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## NATIONALIZING TRIPS: AN EXAMINATION THROUGH EXCEPTIONS

EVAN H. TALLMADGE

### ABSTRACT

What should not be patentable? The Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) codifies certain categories of subject matter that nations can exclude from patent protection. This Article examines how nations have interpreted these exclusions through an analysis of their national manuals of patent examining procedure and more importantly what explicit exceptions to patentability these countries have listed. The Article proceeds to analyze both the similarities and differences in approaches towards exclusions that attempt to ban the same subject matter from patentability and differences in what countries have chosen to bar from patenting. The Article concludes with an argument for a harmonization of the international patent regime, noting how some countries have taken substantial liberties with the TRIPS language.

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## NATIONALIZING TRIPS: AN EXAMINATION THROUGH EXCEPTIONS

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## I. INTRODUCTION

What can be patented? What shouldn't be patentable? Where and how should countries draw these lines? These are some of the central questions of national policy debates in trying to incentivize innovation with the patent system.<sup>1</sup> Over the last hundred years,<sup>2</sup> the international community has been moving towards answering this among other important questions of national patent policy, and some consensus has developed over what things shouldn't be patentable. The outlines of an international standard of patentability were codified in the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") Article 27<sup>3</sup> and incorporated into the national law and regulations of members of the World Trade Organization ("WTO").<sup>4</sup> Each member nation of the WTO is responsible for implementing TRIPS into their own national laws,<sup>5</sup> and different WTO member states have decided differently on the questions of what is eligible subject matter and what should explicitly be excluded from patentability in their national implementation of TRIPS.

Until the late 19th century, patent law was an entirely national affair.<sup>6</sup> In 1883 eleven countries signed the Paris Convention for the Protection of Industrial Property, the first major multilateral international intellectual property treaty.<sup>7</sup> In the negotiations leading up to the Paris Convention proposals were considered for a substantially harmonized international patent system, but due to major differences in national patent law these proposals were not incorporated into the final treaty.<sup>8</sup> The Paris Convention did establish a set of basic principles for the grant of intellectual property and a process by which individuals could more easily apply for patents in all of the national patent offices of the member states.<sup>9</sup> This desire for patent harmonization, both procedural and substantive, led to additional treaties and the

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<sup>1</sup> See, e.g., Andrew Beckerman-Rodau, *What Should Be Patentable - A Proposal for Determining the Existence of Statutory Subject Matter under 35 U.S.C. Section 101*, 13 WAKE FOREST J. BUS. & INTELL. PROP. L. 145 (2013).

<sup>2</sup> *About WIPO*, World Intellectual Property Organization, <http://www.wipo.int/about-wipo/en/history.html> (last visited Mar. 27, 2019).

<sup>3</sup> Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Apr. 15, 1994, 1869 U.N.T.S. 154, 33 I.L.M. 1144 [hereinafter TRIPS].

<sup>4</sup> TRIPS Art. 1.

<sup>5</sup> *Id.*

<sup>6</sup> E. Wyndham Hulme, *On the History of Patent Law in the Seventeenth and Eighteenth Centuries*, 18 L. Q. REV. 280, 280 (1902).

<sup>7</sup> MARGO A. BAGLEY, RUTH L. OKEDIJI, & JAY A. ERSTLING, *INTERNATIONAL PATENT LAW AND POLICY* 3 (1st ed. 2013)

<sup>8</sup> *Id.*

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

eventual establishment of the World Intellectual Property Organization (“WIPO”).<sup>10</sup> Although WIPO strove for the “development of a balanced and effective international intellectual property (IP) system that enables innovation and creativity for the benefit of all,”<sup>11</sup> there was a substantial conflict between what developed and developing countries viewed as “balanced and effective.”<sup>12</sup> The developed countries, faced with this conflict, decided to shift the forum of the debate to the General Agreement on Tariffs and Trade (“GATT”).<sup>13</sup> Developing countries, dependent on the access to developed countries’ markets GATT provided, acceded to this transition.<sup>14</sup> In 1986, the Uruguay Round of trade negotiations began under the aegis of GATT.<sup>15</sup>

After seven years, the Uruguay Round of trade negotiations produced TRIPS, and saw the replacement of GATT with the WTO.<sup>16</sup> TRIPS mandated minimum protection for intellectual property from the member countries of the WTO, enforced by trade sanctions.<sup>17</sup> Participation in TRIPS was incentivized by the trade benefits of joining the WTO, a powerful lure for developing countries who would otherwise have not agreed to more stringent intellectual property protections.<sup>18</sup>

TRIPS covered copyrights, patents, and trademarks and established standards. TRIPS Article 27 defines what categories of subject matter WTO member countries must grant patents on, stating:

1. Subject to the provisions of paragraphs 2 and 3, 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*. [For the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively.] Subject to paragraph 4 of Article 65 [transitional arrangement which allow developing countries to delay implementation], paragraph 8 of Article 70 [transitional structure for countries who do not initially have available pharmaceutical and agricultural chemical products patents] and paragraph 3 of this Article, patents shall be available and patent rights enjoyable

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<sup>10</sup> *About WIPO*, World Intellectual Property Organization, <http://www.wipo.int/about-wipo/en/history.html> (last visited Mar. 27, 2019).

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

<sup>12</sup> BAGLEY ET AL., *supra* note 7, at 3.

<sup>13</sup> *Id.* at 4.

<sup>14</sup> Timothy Geithner & Gobind Nankani, *Market Access for Developing Country Exports — Selected Issues* 4–7 (Sept. 26, 2002), <https://www.imf.org/external/np/pdr/ma/2002/eng/092602.pdf>.

<sup>15</sup> *The Uruguay Round*, WTO, [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact5\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm) (last visited Mar. 27, 2019).

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

<sup>17</sup> TRIPS Art. 64; *see also Historic Development of the WTO Dispute Settlement System*, WTO, [https://www.wto.org/english/tratop\\_e/dispu\\_e/disp\\_settlement\\_cbt\\_e/c2s1p1\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c2s1p1_e.htm) (last visited Mar. 27, 2019).

