of basic research to a patent monopoly.

[28] Nonetheless, the topic remains controversial as American scholarship trends away from expanding patentable subject matter to the basic elements or tools of research, on the grounds that they represent scientific or intellectual “commons.” Peter Lee continues this tradition by arguing that patent law

[S]pecifically prohibits the patenting of . . . natural laws, natural phenomena, and abstract principles on a ‘fundamentality’ rationale; these assets enable wide varieties of derivative applications and are better suited for common ownership in the public domain where all persons can freely draw upon them in their innovative endeavors.<sup>73</sup>

[29] He argues that if we accept this basis (which is the prevailing exclusionary theory in the United States against the patentability of those items), then elements of biotechnology like human embryonic stem cells, which are patentable technologies when isolated and purified outside of the human organism and equally as fundamental, may facilitate the advancement of much of the biological sciences.<sup>74</sup> Like Williams, the crux of Lee’s article is that many advances in biotechnology that are currently considered patentable ought not be, since those innovations form the basic research tools in the biological sciences.<sup>75</sup>

[30] The argument against the expansion of patentable subject matter on the grounds of fundamentality, as Lee puts it, will be examined in more

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<sup>72</sup> *See id.*

<sup>73</sup> Peter Y. Lee, Abstract, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine to Constrain Patents on Biotechnology Research Tools*, 19 HARV. J.L. AND TECH. 79 (2005), available at <http://ssrn.com/abstract=897629>.

<sup>74</sup> *Id.* at 88 (“Stem cell research promises to advance fundamental knowledge of human developmental biology and cell regeneration.”).

<sup>75</sup> *See id.* at 81.

depth in Part VI. Yet, it may well be that advances in biotechnology are viewed as the tools of scientific research since the field is new and revolutionary. If we accept this line of argument, then *any* scientific breakthrough that peels back another layer of “fundamentality” (which is what science does) will reveal that the existing layer was not truly fundamental after all and that awarding patents for that previously fundamental layer is now acceptable, ad infinitum.

#### V. INTERNATIONAL APPROACHES TO INVENTION

[31] Since the mid 1990s, TRIPS has become the principal tool of international intellectual property standard setting. Article 27.1 of TRIPS provides that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”<sup>76</sup> TRIPS arguably creates a subject matter threshold, as well as a patentability threshold—in that there must first be an “invention,” which in turn, will only receive patent protection once it satisfies the usual hallmarks of patentability (namely, novelty, inventiveness and industrial applicability).<sup>77</sup>

[32] The subtlety of this drafting has been addressed by writers such as George Wei<sup>78</sup> and Luigi Palombi.<sup>79</sup> Palombi’s writing on gene patents discusses the compatibility of TRIPS and the European Biotechnology Directive.<sup>80</sup> Palombi points out that the TRIPS “invention” requirement is supported by many cases such as *Genentech Inc.’s Patent*,<sup>81</sup> but undermined by other holdings, demonstrated by Lord Hoffman’s remarks in *Biogen Inc. v. Medeva Plc.*<sup>82</sup> Lord Hoffman, dismissed the initial question of whether something is an “invention” as an invariably

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<sup>76</sup> TRIPS, *supra* note 3, art. 27.

<sup>77</sup> Luigi Palombi, *Patentable Subject Matter, TRIPS and the European Biotechnology Directive: Australia and Patenting Human Genes*, 26 U.N.S.W.L.J. 782, 782 (2003) (Austl.).

<sup>78</sup> George Wei, *Inventions, Genes and Napoleonic Victories*, 9 SING. ACAD. L.J. 1 (1997).

<sup>79</sup> Palombi, *supra* note 77.

<sup>80</sup> *Id.*, at 782-84.

<sup>81</sup> *Genentech Inc.’s Patent*, *supra* note 1.

<sup>82</sup> *Biogen Inc. v. Medeva Plc*, 114 R.P.C. 1, 41-42 (1997) (U.K.).



“academic” consideration.<sup>83</sup> He found that when the Court determines patentability, the first inquiry should not be what is an “invention”; rather, “[j]udges would . . . be well advised to put on one side their intuitive sense of what constituted an invention until they have considered the questions of novelty, inventiveness and so forth.”<sup>84</sup> Wei rightly argues that this commonsense approach is undoubtedly the most practical way for the Courts to ordinarily proceed, however, there can be no doubt that there is a residue of cases where the issue of defining an “invention” is still very much alive, and not to be cursorily labelled as “academic.”<sup>85</sup> Indeed, Palombi’s contention is that the European Biotechnology Directive actually violates TRIPS and its subtle drafting (as I have characterized it).<sup>86</sup> Article 1.1 of the Directive states that: “Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.”<sup>87</sup>

[33] Palombi notes that TRIPS requires all member states to *consider* inventions for patentability equally and consistently across “all fields of technology.”<sup>88</sup> The Directive therefore presumes that biotechnological inventions are indeed inventions, and ignores the subject matter threshold step (or test) mandated by TRIPS and is “a direct violation of [article] 27.1 of TRIPS.”<sup>89</sup> Admittedly, the Directive does appear to be a violation of TRIPS on its face. Palombi fails to mention, however, that the very next subsection of the Directive (Article 1.2) provides that “[t]his Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPS Agreement and the Convention on Biological Diversity.”<sup>90</sup> Therefore, the Directive—far from being a violation of TRIPS—now appears toothless in light of the fact that TRIPS is seemingly intended to take priority over it.

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<sup>83</sup> *Id.* at 42.

<sup>84</sup> *Id.*

<sup>85</sup> *See* Wei, *supra* note 78, at 15.

<sup>86</sup> Palombi, *supra* note 77, at 783; *see also* Council Directive 98/44, art. 1, 1998 O.J. (L 213) 13 (EC).

<sup>87</sup> Council Directive 98/44, *supra* note 86.

<sup>88</sup> Palombi, *supra* note 77, at 790.

<sup>89</sup> *See Id.* (alteration in original).