<sup>18</sup> Ruth L. Okediji, *The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System*, 7 SING. J. INT’L & COMP. L. 315, 323–325 (2003).

without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members *may exclude* from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members *may also exclude* from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.<sup>19</sup>

TRIPS thus has standardized how members must address the question of whether to grant a patent by setting up three general barriers to patentability: (1) is there a claim to an “invention;” (2) is that invention of a character to be “worth to the public the embarrassment of an exclusive patent;”<sup>20</sup> and (3) is that “patentable invention” subject matter in a class of inventions explicitly excluded from patentability.

Within answering the question of if there is a claim to an invention, there is one expressed hurdle to patentability: the claimed subject matter must be within an acceptable category of invention — a product or process. Different countries have nationalized this requirement slightly differently: from South Korea’s “highly advanced creation of a technical idea using the rules of nature”<sup>21</sup> to the United State’s “process, machine, manufacture, or composition of matter.”<sup>22</sup> Countries generally agree that there is some subject matter that, even if novel and nonobvious, is inherently outside what society thinks of as an “invention.” The most common example of this is the discovery of a natural law: neither the photoelectric effect nor  $E=mc^2$  could ever have been monopolized by Einstein under patent. “Such discoveries are ‘manifestations of . . . nature, free to all men and reserved exclusively to none’<sup>23</sup> and thus outside of the patent system’s reach entirely. Therefore, under TRIPS a patent cannot be denied on the basis that the subject matter is in a certain area of technology

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<sup>19</sup> TRIPS Art. 27.

<sup>20</sup> Letter from Thomas Jefferson to Isaac McPherson, (Aug. 13, 1813), (on file with the University of Chicago Law School Library), [http://presspubs.uchicago.edu/founders/documents/a1\\_8\\_8s12.html](http://presspubs.uchicago.edu/founders/documents/a1_8_8s12.html) (last visited Mar. 27, 2019).

<sup>21</sup> Patent Act, Article 2(1) (S. Kor.) <http://www.kipo.go.kr/upload/en/download/PatentAct.pdf> (last visited Mar. 27, 2019).

<sup>22</sup> 35 U.S.C. § 101 (2012).

<sup>23</sup> Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

and is therefore not an “invention.” A patent may be denied though if the claimed subject matter is not to a product or process, such as a propagating electromagnetic signal.

An important addition to these exclusions given the debate in the legal world around the intellectual property protection for computer programs:<sup>24</sup> computer programs are offered protection under copyright, and not under patent according to TRIPS.<sup>25</sup> Most countries have chosen to rule that computer programs are neither a process nor a product, and thus are not in an acceptable category of invention, rendering them not an “invention” and thus not patentable.<sup>26</sup>

Even if the claim passes the first hurdle and can thus be thought of as an “invention,” some inventions are not “patentable inventions” because the cost of granting a monopoly gains society nothing in return. To qualify as a “patentable invention, the claimed subject matter must be new, involve an inventive step (known as non-obviousness invention in American patent parlance),<sup>27</sup> and it must be capable of industrial application (the useful criteria in American patent law).<sup>28</sup> If a patent was granted on known, obvious, or non-useful inventions, society would not be getting the benefit of the bargain of the patent system, exchanging a monopoly for nothing. TRIPS recognizes this essential tradeoff and countries have nationalized these requirements in differing, albeit similar ways.

If the claimed subject matter passes the aforementioned two hurdles, it can be thought of as a “patentable invention.” However, even if there is a claim to an invention, a patent may not be issued if the invention is covered by one of the exceptions listed in TRIPS 27(2) and (3) *if* a nation chooses to incorporate them into its national law.<sup>29</sup> As a matter of public policy, some countries do not want to grant incentives for innovation into areas which are so offensive to public morality such as human cloning, or to grant monopolies on the essential life-saving skills of doctors. TRIPS thus allows national governments to exclude narrow categories of otherwise patentable inventions from patentability if the nation decides to do so. These three hurdles to patentability — invention, patentable invention, and public policy exclusions — form the baseline of intellectual property protection for all WTO countries.

TRIPS Article 27 gives countries significant flexibility in crafting their national laws to be in compliance with the three hurdles. What constitutes an inventive step? How offensive must an invention be to be denied patent protection – would a machine who’s only function was to make a farting sound count, or should the standard be set to only bar methods of brutally massacring human beings?<sup>30</sup> Is it in a country’s best interest to grant patents on animal-focused surgical methods? If so, that country may

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<sup>24</sup> See, e.g., *Alice Corp. Pty. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014); *Oracle Am., Inc. v. Google Inc.*, 750 F.3d 1339 (Fed. Cir. 2014).

<sup>25</sup> TRIPS Art. 10 (“Computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention”).

<sup>26</sup> See, e.g., USPTO, *MANUEL OF PATENT EXAMINING AND PROCEDURE* § 2106 (9th ed. 2017) (last revised Jan. 2018) [hereinafter MPEP]; *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972).

<sup>27</sup> TRIPS Art. 27.

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

<sup>29</sup> *Id.*

<sup>30</sup> Compare Japanese public morality exception to Indian public morality exception, *infra* Section III.E.1.

choose to not nationalize the exception to animal diagnostic, therapeutic, and surgical methods, but retain the exception with regards to human methods.<sup>31</sup> This voluntary nature of the exceptions has resulted in a patchwork of national laws and regulations.<sup>32</sup> In addition, although TRIPS obligates member states to have written patent laws<sup>33</sup> that meet the minimum specifications of patentability in Article 27, TRIPS does not bar higher standards of patentability so long as they are not applied in a discriminatory manner.<sup>34</sup> This results in a patchwork of standards for novelty, nonobviousness, and usefulness.<sup>35</sup> These heightened standards can be used as sources of exceptions, as a country could determine that a product that exists in nature is not novel.<sup>36</sup> This Article argues that the next multilateral intellectual property treaty should seek to harmonize these exceptions in order to promote the goal of a unified world patent system.

This Article looks at what specific technologies or categories of subject matter national patent offices have explicitly excluded from patentability. The primary sources of information used in this Article are the national manuals of patent examining procedure which serve as a unified reference of laws, legal judgments, and agency regulations. There are many claims to subject matter or inventions which may not be patentable, but this Article focuses only on those which have warranted inclusion as “expressly excluded from patentability.”<sup>37</sup> Different patent offices have chosen to provide very different levels of detail in their lists of exclusions. Despite these limitations, this paper attempts to extract some insight into “what’s in and what’s out”<sup>38</sup> and argue for harmonizing these exclusions in an attempt to move towards a unified international patent system.

The focus of this Article is on the explicitly listed exclusions to patentability in each patent office, and specifically on examples these patent offices provide to illustrate these exclusions. Unlike the standards for novelty, nonobviousness, and usefulness, explicit exclusions provide bright lines upon which a policy decision has been made. This is useful for the outside researcher because it allows for direct comparisons of subject matter across national patent offices with some definiteness, as opposed to the unsatisfying debate as to whether an invention is nonobvious under the imprecise standards of each office. This Article will leverage this definiteness to see how various patent offices draw lines in the sand for determining patentability in light of TRIPS Article 27. This bright-line approach to analysis is also useful for determining compliance, as these exceptions to patentability can be directly measured against TRIPS mandates irrespective of the actual practice of the national patent office.

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<sup>31</sup> See, e.g., Section II.D.3.

<sup>32</sup> See *infra*, Part III.

<sup>33</sup> See *India — Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO DS50 (Apr. 28, 1999), [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds50\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm).

<sup>34</sup> See TRIPS Art. 1(3).

<sup>35</sup> See *infra*, Part III.

<sup>36</sup> See *infra*, Section III.B.

<sup>37</sup> *How to Get a European Patent: Guide for Applicants*, EPO, ¶28 (18th ed. 2018), [http://documents.epo.org/projects/babylon/eponet.nsf/0/8266ED0366190630C12575E10051F40E/\\$File/how\\_to\\_get\\_a\\_european\\_patent\\_2018\\_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/8266ED0366190630C12575E10051F40E/$File/how_to_get_a_european_patent_2018_en.pdf) (last visited Mar. 27, 2019).

<sup>38</sup> Mark P. McKenna & Christopher Jon Sprigman, *What’s In, and What’s Out: How IP’s Boundary Rules Shape Innovation*, 30 HARV. J.L. & TECH. 491 (2017).

An important aside to this discussion is what constitutes compliance with international law. If the laws of the country are in compliance with TRIPS, is the country in compliance if the regulations of the patent office exclude inventions from patentability that go beyond what TRIPS allows? Is the country in compliance if the regulations of the patent office are TRIPS compliant, but the practice of the office is not? This is a deeply contested debate among academic circles,<sup>39</sup> and will not be explored in detail here. However, given the focus of this Article is on the written regulations of national patent offices, hereinafter compliance with TRIPS will be viewed as a comparison between the written mandates of TRIPS and the written regulations of each national patent office. The actual practice of patent offices in enforcing their own regulations and not going beyond the listed prohibitions to patentability is beyond the ambit of this Article.

As a matter of background, the reader should be familiar with the ideas of novelty, nonobviousness, and utility upon which many of the following exceptions are based. At the core, the patent bargain is a trade of monopoly power for disclosure of an invention to society.<sup>40</sup> In light of past instances where monopoly power was handed out as a government prerogative as a reward to backers and influencers,<sup>41</sup> nations have codified this patent bargain to include some qualifiers for what needs to be disclosed to make the monopoly worth it to society. These qualifiers are novelty, nonobviousness, and utility. They serve to narrow the field of inventions which qualify for the grant of monopoly to those society does not already have access to.<sup>42</sup> In general, novelty requires that the invention has not been made available to the public before.<sup>43</sup> Nonobviousness generally requires that, even if the invention has not been described in its claimed form or otherwise available to the public, it is not a mere trivial variation on something that is already available.<sup>44</sup> Utility generally requires that the invention have some known use that is disclosed, preventing speculative patents where monopoly is granted on some substance without the corresponding benefit to society of the knowledge of what that substance does.<sup>45</sup> Each country has nationalized these requirements for patentability slightly differently, but the general requirements are the same even if the exact level of novelty or nonobviousness required to qualify for a patent are different. These general requirements form the groundwork upon which many of the aforementioned exclusions to patentability are based, and so reference should be made to the national requirements for these categories when analyzing the exceptions.

This Article will examine the manuals of patent examining procedure from Canada, the EPO, India, Japan, South Korea, Singapore, and the United States. These countries were chosen for study for a variety of reasons: WIPO has English translations

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<sup>39</sup> See, e.g., Benedict Kingsbury, *The Concept of Compliance as a Function of Competing Conceptions of International Law*, 19 MICH. J. INT'L L. 345 (1998); Joel P. Trachtman, *International Law and Domestic Political Coalitions: The Grand Theory of Compliance with International Law*, 11 CHI. J. INT. L. 127 (2010).

<sup>40</sup> Shubha Ghosh, *Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor After Eldred*, 19 BERKELEY TECH. L.J. 1315, 1315 (2004).

<sup>41</sup> *Blackstone's Commentaries on the Laws of England*, YALE, [http://avalon.law.yale.edu/18th\\_century/blackstone\\_bk2ch21.asp](http://avalon.law.yale.edu/18th_century/blackstone_bk2ch21.asp) (last visited Mar. 27, 2019).

<sup>42</sup> WILLIAM MARTIN, *THE ENGLISH PATENT SYSTEM* 74 (1st ed. 1904).

<sup>43</sup> See, e.g., MPEP § 2131.

<sup>44</sup> See, e.g., *Id.* § 2141.