<sup>90</sup> Council Directive 98/44, *supra* note 86.

If a subject matter threshold step (or test) is required before we consider the usual hallmarks of patentability, then we cannot presume that biotechnological innovations are inventions *ab initio*.

## VI. THE SIGNIFICANCE OF PATENTS ON INTANGIBLES

[34] Implicitly or explicitly, a considerable portion of Parts III, IV and V, is devoted to the problems that biotechnology, in particular, present for many of the fundamental patent doctrines, and traditional exclusions from patentability. The following sections break from this tradition, and examine the subject matter eligibility of intangibles—business methods, software, signals and even sporting techniques. Next, in Part VII, I survey some of writings on the role that ethics play—or ought *not* to play—in demarcating patent-eligible subject matter. I will also examine the emerging literature on human-animal chimeras which are inexorably tied to such concerns.

[35] By commenting on patents for business methods (i.e., patents covering methods for performing business operations), Nari Lee provides a comparative insight into these patents' treatment across Japan, the U.S., and Europe.<sup>91</sup> Lee traces how the courts and patent offices in those countries or regions have redefined the meaning of technology, and inventions thereof, from the context of physical instantiation (i.e., physical transformation) to the level of conceptual instantiation (i.e., useful information) in order to bring business methods within the realm of patentable subject matter.<sup>92</sup>

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<sup>91</sup> Nari Lee, *Patent Eligible Subject Matter Reconfiguration and the Emergence of Proprietary Norms - The Patent Eligibility of Business Methods*, 45 IDEA 321, 327-28 (2005).

<sup>92</sup> Patents are granted based on two substantive tests. A “categorical test on patentable subject matter” and a “series of tests to ensure the validity of a specific patent” including the usual hallmarks of patentability “novelty, inventiveness/non-obviousness, and utility/industrial applicability.” *Id.* at 331.

[36] Lee argues that this change in institutional thinking (whether through the courts or the patent offices) reflects a change in philosophy from utilitarian instrumentalism to proprietarianism.<sup>93</sup>

In this aspect, reconfiguration reflects a change in the normative justification of patent institution. It is difficult to justify business method patenting under the traditional utilitarian instrumentalism . . . . The reconfiguration of patentable subject matter to protect the values created by business methods with patent property rules, instead of creating a new exclusionary right, could be characterized as proprietarian.<sup>94</sup>

I disagree with this view. Indeed, it is perhaps convenient that Lee ties patentability solely to utilitarian instrumentalism, and ignores that labour-desert theory<sup>95</sup> can, just as readily, justify patents (in general), and business method patents (in particular).<sup>96</sup> There is no necessary movement towards proprietarianism here.

[37] With respect to software, it is common knowledge that such subject matter is now considered patent eligible; although it must usually produce some “useful, concrete and tangible result,”<sup>97</sup> possess a technical character,<sup>98</sup> or be integrated with other statutory matter (computer

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<sup>93</sup> Peter Drahos describes “proprietarianism” as “a creed and an attitude which inclines its holders towards a property fundamentalism.” PETER DRAHOS, A PHILOSOPHY OF INTELLECTUAL PROPERTY 201 (1996). See Lee, *supra* note 91, at 351-55.

<sup>94</sup> Lee, *supra* note 91, at 358-59.

<sup>95</sup> See *supra* notes 70-72 and accompanying text.

<sup>96</sup> I am not saying that labour-desert theory is a necessarily sound or wholly satisfactory theory either. Rather, I am arguing that Lee simply failed to consider it in his quest to *find* proprietarianism. Lee’s work also ignores the role that policy plays in legislative attitudes and judicial decision-making. It may well be that business methods are now considered a protected form of knowledge—whereas traditional knowledge is not—chiefly because of the extensive lobbying and commercial interests at play.

<sup>97</sup> *Diamond v. Diehr*, 450 U.S. 175 (1981); *AT&T v. Excel Comm’ns, Inc.*, 172 F.3d 1352, 1359 (Fed. Cir. 1999); *State Street Bank & Trust Co. v. Signature Fin. Group Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998); *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1056 (Fed. Cir. 1992).

<sup>98</sup> Although Art. 52(2) of the European Patent Convention enumerates “programs for computers” as outside the definition of invention, Art. 52(3) limits that exclusion by

implement inventions).<sup>99</sup> Jinseok Park, in examining the software patenting practices across United States, European, and Japanese Patent Offices, notes that USPTO, EPO, and JPO have all agreed that to “merely automate a *known* human transaction process using *well-known* automation techniques [i.e., a computer-implemented business process] is

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stating that it applies “only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.” European Patent Office, European Patent Convention, pt. II, ch. I (July 2007), [http://documents.epo.org/projects/babylon/eponet.nsf/0/E4F8409B2A99862FC125736B00374CEC/\\$File/EPC\\_13th\\_edition.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/E4F8409B2A99862FC125736B00374CEC/$File/EPC_13th_edition.pdf). Hence, computer software is patentable in Europe insofar as it produces a technical character. *Id.* pt. III, ch. II, R. 42. But the technical character requirement is not directed to software *per se*; rather, it protects certain concrete or “‘real world’ activities.” Case of Vicom, T-208/84 Technical Board of Appeal 15 July 1986, O.J. EPO 1987/014, *available at* <http://legal.european-patent-office.org/dg3/biblio/t840208ep1.htm>.

<sup>99</sup> This appears to be the current situation in Canada. Following the decision in *Schlumberger Canada Ltd. v. Commissioner of Patents*, [1981] 1 F.C. 845 (the only court decision in Canada to expressly deal with the patentability of software), the *Manual of Patent Office Practice* identified the subject matter which is eligible for patenting as follows:

The claimed subject matter must fall in one of the recognized categories of art, process, machine, manufacture or composition of matter . . . .

. . . [C]omputer related subject matter is not excluded from patentability if the traditional criteria for patentability are satisfied. Software that has been integrated with statutory subject matter may be patentable.

. . . .

A claim to a method consisting only of making certain calculations according to certain formulae is, even if it results in useful information, excluded from patentability under subsection 27(8) of the *Patent Act*. Such a method does not include an act or series of acts performed by some physical agent upon some physical object and producing in such object some change either of character or of condition. Furthermore, the method does not produce an essentially economic result relating to trade, industry or commerce . . . .

CANADIAN PATENT OFFICE, MANUAL OF PATENT OFFICE PRACTICE 16-3 (1998 ed., Feb. 2005).

not patentable.”<sup>100</sup> The utility of this statement is entirely lost when one considers that any human transaction which is already *known* and uses *well-known* techniques would fail to meet the novelty requirements required for patentability irrespective of any discussion as to whether the subject matter itself is patentable. So, aside from the fact that software generally qualifies as patent-eligible subject matter across much of the world, there is little other multinational conformity to be found.

[38] On the larger issue of intangible inventions and their subject matter eligibility, Richard Gruner examines the current boundaries of the patent system to determine when, if, or how they should be redrawn so as to “ensure that patent rights serve the same valuable functions concerning intangible innovations” as they have served for their earlier physical or mechanical counterparts.<sup>101</sup> Gruner identifies “algorithms, scientific discoveries, naturally occurring items, mental steps, and printed matter” as subject matter traditionally beyond such boundaries.<sup>102</sup> While the first three are simply restatements of the unholy trinity, I will briefly discuss the printed matter exclusion as it has not received any treatment in the literature up to this point.

[39] Informational text or images recorded on printed matter have generally been held unpatentable by U.S. courts.<sup>103</sup> These courts held the view that merely reducing an idea, abstraction, method, or process to

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<sup>100</sup> Jinseok Park, *Has Patentable Subject Matter Been Expanded?-A Comparative Study on Software Patent Practices in the European Patent Office, the United States Patent and Trademark Office and the Japanese Patent Office*, 13 INT’L J. L. & INFO. TECH. 336, 371-72 (2005) (emphasis added); see REPORT ON COMPARATIVE STUDY CARRIED OUT UNDER TRILATERAL PROJECT B3B, available at [http://www.trilateral.net/projects/other\\_project/business\\_method/](http://www.trilateral.net/projects/other_project/business_method/).

<sup>101</sup> Richard S. Gruner, *Intangible Inventions: Patentable Subject Matter for an Information Age*, 35 LOY. L.A. L. REV. 355, 355 (2002).

<sup>102</sup> See *id.* at 384.

<sup>103</sup> *In re Rice*, 132 F.2d 140 (C.C.P.A. 1942) (“It is well established in patent law that invention cannot rest alone in novel printing arrangement, although it may reside in some physical structures of printed matter.”); see also Note, *The Patentability of Printed Matter: Critique and Proposal*, 18 GEO. WASH. L. REV. 475, 476 (1950) (“The origin of the printed-matter doctrine is found in the longstanding rule that abstractions, mental theories or business methods are not patentable subject matter.”).

writing did not amount to an invention.<sup>104</sup> Even before the court in *State Street Bank & Trust Company v. Signature Financial Group, Inc.* put the “ill-conceived” business method exemption aside,<sup>105</sup> there was little discussion in the jurisprudence to explain why the printed matter doctrine existed.<sup>106</sup> Nonetheless, an important exception to this doctrine exists

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<sup>104</sup> *Boggs v. Robertson*, 13 U.S.P.Q. (BNA) 214, 214 (D.C. June 23, 1931) (“The authorities are uniform in holding printed matter per se to be unpatentable, i.e., where an idea is simply an abstraction the mere reduction of it to writing does not amount to invention.”).

<sup>105</sup> 149 F.3d 1368, 1375 (Fed. Cir. 1998).

<sup>106</sup> For instance, in *Hotel Security Checking Co. v. Lorraine Co.*, 160 F. 467, 469 (2d Cir. 1908), the Court quotes *Fowler v. City of New York*, 121 F. 747, 478. (2d Cir. 1903), in reaching its decision (“No mere abstraction, no idea, however brilliant, can be the subject of a patent irrespective of the means designed to give it effect.”). Although *Fowler* did not deal with printed matter, the *Hotel Security* holding derived the principle that abstractions rendered to paper cannot be patentable. *Hotel Security*, 160 F. at 469. Many later cases cite to *Hotel Security* directly. *See, e.g., In re Dixon*, 44 F.2d 881, 881 (C.C.P.A. 1930); *Guthrie v. Curlett*, 10 F.2d 725, 726 (2d Cir. 1926); *Moore v. United States*, 50 Ct. Cl. 120, 126 (1915); *Berardini v. Tocci*, 200 F. 1021, 1022 (2d Cir. 1912). Other cases cite cases which, in turn, cite the *Hotel Security* decision. *See, e.g., Boggs*, 13 U.S.P.Q. (BNA) at 216; *In re Russell*, 48 F.2d 668, 669 (C.C.P.A. 1931); *Flint v. G. R. Leonard & Co.*, 27 F.2d 215, 217 (7th Cir. 1928). Pamela Samuelson has offered two rationales:

One reason for the “printed matter” rule may be a perception that although printing itself is a manufacturing process and part of the technological arts, the printed matter itself—and its contents, in particular—are not “in the technological arts,” even when about the technological arts. A book describing how to organize one’s work force in a rubber curing plant most effectively might be the product of a manufacturing process (*i.e.*, the book) and it might be about a manufacturing process, but the content of the work would still not be the kind of manufacture or process traditionally considered to be patentable.

Underlying the “printed matter” rule may be a perception that printed matter is among the set of things that are “writings” protectible by copyright law, not inventions in the “useful arts,” and that copyright law strikes the appropriate balance between protection of expression and nonprotection of ideas for written texts. This balance would be disrupted if patents were available based on the content of the “printed matter.” When “printed matter” has been patented, it has generally been in situations in which it has been integrated into some machine or physical structure which then supports the patent.

where the printed matter is somehow functionally connected to a physical structure or otherwise produces a functionally useful result.<sup>107</sup>

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Pamela Samuelson, *Benson Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions*, 39 EMORY L.J. 1025, 1037 n.36 (1990).