<sup>45</sup> See, e.g., *Id.* § 2107.

of their manuals of patent examining procedure,<sup>46</sup> the selected countries have detailed manuals and not more general guidelines,<sup>47</sup> and they represent a broad swath of the world within the preceding two categories. Since the EPO was studied, no manuals of patent examining procedure from its constituent countries were included in this analysis, even though there is a very interesting dynamic between the EPO and each national patent office.<sup>48</sup>

Part II of the Article details the regulations concerning exclusions of patentability from the aforementioned selection of national patent offices. Part III examines the commonalities and differences between these national regulations and compares them to the mandates of TRIPS. Part IV concludes this article with an analysis of areas of patentability still in dispute between nations, and suggests reasonable compromises in light of the trend towards a unified international patent system.

## II. NATIONAL PATENT REGULATIONS ON PATENTABILITY

### *A. Regulations of the Canadian Intellectual Property Office*

Section 12.03 of the Canadian Manual of Patent Office Practice lists nine categories of subject matter excluded from patentability.<sup>49</sup> It includes exclusions of patentability under theories that the subject matter doesn't satisfy the requirements to be an invention, that the invention is not industrially applicable, and that the invention is against public morality. It does not contain statutory exclusions under the theories of novelty or nonobviousness. Of note, Canada categorizes many of its listed exclusions under the theory of industrial inapplicability, such as the exclusion on aesthetic creations, whereas many other nations treat similar subject matter as not an invention.

#### *1. Categories of Invention*

The Canadian Manual of Patent Office Practice excludes scientific principals and abstract ideas from patentability as they are not statutory subject matter.<sup>50</sup> Subject matter that fits under this section is mathematical formulae, natural phenomena, and laws of nature. General claims to such intangible subject matter are unpatentable, but the office does not exclude claims that rely upon the idea or principal in operating a practical form of the invention.<sup>51</sup>

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<sup>46</sup> *Guidelines and Manuals of National / Regional Patent Offices*, WIPO, <http://www.wipo.int/patents/en/guidelines.html> (last visited Mar. 27, 2019).

<sup>47</sup> *See, e.g., Patents*, CZECH INDUSTRIAL PROPERTY OFFICE, <http://www.upv.cz/en/ip-rights/patents.html> (last visited Mar. 27, 2019).

<sup>48</sup> *The Unitary Patent and Unified Patent Court*, UNITED KINGDOM INTELL. PROP. OFF. (May 22, 2014), <https://www.gov.uk/guidance/the-unitary-patent-and-unified-patent-court>.

<sup>49</sup> CANADIAN INTELLECTUAL PROPERTY OFFICE, *MANUAL OF PATENT OFFICE PRACTICE* §12.03 (Can.) (2017).

<sup>50</sup> *Id.* § 12.03.01.

<sup>51</sup> *Id.*

The Canadian Intellectual Property Office also excludes forms of energy such as electromagnetic or acoustic signals from patentability on the basis that they are not inventions.<sup>52</sup> The office states that electromagnetic waves fit neither the definition of process nor the definition of a composition of matter, even though electromagnetic waves are a mode by which a physical effect is produced, the traditional definition of process.<sup>53</sup>

## 2. *Industrial Application*

Canadian patent law approaches the TRIPS criteria of Industrial Application by requiring that inventions solve a practical problem.<sup>54</sup> Inventions that do not solve a practical problem are thus not patentable in Canada.

Features of solely intellectual or aesthetic significance are not patentable inventions,<sup>55</sup> nor are printed matter generally.<sup>56</sup> This is because aesthetic features “cannot change the manner in which the practical form of an invention operates to solve the problem for which it is the solution.”<sup>57</sup> However, if a printed matter is useful in more than the aesthetic sense it is patentable,<sup>58</sup> such as printing on textiles to allow greater precision in the manufacturing process.<sup>59</sup>

Likewise, fine arts such as “exercising, dancing, acting, writing, teaching, hair dressing, cosmetology, flower arranging, painting pictures and playing musical instruments” are not patentable inventions.<sup>60</sup> Since these inventions do not solve a practical problem, they are considered outside of the scope of patentability.

Schemes, plans, rules, and mental processes are not patentable inventions.<sup>61</sup> The office states that because these categories of inventions are disembodied, they are not a practical form of invention.<sup>62</sup>

## 3. *TRIPS Article 27(2) & (3) Exclusions*

The Canadian Patent Office explicitly excludes methods of medical treatment on living humans or animals from patentability.<sup>63</sup> Any method which provides a practical therapeutic benefit to a subject is not patentable, even if this benefit is not the method’s primary or even intended purpose.<sup>64</sup> The office sets the definition of therapeutic benefit as “the method should cure, prevent or ameliorate an ailment or pathological condition,

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<sup>52</sup> *Id.* § 12.03.04.

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

<sup>54</sup> *Id.* § 9.03.

<sup>55</sup> *Id.* § 12.03.05.

<sup>56</sup> *Id.* § 12.03.06.

<sup>57</sup> *Id.* § 12.03.05.

<sup>58</sup> *Id.* § 12.03.06 (printed matter provided a new mechanical functionality to the combination).

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

<sup>60</sup> *Id.* § 12.03.07.

<sup>61</sup> *Id.* § 12.03.08.

<sup>62</sup> *Id.*

<sup>63</sup> *Id.* § 12.03.02.