<sup>107</sup> The Court in *Boggs* summarized the law well:

[T]he claims were properly refused in the Patent Office on the ground that the subject-matter does not come within the purview of section 4886, Revised Statutes (35 U.S.C.A. 31).

....

The transfer ticket case, *Cincinnati Traction Co. v. Poue*, 210 F. 443, involved in general the street-car transfer ticket in general use today with a coupon to be either torn off or left on to indicate a.m. or p.m. use of the ticket. The paper on which the printed matter appeared was used physically in addition to serving as a mere support for the printed matter. The coupon was also arranged to be punched to indicate dates and time of the day.

The scrip book case, *Rand, McNally & Co. v. Exchange Scrip Book Co.*, 187 F. 984, involved a book having a series of coupons to be detached from a strip for use in payment of transportation calculated in terms of money instead of mileage coupons.

*The Benjamin Menu Card Co. v. Rand, McNally Co.*, 210 F. 285, involved a menu card consisting of a combined waiter's check, a cook's check, and a guest's check. . . .

The advertising card case, *Mitchell v. International Tailoring Co.*, 170 F. 91, involved an advertising card consisting of two parts so designed that one of the parts could be thrown away after having served its purpose while the other part was designed to be kept. The card was physically used in addition to its use as a support for the printed matter.

In each of these cases the thing involved was a physical object adapted to be handled and used in a certain manner due to the physical construction thereof; in each case the complete object was formed of a definite form and substance of a physical body supplemented by indicia disposed thereof in a particular manner to provide an actual physical cooperation between the body and indicia.

In the present case, no article comprising a definite physical body and structurally-related indicia is shown; but merely a system of lines without reference to any tangible article.

. . . I am of opinion that in all cases where the printed matter, irrespective of the material upon which it is printed, is the sole feature

[40] Gruner notes that while printed matter and the unholy trinity continue to receive much judicial “hostility,” the acceptance of algorithms as patentable subject matter should suggest a general framework for recognizing and dealing with patentable subject matter in otherwise intangible inventions.<sup>108</sup> According to Gruner, the *Arrhythmia* analysis: “whether the claimed invention as a whole is no more than the algorithm itself; that is, whether the claim is directed to a mathematical algorithm that is not applied to or limited by physical elements or process steps”<sup>109</sup> is the proper analysis to apply when determining whether intangible inventions contain patentable subject matter or if the invention or method

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of alleged novelty it does not come within the purview of the statute, as it is merely an abstract idea. *But where the paper or physical body upon which the matter is printed is designed to be used with the printed matter, as by tearing apart or punching, it becomes more than an abstract idea but an actual physical article of manufacture* within the terms of [the Patent Statute], and as such is patentable if it be a new and useful inventive concept.

The decisions make this distinction – *that where no dependence exists between the printed matter and the object on which arranged such matter is merely an idea reduced to writing and is not a manufacture.*

*Boggs*, 13 U.S.P.Q. (BNA) at 215 (emphasis omitted) (emphasis added) (alteration in original) (citing Act of May 23, 1930, ch. 312, 46 Stat. 376 (codified as amended at 35 U.S.C. §§ 101, 161 (2000))).

<sup>108</sup> Gruner, *supra* note 101, at 396-97, 467.

<sup>109</sup> *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1058 (Fed. Cir. 1992).

Determination of statutory subject matter has been conveniently conducted in two stages, following a protocol initiated by the Court of Customs and Patent Appeals in *In re Freeman*, 573 F.2d 1237, 197 U.S.P.Q. 464 (C.C.P.A. 1978); modified after the Court’s *Flook* decision by *In re Walter*, 618 F.2d 758, 205 U.S.P.Q. 397 (C.C.P.A. 1980); and again after the Court’s *Diehr* decision by *In re Abele*, 684 F.2d 902, 214 U.S.P.Q. 682 (C.C.P.A. 1982).

*Id.*



lacks the requisite physical significance or relevance.<sup>110</sup> Inevitably, many of these concerns can be addressed by proper claim drafting.<sup>111</sup>

[41] Gruner's analysis concludes with what he believes to be a new framework for encouraging innovation in intangible inventions.<sup>112</sup> He argues that inventions are the products of "agency processes in which an inventor acts as the agent for a group of principals comprised of the potential users of the inventor's discoveries."<sup>113</sup> Gruner misses the mark here. There are too many neglected nuances in this assertion. Granted, he provides a useful insight into the shift from subject matter ineligibility to eligibility for intangible inventions; but his suggestion that inventors are agents for potential users goes too far.<sup>114</sup> This concept is foreign to patent law. Inventors invent. An "invention" is the right to exclude others. It is *not* a right to produce or create that invention. If inventors were seen as "mere" agents acting for the benefit of the "potential users," this would imply that somewhere within the concept of inventorship lay a positive duty to produce or create that invention.

[42] In a similar vein, one would imagine that propagated signal claims – transient manufactured<sup>115</sup> phenomena like electrical, optical or acoustical signals – ought to have presented similar problems with respect to their ephemerality and intangibility. Authors, such as Kunin, Lytle,<sup>116</sup> and Han,<sup>117</sup> however, argue that as far back as 1854 the U.S. Supreme Court

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<sup>110</sup> See Gruner, *supra* note 101, at 396 (“[A]n analytic method will be patentable subject matter if the method is used to evaluate data or information with physical significance or relevance, giving the result further physical significance and practical utility.”).