<sup>64</sup> MANUAL OF PATENT OFFICE PRACTICE §12.03 (Can.) (2017).

or treat a physical abnormality or deformity such as by physiotherapy or surgery.”<sup>65</sup> Excluded from this are natural conditions, including ageing, pregnancy, baldness, and wrinkles which are not considered pathological, and thus patents on methods to treat these conditions are allowed.<sup>66</sup> All methods of surgery, therapeutic or not, are excluded. The office states that certain noninvasive methods of diagnosing a disease or medical condition either *in vitro* or *in vivo* are patentable. The Office clarifies that these methods are patentable so long as there is no secondary therapeutic benefit. Treating an animal solely to derive an economic benefit or methods for achieving a cosmetic result may not be excluded from patentability on a per se basis.<sup>67</sup>

Canada excludes higher life forms from patentability on the basis that higher life forms are not inventions,<sup>68</sup> but TRIPS allows this exclusion under Article 27(3)(b). Higher life forms are defined as multicellular life,<sup>69</sup> and are excluded from patentability because they are not compositions of matter or manufactures and so are not considered inventions.<sup>70</sup> The designation of a higher life form is applicable at any stage of development, so fertilized eggs and totipotent stem cells are excluded from patentability.<sup>71</sup> Organs and tissues are generally not patentable.<sup>72</sup> However, a cell which is not alone capable of development into an organism is not considered a higher life form, so embryonic, multipotent, and pluripotent cell lines are patentable.<sup>73</sup>

### *B. Regulations of the European Patent Office*

The European Patent Office only provides two classes of unpatentable subject matter: subject matter that does not qualify as an “invention” and subject matter that offends public morality.

#### *1. Categories of Invention*

The European Patent Office does not provide a definition for invention, but does provide a non-exhaustive list of inventions which it does not consider inventions.<sup>74</sup> Given examples are “(a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information.”<sup>75</sup>

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<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

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

<sup>68</sup> *Id.* § 12.03.03.

<sup>69</sup> *Id.* § 17.02.01.

<sup>70</sup> *Id.* § 12.03.03.

<sup>71</sup> *Id.* § 17.02.01.

<sup>72</sup> *Id.* § 17.02.02.

<sup>73</sup> *Id.*

<sup>74</sup> *How to Get a European Patent: Guide for Applicants*, EPO, ¶128 (18<sup>th</sup> ed. 2018), [http://documents.epo.org/projects/babylon/eponet.nsf/0/8266ED0366190630C12575E10051F40E/\\$File/how\\_to\\_get\\_a\\_european\\_patent\\_2018\\_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/8266ED0366190630C12575E10051F40E/$File/how_to_get_a_european_patent_2018_en.pdf) (last visited Mar. 27, 2019).

<sup>75</sup> EUROPEAN PATENT OFFICE, EUROPEAN PATENT CONVENTION Art. 52(2) (16<sup>th</sup> ed. 2016) (Eur.).

Computer programs are not regarded as inventions if claimed as such. This is immaterial to whether the program is claimed by itself, as a data medium storing system, or a part of a computer system.<sup>76</sup> However, computer programs are patentable if, when running on a computer, the program causes a further technical effect going beyond the normal physical interaction between software and hardware such as a program that serves to control a technical process or governs the operation of a technical device. This added functionality is considered sufficiently inventive to warrant a patent.

## 2. TRIPS Article 27(2) & (3) Exclusions

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods are expressly excluded from patentability.<sup>77</sup> The EPO states that this is because they do not constitute an invention,<sup>78</sup> but the EPO could have relied on TRIPS to exclude them without narrowing the definition of invention. This exclusion doesn't apply to products or compositions of matter for use in such methods.<sup>79</sup> Treatment of tissues after they have been removed and diagnostic mechanisms applied to those tissues are patentable so long as the tissue isn't returned to the same body.<sup>80</sup>

The EPO prohibits granting patents on inventions whose commercial exploitation would be contrary to public morality.<sup>81</sup> In particular, patents will not be granted on the cloning of human beings, modification of the germ line of humans, the use of human embryos for industrial or commercial purposes, or the modification of the genetic identity of animals that are likely to cause them suffering without any substantial medical benefit to man or animal.<sup>82</sup>

Plant and animal varieties and essentially biological processes for the production of plants or animals are unpatentable under utility patents.<sup>83</sup> Similar to methods of surgery, the EPO defines plant and animal varieties as not inventions,<sup>84</sup> but they are allowed to explicitly exclude them from patentability even if they had met the definition of invention. The EPO notes that plant patents are available in the national offices of contracting states, but the EPO does not issue plant patents itself.<sup>85</sup>

Sexual crossing of whole genomes, even if other technical steps relating to preparation or further treatment are present, are included in this prohibition against patents on essential biological processes.<sup>86</sup> This exclusion does not apply to microbial processes or products.<sup>87</sup> Biotechnology inventions are explicitly patentable if they

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<sup>76</sup> EUROPEAN PATENT OFFICE, EUROPEAN PATENT CONVENTION Art. 52, ¶29.

<sup>77</sup> *Id.* ¶30.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> *Id.* ¶31(a).

<sup>82</sup> *Id.*

<sup>83</sup> *Id.* ¶31.

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

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

concern biological material that is isolated from its natural environment or produced by means of a technical process even if its previously occurred in nature.<sup>88</sup>

*C. Regulations of the Indian Office of Controller General of Patents, Designs, and Trademarks*

The Indian Manual of Patent Office Practice and Procedure Section 08.03.06 lists fifteen categories of explicitly unpatentable inventions.<sup>89</sup> These enumerated categories are sometimes covered by more general doctrines of patentability in the Indian Manual of Patent Office Practice and Procedure. An example of this double-coverage is that a mere rearrangement of known components functioning independently, explicitly banned under § 08.03.06.05, would fail the Indian Patent Office's definition of nonobviousness.<sup>90</sup> Even so, the Indian patent office sees fit to list these novelty and obviousness exceptions under their enumeration of specific exceptions to patentability, and thus they will be listed here for the sake of completeness.

The Indian Office of the Controller General of Patents, Designs, and Trademarks does not characterize most of the exceptions into the TRIPS categories, but there are parallels with the categories of exceptions from countries that do characterize the exceptions. India excludes plant varieties<sup>91</sup> and the topography of integrated circuits,<sup>92</sup> but provides intellectual property protection for these inventions in other sections of its legal code.<sup>93</sup> One listed exclusion that does not neatly fit into any of the allowable TRIPS categories is India's prohibition of patents on methods of agriculture.

*1. Categories of Invention*

Frivolous claims or inventions which claim anything obviously contrary to well established laws such as perpetual motion machines are not patent eligible.<sup>94</sup> Other countries typically treat these incredible "inventions" which are not possible as not qualifying for the status of an invention.

The discovery of a scientific principal or an abstract theory or a living thing or a non-living substance occurring in nature is not patentable.<sup>95</sup> A scientific principal used in a process of manufacture does not make that process unpatentable.<sup>96</sup> Given as an example, the discovery that a material can withstand mechanical shock is an unpatentable discovery; a railway sleeper made of the material is patentable.<sup>97</sup>

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<sup>88</sup> *Id.*

<sup>89</sup> OFFICE OF CONTROLLER GENERAL OF PATENTS, DESIGNS AND TRADEMARKS, MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE, § 08.03.06 (India) (2010).

<sup>90</sup> See Definition of "Inventive Step," Manual of Patent Office Practice and Procedure § 02.02.04.

<sup>91</sup> OFFICE OF CONTROLLER GENERAL OF PATENTS, DESIGNS AND TRADEMARKS, MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE, § 08.03.06.09.

<sup>92</sup> *Id.* § 08.03.06.14.

<sup>93</sup> *Id.* §§ 08.03.06.09, 08.03.06.14.

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* § 08.03.06.03.

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

Mathematical methods, business methods, computer programs, and algorithms are ineligible for patents.<sup>98</sup> Hardware with specific computer programs may be patentable; however, a program which may work on any general-purpose computer is not patentable.<sup>99</sup>

A scheme or rule or method of performing a mental act or a method of playing a game are explicitly mentioned as unpatentable.<sup>100</sup> Given examples of such methods include a method of playing chess, a method of teaching, and a method of operating a machine as per a set of instructions.<sup>101</sup> These functions are considered as the outcome of mere mental processes and thus not inventions.<sup>102</sup>

Literary, dramatic, musical, or artistic works are all excluded from patentability.<sup>103</sup> These works fall within the purview of the Indian Copyright Act of 1957.<sup>104</sup> The Indian Office of the Controller General of Patents, Designs, and Trademarks sees fit to explicitly exclude such works from the ambit of utility patents.

The presentation of information is unpatentable in India, no matter what form this presentation takes.<sup>105</sup> Given examples of unpatentable presentations of information are railway tables, calendars, and rhythmic instructions for speeches.<sup>106</sup>

## 2. Novelty

A new form of a known substance that does not result in the enhancement of the known efficacy or the discovery of a new property or new use of a known substance is not patentable.<sup>107</sup> The Indian Office of the Controller General of Patents, Designs, and Trademarks notes that patents are not to be given on polymorphs, isomer mixtures, or complexes of known material unless the new material differs significantly in properties with regard to efficacy.<sup>108</sup> This is in contrast to the United States, where “[i]somers having the same empirical formula but different structures are not necessarily considered equivalent by chemists skilled in the art and therefore are not necessarily suggestive of each other.”<sup>109</sup> The key here is the difference in burdens: Indian patent applicants must prove different efficacy, whereas US patent applicants are given the presumption of different efficacy. The Indian Office of the Controller General of Patents, Designs, and Trademarks defines efficacy as the therapeutic effect, the “healing a disease having a good effect on the body”<sup>110</sup>

Traditional knowledge or inventions that are an aggregation or duplication of known properties of traditionally known components is unpatentable because it isn’t

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<sup>98</sup> *Id.* § 08.03.06.10.

<sup>99</sup> *Id.*

<sup>100</sup> *Id.* § 08.03.06.12.

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> *Id.* § 08.03.06.11.

<sup>104</sup> *Id.*

<sup>105</sup> *Id.* § 08.03.06.13.

<sup>106</sup> *Id.*

<sup>107</sup> *Id.* § 08.03.06.04.

<sup>108</sup> *Id.*

<sup>109</sup> MPEP § 2144.09.

<sup>110</sup> OFFICE OF CONTROLLER GENERAL OF PATENTS, DESIGNS AND TRADEMARKS, MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE § 08.03.06.04.

new knowledge.<sup>111</sup> Specific examples include the antiseptic properties of turmeric for wound healing and the pesticidal and insecticidal properties of *neem*.<sup>112</sup>

### 3. *Nonobviousness*

The Indian Office of the Controller General of Patents, Designs, and Trademarks explicitly excludes from patentability mixtures of components where the resulting properties are merely a mix of the properties of its component parts.<sup>113</sup> Mixtures of components that result in new properties, or mixtures that produce known properties in a more economical manner are explicitly acknowledged as patentable.<sup>114</sup>

The mere arrangement, rearrangement, or duplication of known devices each functioning independently is noted as unpatentable.<sup>115</sup> Such a combination must be more than a mere workshop improvement.<sup>116</sup> The juxtaposition of devices which function independently aren't patentable.<sup>117</sup> As mentioned earlier, this rearrangement would fail the Indian Office of the Controller General of Patents, Designs, and Trademarks' definition of nonobviousness absent any explicit exclusion.<sup>118</sup>

### 4. *TRIPS Article 27(2) & (3) Exclusions*

Inventions whose primary or intended use or commercial exploitation would be contrary to public order or morality, or which causes serious prejudice to human, animal, or plant life or health, or to the environment, are excluded from patenting.<sup>119</sup> Given examples of these inventions are a machine or method for committing burglary, a method for counterfeiting currency, a method for gambling, methods of adulteration of food, a method of cloning humans, and terminator gene technology.<sup>120</sup>

The Indian Office of the Controller General of Patents, Designs, and Trademarks excludes from patentability any process used for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic, or similar treatment of human beings, or the parallel treatment of animals.<sup>121</sup> Examples of excluded methods of treatment are processes of administering medicines through a dermal patch, a method of stitch-free surgical incision for cataract removal, a method of vaccination, and a method of cleaning plaque from teeth.<sup>122</sup> The application of substances to the body for purely cosmetic purposes is not within the definition of therapy, and therefore patentable.<sup>123</sup>

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<sup>111</sup> *Id.* § 08.03.06.15.