<sup>111</sup> See generally WIPO Second International Conference on Electronic Commerce and Intellectual Property, Sept. 19-21, 2001, Business Method Patents and Beyond: Why E=mc<sup>2</sup> Is Inherently Patentable (at least in the U.S. and Australia), WIPO/EC/CONF/01/SPK/3C, available at [http://www.wipo.int/edocs/mdocs/e-commerce/en/wipo\\_ec\\_conf\\_01/wipo\\_ec\\_conf\\_01\\_spk\\_3c.pdf](http://www.wipo.int/edocs/mdocs/e-commerce/en/wipo_ec_conf_01/wipo_ec_conf_01_spk_3c.pdf) (discussing the inherent patentability of abstract concepts).

<sup>112</sup> Gruner, *supra* note 101, at 467-69.

<sup>113</sup> *Id.* at 467.

<sup>114</sup> See *id.*

<sup>115</sup> As opposed to naturally occurring signals, these are propagated by “man.”

<sup>116</sup> Stephen G. Kunin & Bradley D. Lytle, *Patent Eligibility of Signal Claims*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 991, 994 (2005).

<sup>117</sup> Sam S. Han, *Analyzing the Patentability of "Intangible" Yet "Physical" Subject Matter*, 3 COLUM. SCI. & TECH. L. REV. 1, ¶ 25 (2002). In reviewing the jurisprudence

upheld a patent on Samuel Morse's telegraphy patents for his invention of "a new and useful improvement in the mode of communicating information by signals, by the application of electro-magnetism," holding only the eighth claim (the exclusive use of electro-magnetism) unpatentable because it was overly broad.<sup>118</sup>

[43] More recently in *Ex parte Rice*, the USPTO's Board of Patent Appeal and Interferences reversed a patent examiner's rejection of a signal claim as being directed to non-statutory subject matter, holding instead that electromagnetic signals although "transitory and ephemeral in nature" are nonetheless statutory subject matter.<sup>119</sup> It might be a trite observation, but as the matter was decided by the Board of Patent Appeal and Interferences, it serves no precedential value. Despite this trend towards patentability for signals per se, in *In re Nuijten*, a majority of the Court of Appeals for the Federal Circuit held that transitory, propagating signals fell outside the concept of an "invention" as being neither a process, machine, manufacture, nor composition of matter.<sup>120</sup>

[44] Kunin and Lytle have traced the acceptance of such claims in Canada and Japan. They argue that while the situation with respect to signal claims is unclear under the European Patent Convention, there is still an increasing trend towards the acceptance of such claims.<sup>121</sup> Yet, the Canadian Intellectual Property Office has recently issued a practice notice stating that electromagnetic and acoustic signals per se do not constitute statutory subject matter within the definition of invention under section 2

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with respect to algorithm patents, Han identifies that certain subject matter are excluded from patentability by virtue of the fact that they form the basic tools of scientific research and work. He does not expressly address, however, that patents on signals *per se* may well be caught by this doctrine as well. *See Id.* ¶¶ 77-85.

<sup>118</sup> *O'Reilly v. Morse*, 56 U.S. 62, 62, 84 (1853).

<sup>119</sup> *Ex parte Rice*, No. 2002-1554 (B.P.A.I. Feb. 13, 2003), available at <http://des.uspto.gov/Foia/ReterivePdf?system=BP&fNm=fd021554>.

<sup>120</sup> *In re Nuijten*, 500 F.3d 1346, 1357 (Fed. Cir. 2007). Justice Linn, dissenting in part, argued that "manufacture" ought to be given an expansive reading; and new, useful and non-obvious "man-made" signals were within its breadth as being directed towards statutory subject matter. *Id.* at 1358.

<sup>121</sup> Kunin & Lytle, *supra* note 116, at 1000.

of the Canadian Patent Act.<sup>122</sup> Neither Canadian jurisprudence, nor the Canadian Patent Act, provides any basis to support the Canadian Intellectual Property Office's restriction (but there does appear to be an implicit acceptance of it in the U.S. decision in *In re Nuijten*).<sup>123</sup>

[45] Kunin and Lytle explain that signal claims are potentially more useful to patent holders than actual product claims since the patent holder could "sue anyone who makes, uses, offers, or sells the invention."<sup>124</sup> Although this would also leave "intermediaries" like Internet service providers ("ISPs") and telecommunications companies vulnerable to litigation since they would be making, using, and perhaps even inadvertently selling or offering to sell, such patented signals in their transmissions.<sup>125</sup> Kunin and Lytle label such intermediaries as "innocent infringers" and postulate that the courts may deal with the situation in the same way that they have dealt with so-called "innocent infringers" in the context of online copyright infringement.<sup>126</sup> Patent infringement, however, is a strict liability offence, and there is no concept of an "innocent infringer" in patent law.<sup>127</sup>

[46] Furthermore, to analogize and propose a solution from copyright law is tenuous at best. Consider that both copyright law and trademark law in the U.S. have evolved to protect parodies (though, there is no such defence in patent law). So, by Kunin and Lytle's line of argument, if I were to parody an invention by making an inane or obscure use of it, then I can perhaps avoid liability in patent law since this defence has been accepted in both copyright and trademark law in the U.S.

[47] Moving from tenuous to imaginative, Derek Bambauer provides some focus to an ill-forgotten area of patentable subject matter, the

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<sup>122</sup> Canadian Intellectual Property Office, Office Practice Regarding Signals (Aug. 14, 2007), [http://www.strategis.ic.gc.ca/sc\\_mrksv/cipo/patents/notice\\_aug14\\_07-e.html](http://www.strategis.ic.gc.ca/sc_mrksv/cipo/patents/notice_aug14_07-e.html).

<sup>123</sup> See *In re Nuijten*, 500 F.3d at 1357 (determining whether a signal of electric potential or electromagnetic fields constitutes a composition of matter under patentable subject matter); *id.*

<sup>124</sup> Kunin & Lytle, *supra* note 116, at 999.

<sup>125</sup> *Id.*

<sup>126</sup> *Id.* at 1002.