<sup>112</sup> *Id.*

<sup>113</sup> *Id.* § 08.03.06.05.

<sup>114</sup> *Id.*

<sup>115</sup> *Id.* § 08.03.06.06.

<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> See Definition of "Inventive Step," MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE § 02.02.04.

<sup>119</sup> MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE, § 08.03.06.02.

<sup>120</sup> *Id.*

<sup>121</sup> *Id.* § 08.03.06.08.

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

Diagnostic methods are unpatentable, and they are defined as prohibited if they include a deductive step of making the diagnosis and preceding steps constructive for making that diagnosis involving specific interactions of a technical nature with the human or animal body.<sup>124</sup> Therefore, general fitness tests are patentable.<sup>125</sup>

For animals, any treatment to render them free of disease or to increase their economic value is unpatentable.<sup>126</sup> Given examples of exempt methods range from methods for treating sheep for increasing wool yield, to methods of artificially inducing the increase of the body mass of poultry.<sup>127</sup>

Plants and animals in whole or in part other than microorganisms are ineligible for patent protection.<sup>128</sup> Seeds or essential biological processes for production or propagation of plants and animals are included in this prohibition. A method of manufacture of a vaccine is patentable even though the end product contains a living organism.<sup>129</sup>

### *5. Other Exclusions*

Trademarks explicitly excludes methods of agriculture and horticulture from patentability.<sup>130</sup> Examples of such excluded methods include a method for producing a new form of a known plant, a method of producing improved soil, a method of producing mushrooms, or a method for cultivation of algae.<sup>131</sup>

The Indian Patent Office will not issue utility patents on the topography of integrated circuits.<sup>132</sup> These designs are otherwise protected under the Semiconductor Integrated Circuit Lay-out Designs Act of 2000.<sup>133</sup>

### *D. Regulations of the Japan Patent Office*

The Japanese Patent Examination Guidelines deals with excluding subject matter in three distinct categories. Chapter 2.1 exempts certain subject matter from the definition of invention, Chapter 3.1 exempts specified subject matter from being considered industrially applicable, and Chapter 5.2 exempts specific subject matter from being considered patentable due to concerns of public morality.

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<sup>124</sup> MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE, § 08.03.06.08.

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

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

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

<sup>128</sup> *Id.* § 08.03.06.09.

<sup>129</sup> *Id.*

<sup>130</sup> *Id.* § 08.03.06.07.

<sup>131</sup> *Id.*

<sup>132</sup> *Id.* § 08.03.06.14.

<sup>133</sup> *Id.*

### 1. *Categories Invention*

The Japanese Patent Examination Guidelines note that a law of nature as such is not a patentable invention.<sup>134</sup> Given unpatentable inventions include the law of the preservation of energy and the law of universal gravitation.<sup>135</sup>

Mere discoveries and not creations are not considered inventions by the Japan Patent Office.<sup>136</sup> Ores, natural phenomenon, and other discoveries where the applicant “does not create any technical idea with intention” are ineligible for patent protection.<sup>137</sup> Chemical substances or microorganisms isolated artificially from their surroundings are patentable.<sup>138</sup>

Claims for inventions that are contrary to a law of nature are ineligible for patents.<sup>139</sup> Perpetual motion machines and other incredible inventions are given as examples of claims that are excluded from patentability under this section.<sup>140</sup>

Inventions where a law of nature is not utilized are unpatentable.<sup>141</sup> This exclusion includes economic laws, mathematical formula, mental activities, methods for doing business, and arbitrary arrangements such as rules for playing a game.<sup>142</sup> Computer programming languages are noted to usually be excluded from patentability, but software for causing a computer to execute a method which is statutory is patentable.<sup>143</sup> Examples of computer programs that sufficiently execute a statutory method are engine control software or software for running a polymerase chain reaction machine.<sup>144</sup>

Subject matter that is not regarded as a technical idea is not patent eligible in Japan.<sup>145</sup> Inventions which are acquired through personal experience and skill that cannot be shared with others as knowledge due to lack of objectivity, such as methods of throwing a ball, are unpatentable.<sup>146</sup> Mere presentations of information likewise generally lack a sufficient technical idea.<sup>147</sup> If technical features reside in the presentation of information, it may be patentable, such as a test pattern for use in checking the performance of a television set.<sup>148</sup>

Claims which purport to solve a problem, but it is clearly impossible to solve said problem by any means presented in the claim, are unpatentable.<sup>149</sup> A given example of this exclusion is a method of preventing volcanic eruptions by throwing neutron-absorbing metal balls into a volcano would be unpatentable because volcanic eruptions

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<sup>134</sup> JAPAN PATENT OFFICE, PATENT EXAMINATION GUIDELINES, § 2.1.1 (Japan) (Oct. 1, 2015).

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

<sup>136</sup> *Id.* § 2.1.2.

<sup>137</sup> *Id.*

<sup>138</sup> *Id.*

<sup>139</sup> *Id.* § 2.1.3.

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

<sup>141</sup> *Id.* § 2.1.4.

<sup>142</sup> *Id.*

<sup>143</sup> *Id.* § 2.2.

<sup>144</sup> *Id.*

<sup>145</sup> *Id.* § 2.1.5.