<sup>127</sup> *Id.*

patenting of *actual sporting techniques and rules* (so called “sports patents”).<sup>128</sup> His work actually builds on a brief commentary in the *Colorado Law Review*, in which Jeffery Smith argues that sports moves should not be considered patentable, on policy grounds,<sup>129</sup> and on a non peer-reviewed publication by Robert Kunststadt who argues that the sporting industry is “open for savvy athletes and their agents to protect their innovations through patent law.”<sup>130</sup>

[48] Bambauer traces how this area is now considered patentable, despite the considerable doubt as to its viability in the past, and finds philosophical support for sports patents under the labour-desert theory (though he admits that sports patents fail the “utilitarian test”).<sup>131</sup> Bambauer proposes that many of the concerns regarding the monopolization of sporting techniques can be overcome by effective licensing, or patent pooling, and intra-league cross-licensing requirements.<sup>132</sup> Capitalism is, of course, the answer. An answer which holds true only if the patent owner is economically motivated; one could just as easily patent techniques to prevent *everyone* from using them. For instance, it appears as though I could patent sporting techniques in the U.S. and, perhaps out of sheer Canadian patriotism, inter alia, prevent U.S. Olympic athletes from using them in their training or qualifying rounds.

## VII. ETHICS AND SUBJECT MATTER ELIGIBILITY

[49] The role that ethics ought to play (if any) in determinations of subject matter eligibility is fiercely contested in the literature, especially in light of the recent attempt by Stuart Newman and Jeremy Rifkin to patent a human animal chimera (hereafter the “Newman-Rifkin patent application”) in the

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<sup>128</sup> Derek Bambauer, *Legal Responses to the Challenges of Sports Patents*, 18 HARV. J. L. & TECH. 401, 402 (2005).

<sup>129</sup> Jeffery A. Smith, *It’s Your Move—No, It’s Not! The Application of Patent Law to Sports Moves*, 70 U. COLO. L. REV. 1051, 1052 (1999).

<sup>130</sup> Robert M. Kunststadt et al., *Are Sports Moves Next in IP Law?*, NAT’L L. J., May 20, 1996, at C2.

<sup>131</sup> Bambauer, *supra* note 128, at 413, 420.

<sup>132</sup> *Id.* at 404, 429.

USPTO<sup>133</sup> and the European Patent Convention's prohibition against patenting inventions "the exploitation of which would be contrary to 'ordre public' or morality."<sup>134</sup>

[50] Valerie Phillips<sup>135</sup> discusses how the Newman-Rifkin patent application was crafted to cover humans per se,<sup>136</sup> but claimed only chimeras containing less than 50% of human genetic material.<sup>137</sup> Phillips traces the origins and development of the "moral utility" doctrine in U.S. patent law. The American origin of the doctrine can be traced to the Honorable Justice Story in *Lowell v. Lewis*, wherein the Honorable Justice stated that "[a]ll that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society."<sup>138</sup> Phillips postulates that the doctrine, though infrequently invoked for nearly two centuries, may have a greater significance to

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<sup>133</sup> Posting of Lawrence B. Ebert to IPBiz.blogspot.com, <http://ipbiz.blogspot.com/2005/02/newmanrifkin-effort-succeeds-patent.html> (Feb. 15, 2005).

<sup>134</sup> European Patent Office, European Patent Convention, pt. II, ch II, art. 53, [http://documents.epo.org/projects/babylon/eponet.nsf/0/E4F8409B2A99862FC125736B00374CEC/\\$File/EPC\\_13th\\_edition.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/E4F8409B2A99862FC125736B00374CEC/$File/EPC_13th_edition.pdf).

<sup>135</sup> Valerie Phillips, *Half-Human Creatures, Plants & Indigenous Peoples: Musings on Ramifications of Western Notions of Intellectual Property and the Newman-Rifkin Attempt to Patent a Theoretical Half-Human Creature*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 383, 385 (2005); see also Indrė Kelmelytė, *Can Living Things Be Objects of Patents?*, 2 INT'L J. BALTIC L. 2, 4 (2005) (discussing the patentability requirements under the European Patent Convention, Lithuania in particular, and the U.S.); Alexandra MacBean, *The Patentability of Human Beings: The Effect of a Proposed Exclusion in the Patents Act 1953*, 33 VUWLR 379, 379 (2002) (Austl.) (discussing whether human beings ought to be patentable).

<sup>136</sup> In 1987, the USPTO issued amended examination guidelines which prohibited the patenting of humans. No statutory or jurisprudential basis was identified for such a ban. See Thomas L. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 448 (1999).

<sup>137</sup> How much genetic material *do* you need to be considered human? Would it matter if the resulting life-form was "highly" anthropomorphic? Or sentient? These questions are, as yet, unanswered in the literature.

<sup>138</sup> *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C. Mass. 1817). The doctrine is very much akin to the Article 53(a) prohibition of the European Patent Convention against "inventions the publication or exploitation of which would be contrary to 'ordre public' or morality." Jasmine Chambers, *Patent Eligibility of Biotechnical Inventions in the United States, Europe, and Japan: How Much Patent Policy Is Public Policy*, 34 GEO. WASH. INT'L L. REV. 223, 233 (2002).

assume in modern jurisprudence as it relates to biotechnological advances.<sup>139</sup> Unlike writers like Guerra and Chambers (discussed below), Phillips believes that moral inquiries ought to play a role in subject matter eligibility.<sup>140</sup>

[51] Although the Newman-Rifkin patent application was abandoned in March of 2005, the patent application was first issued a Final Rejection by the USPTO in August of 2004, on the grounds that the application would either be, inter alia: 1) Inconsistent with the constitutional right to privacy – since holders of the patent would be entitled to prevent others from making or working the claimed invention, hence denying the actual person with the right to decide when, or if, to procreate; or 2) Tantamount to slavery (prohibited under the 13<sup>th</sup> Amendment), since patents preclude others from “using” the invention, and employment can be construed as a “use” – which “would be tantamount to involuntary servitude.”<sup>141</sup>

[52] It is apparent that the USPTO took the view that even chimeras with less than 50% of their genetic materials originating from humans were nonetheless still human “enough” to justify the rejection. Even if we sidestep the imprecise equivocation that 1% - 49% of raw human genetic material is “enough” to consider something “human,” hence, worthy of protection under the U.S. Constitution,<sup>142</sup> there is still the objection that none of the principal reasons cited by the USPTO are reasons against patentable subject matter eligibility *per se*, rather they are objections with respect to *enforceability*.

[53] Indeed, Richard Guerra believes that employing the patent system to solve, in whole or in part, the ethical dilemmas posed in demarcating between reproductive cloning and therapeutic cloning, or between the

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<sup>139</sup> Phillips, *supra* note 135, at 423.

<sup>140</sup> *Id.* at 448.

<sup>141</sup> United States Patent and Trademark Office - Patent Examiner’s Final Rejection, [http://portal.uspto.gov/external/PA\\_1\\_0\\_15H/view/BrowsePdfServlet?objectId=DXEQQX7RPPOPY2&lang=DINO](http://portal.uspto.gov/external/PA_1_0_15H/view/BrowsePdfServlet?objectId=DXEQQX7RPPOPY2&lang=DINO) (last visited Oct. 29, 2008). The File Wrapper of the Newman-Rifkin patent application is available at the USPTO’s Public Patent Application Information Retrieval site, <http://portal.uspto.gov/external/portal/pair>. See also *supra* note 133 and accompanying text.

<sup>142</sup> *But see* *Roe v. Wade*, 410 U.S. 113, 158 (1973) (stating in dicta that unborn fetuses have no rights under the U.S. Constitution).

stages at which we consider life to be “human,” is a questionable practice at best.<sup>143</sup> Guerra believes patent law should be considered “an amoral vehicle for commercialization, or as an instrument of wide-ranging moral regulation.”<sup>144</sup> Guerra derives support for his view from the first Patent Act. He notes:

[D]elineating proper subject matter was, and continues to be confined to meeting the novelty, non-obvious, utility, and enablement requirements, and nowhere within the first or current patent statute is there a requirement to conduct a moral consideration of what is contrary to public policy.<sup>145</sup>

[54] Undoubtedly, Guerra is right with respect to the strict, literal wording of the Act. Guerra also cites, but fails, to make the connection with the *Lowell v. Lewis* decision that suggests courts may have read the moral utility doctrine into the Patent Act precisely because Congress intends the Act to be interpreted with this gloss.<sup>146</sup>

#### VIII. POLICY AND SUBJECT MATTER ELIGIBILITY

[55] I have separated the role that policy plays from subject matter eligibility, not because policy and ethics are necessarily or always two different enterprises, but because the writings in this area are simply less concerned with ethics.

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<sup>143</sup> Richard Guerra, Comment, *Therapeutic Cloning as Proper Subject Matter for Patent Eligibility*, 43 IDEA 695, 698-99 (2003).

<sup>144</sup> *Id.* at 709. Indeed, this “amoralization” of patent statutes is also echoed in the Canadian literature. See Concetta Manera, *Owning Humans and Parts Thereof: The Common Law History and the Recent Patent Controversies* (Oct. 2001) (unpublished LL.M. Thesis, Queen’s University) (on file with the National Library of Canada) (arguing that the original goals of the Canadian Patent Act preclude any consideration of moral or ethical grounds for the opposition or rejection of life form patents). At the time of her work’s publication, the Supreme Court of Canada’s decision in *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45 (Can.), had not yet been handed down. Part of the decision entertained such moral and ethical considerations.

<sup>145</sup> Guerra, *supra* note 143, at 710.

<sup>146</sup> 15 F. Cas. 1018, 1019 (C.C. Mass 1817).

[56] Consider the work of Jasmine Chambers, who writes from a decidedly Americentric view of patent policy and the patent eligibility of biotechnological inventions across the U.S., Europe, and Japan and argues that “[w]orldwide, U.S. patent law provides the broadest protection of biotechnological inventions, and significantly, the United States leads the world in this area in terms of advancement and research efforts.”<sup>147</sup> It is not only because of patent protection that that the U.S. leads the way in biotechnological research, as there are a myriad of other connected factors. Patent eligibility may well be the least important of those; Chambers neither explores nor acknowledges this position. Building on Bambauer’s earlier work,<sup>148</sup> the U.S. should also be a leader in most commercially viable sports since it has the broadest protection for sporting techniques. Although the relative lack of success for the U.S. in sports such as soccer,<sup>149</sup> cricket, hockey, and rugby suggests otherwise. If Chambers’s thesis is taken to its logical, and not so distant conclusion, the U.S. should be the leader in every biotechnological field since it offers the broadest patent protection.

[57] Indeed, Chambers employs every single assumption identified by Gold<sup>150</sup> and endeavours to show that lack of patent protection for biotechnological innovation would decrease research funding, decrease the quality of medical services, and ultimately would stifle economic growth.<sup>151</sup> She notes that the European Patent Convention’s prohibition on inventions that contravene ordre public or morality should not be fostered, encouraged, or cultivated in U.S. Patent Law.<sup>152</sup> Accordingly, public policy and public involvement should be left out of the patent eligibility question. She is particularly wary of invoking the moral utility doctrine to deny patent eligibility on human animal chimeras.<sup>153</sup> To Chambers, “good” patent policy would: (a) look something like U.S. patent policy (indeed, she devotes an entire section to the “discrepancies”

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<sup>147</sup> Chambers, *supra* note 138, at 241.

<sup>148</sup> See *supra* notes 128-132 and accompanying text.

<sup>149</sup> This is a reference to the sport commonly known as football in most countries, but commonly known as “soccer” in Canada and the United States.

<sup>150</sup> Gold, *supra* note 17.

<sup>151</sup> Chambers, *supra* note 138, at 233.

<sup>152</sup> *Id.* at 242.

<sup>153</sup> *Id.* at 242.



of European and Japanese patent law); and (b) be completely devoid of public policy concerns.<sup>154</sup>

[58] With the United States leading the way with TRIPS and its agenda of intellectual property standard setting, scholarship like Chambers's ought make us all wary of the import of such international agreements. Indeed, she asserts that "[t]he scope of patent eligible subject matter typically expands as a nation realizes increasing economic growth and industrialization,"<sup>155</sup> without considering the role that TRIPS plays in coercing that ever-expanding scope.<sup>156</sup> Additionally, through negative implication, Chambers suggests that countries that do not expand their patent eligible subject matter may become, or already are, stumped in their level of economic growth.<sup>157</sup>

[59] Whereas Chambers might see the U.S. as the gatekeeper for world patent policy and subject matter eligibility—and to some extent, she may be correct—David Olson believes U.S. Courts assume a lesser gatekeeping role in determining subject matter eligibility.<sup>158</sup> Building on the concerns addressed in Meehan's aforementioned work,<sup>159</sup> Olson specifically examines the Supreme Court's ruling in *Metabolite*. In Olson's view, the June 2006 dismissal of the writ of certiorari, represents the Supreme Court and federal courts' trend towards a more limited "gatekeeping role" in establishing the scope and boundaries of patentable subject matter.<sup>160</sup>

[60] Tracing the "rise and fall" of the need for physical transformation, and the former exclusions of mental steps and business methods from patent eligible subject matter, Olson views the Supreme Court's dismissal as exemplifying a recent tradition of abandonment of its role as a

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<sup>154</sup> See *id.* at 242, 244-45.

<sup>155</sup> *Id.* at 226.

<sup>156</sup> Vaver, *supra* note 6, at 286-307.

<sup>157</sup> Chambers, *supra* note 138, at 244.

<sup>158</sup> See generally David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter* 39 (Boston Coll. Law Sch. Legal Studies Research Paper, Working Paper No. 163, 2006), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=933167](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=933167).

<sup>159</sup> Meehan, *supra* note 39, at 315.

<sup>160</sup> Olson, *supra* note 158, at 7-8.

gatekeeper. Needless to say, he is keen on seeing the gatekeeper role revived through a new administrative agency.

While Congress could take on the role of determining efficient subject matter itself, it is probably not the body best suited to the task. Congress probably does not have the time or the ability to focus extended attention necessary to come up with the best determinations of subject matter patentability. In addition, Congress suffers from the well-known problems of industry capture and susceptibility to lobbying.

A better choice probably would be for Congress to delegate the gatekeeper role to an administrative agency. An administrative agency, such as the PTO, could devote the time and resources necessary for thorough analysis. An agency could hire and/or consult with economists, industry members, academics, etc., so as to have a much greater factual and analytical framework available to it in making its determination than a court would typically have available to it from the submissions of the parties to a dispute.<sup>161</sup>

[61] Olson's posture begs the question: How does more complexity reduce complexity? Under this agency model, would the Courts lack interpretative or appellate powers with respect to patent eligible subject matter? Furthermore, hiring economists, industry members and academics does not solve the problem that Congress faces with respect to lobbying. It is well-known that economists, industry members, academics—everyone—comes to the table with their own research agendas, views, biases, funding, and so forth.<sup>162</sup> Olson's model also assumes that some affirmative "truth" or consensus could be achieved. Relying on an agency that would likely make decisions based on a majority basis, with innumerable concessions along the way, is no different than the way the

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<sup>161</sup> *Id.* at 63-64.

<sup>162</sup> The selection process alone for such economists, industry members, and academics would also be subject to biases, agendas, and so forth.

Courts, the USPTO, or the Board of Patent Appeals and Interferences operate today. Olson's proposal merely compounds the problem.

[62] Leaving Olson's problematic introduction of a specialized agency aside, there is still his very real concern that the Courts have indeed abandoned their implicit role as gatekeepers of patent eligible subject matter. Samuel Oddi has a rather singular answer.<sup>163</sup> Oddi argues that patent eligibility issues, in particular, ought to follow general jurisprudential patterns, especially given the broad, permissive language of patent statutes.<sup>164</sup> In answer to Olson, he finds that

There appears to be a regenerative, self-correcting mechanism at work over time with respect to opinions restricting the scope of patent eligibility. Examples include . . . . *Benson/Flook* [which is corrected] by *Chakrabarty/Diehr/State Street*. These "regenerations" appear to represent repeated reversion to the policy driven decision making process of the formative period.<sup>165</sup>

[63] In truth, the Courts are far from abandoning their roles as gatekeeper, even Olson admits that this is a relatively recent state of affairs; the Courts may simply be unconsciously caught in one of their regenerative cycles, which could eventually be self-corrected.<sup>166</sup>

#### CONCLUSION

[64] Despite the divergence of jurisprudence and geographies of writers in this area, a common thread among them appears to be an implicit acceptance that despite how new, non-obvious, and useful a discovery or

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<sup>163</sup> A. Samuel Oddi, *Regeneration in American Patent Law: Statutory Subject Matter*, 46 IDEA 491(2006).

<sup>164</sup> According to Oddi, there appears to be three identifiable jurisprudential periods in U.S. Law: a formative period arising from the ratification of the Constitution which lasted through the start of the Civil War, a formalistic period spanning the Civil War to somewhere between the World Wars, and a "modern" period following the end of the formalist era. *Id.* at 495-96.

<sup>165</sup> *Id.* at 560.

<sup>166</sup> If Oddi is right, *Metabolite* may represent nothing more than a missed opportunity, rather than a presumed abandonment of a gatekeeping role. *See id.*

development may be, there ought to be some “things” that fail the threshold of invention. “Invention” is a flexible concept, designed to accommodate unforeseen advances in the practical application of human knowledge. New advances in human understanding ought to expand acceptance of what constitutes an invention, not diminish it.