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

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

<sup>149</sup> *Id.* § 2.1.6.

are not caused by nuclear chain reactions, and thus neutron absorption would not serve to prevent eruptions.<sup>150</sup>

## 2. *Industrial Application*

Inventions which are commercially inapplicable are unpatentable.<sup>151</sup> In addition, an invention only for personal use, such as a method for smoking, is unpatentable.<sup>152</sup> Inventions which are for personal use but are still commercially applicable are patentable, for example, a method for weaving hair is patentable due to its commercial potential in the cosmetology market.<sup>153</sup> Inventions which are only for academic or experimental purposes are noted to be incapable of commercial application, and thus excluded from patentability.<sup>154</sup> Kits for scientific experiments are noted to have commercial application, and thus do not fall into this category.<sup>155</sup>

Obviously impracticable inventions are not eligible for patent protection because they cannot be applied industrially.<sup>156</sup> Even if the invention would work in theory, if the application would be absurd, it is unpatentable. For example, a method for preventing an increase of UV rays by covering the whole atmosphere with plastic film could never be applied in practice, and so is excluded from patentability.<sup>157</sup>

## 3. *TRIPS Article 27(2) & (3) Exclusions*

The Japan Patent Office classifies inventions of methods of surgery, therapy, or diagnosis of humans as unpatentable. This is due to their lack of industrial application, and not under the exception provided for in TRIPS Article 27(3).<sup>158</sup> However, animal surgery or diagnosis is patentable if humans are explicitly excluded in the patent claim.<sup>159</sup> Methods excluded for patentability under this provision include methods of implanting substitute organs, methods of preventing disease, and methods of rehabilitative therapy.<sup>160</sup> Medical devices are patentable, as are methods of extracting samples and data from the human body and methods of analyzing those samples.<sup>161</sup> Extracted samples are presumably not returned and so methods of diagnosis on them is patentable.<sup>162</sup> However, if a sample is to be returned to a human body, the claim may still be patentable if it is a method for manufacturing a medical product, material, or intermediate product made by utilizing raw material collected from a human body such as vaccine preparation or a cultured sheet of skin.

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<sup>150</sup> JAPAN PATENT OFFICE, PATENT EXAMINATION GUIDELINES, § 2.1.6.

<sup>151</sup> *Id.* § 3.2.2.

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

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

<sup>154</sup> *Id.*

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

<sup>156</sup> *Id.* § 3.1.3.

<sup>157</sup> *Id.*

<sup>158</sup> *Id.* § 3.2.1.

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

Inventions which are liable to injure public order, morality, or public health are unpatentable.<sup>163</sup> The Japan Patent Office notes that it is very cautious when applying this exception, noting that definitions of public morality can change with time.<sup>164</sup> The Office, in line with the TRIPS mandates, clearly states that an invention isn't unpatentable just because the exploitation of the invention is illegal under Japanese law.<sup>165</sup> Examples of categories of inventions that obviously injure public order and are thus unpatentable are humans themselves produced through genetic manipulation, or methods solely used to brutally massacre humans.<sup>166</sup> Poisons, explosives, and apparatuses used for punching holes in bank bills are all mentioned as patentable since they do not meet the high bar of obvious injury to public order.<sup>167</sup>

### *E. Regulations of the Korean Intellectual Property Office*

Similar to the Japanese patent system, the Korean Intellectual Property Office Patent Examination Guidelines deal with excluding subject matter in three distinct categories. Part III Chapter 4.1 exempts certain subject matter from the definition of invention,<sup>168</sup> Chapter 5.1 exempts specified subject matter from being considered industrially applicable,<sup>169</sup> and Chapter 6.1 exempts specific subject matter from being considered patentable due to concerns of public morality.<sup>170</sup>

#### *1. Categories of Invention*

An invention is defined as “a highly advanced creation of a technical idea using the rules of nature.”<sup>171</sup> A law of nature as such is not patentable because it is, but does not use a rule of nature.<sup>172</sup> Therefore, no patent could be granted on the law of conservation of energy.<sup>173</sup>

Mere discoveries and not creations are also not considered inventions, and thus not patent eligible using the same logic.<sup>174</sup> Things in nature that are isolated from their surroundings and the methods of doing so are patentable, however.<sup>175</sup>

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<sup>163</sup> JAPAN PATENT OFFICE, PATENT EXAMINATION GUIDELINES, § 5.2.

<sup>164</sup> *Id.*

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

<sup>166</sup> *Id.*

<sup>167</sup> *Id.*

<sup>168</sup> KOREAN INTELLECTUAL PROPERTY OFFICE, PATENT EXAMINATION GUIDELINES, 199 (S. Kor.) (July 2013).

<sup>169</sup> *Id.* at 205.

<sup>170</sup> *Id.* at 308.

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> *Id.*

<sup>174</sup> *Id.* § 4.1.2.

<sup>175</sup> *Id.*

Claims to inventions that are contrary to the laws of nature are unpatentable, as such claims cannot use a law of nature.<sup>176</sup> Perpetual motion machines are within this exception to patentability.<sup>177</sup>

Claims where a law of nature is not utilized at all are not considered inventions, and neither are arbitrary arrangements nor mental processes.<sup>178</sup> Economic laws, mathematical methods, and business methods all fail to utilize a law of nature, and are thus unpatentable.<sup>179</sup> The claim as a whole must utilize a law of nature – individual steps may not invoke a law of nature, but the claim may still be patentable if other parts of the invention sufficiently use laws of nature.<sup>180</sup>

A personal skill “acquired by personal practice cannot be shared with third parties as knowledge due to lack of objectivity, so it is not considered to be a statutory invention.”<sup>181</sup> A method for throwing a ball or a method of performing musical instruments are given as examples of unpatentable skills.

The mere presentation of information is unpatentable, and the presence of a technical feature does not render it patentable if the main objective of the technical feature is to present the information.<sup>182</sup> Information on a CD is therefore unpatentable, but the novel feature of raised numbers on a credit card presents a sufficient technical feature to be patentable, even though the end result is the conveyance of information.<sup>183</sup> Likewise, aesthetic creations on their own are not patentable.<sup>184</sup> However, a subjective evaluation must be made as to the technical nature of any aesthetic creation; if the creation is “achieved by technical composition or other technical means,” it is patentable.<sup>185</sup>

Computer programming language or computer programs are not patentable.<sup>186</sup> Computer programs are viewed as simply a list of orders and thus don’t constitute an invention.<sup>187</sup> However, where a computer program is specifically executed using hardware, the machine in association with the program may be patentable.<sup>188</sup>

If the outcome of an invention is not achievable or reproducible, the Korean Intellectual Property office notes that the claim is not eligible for patent protection.<sup>189</sup> This does not mean the invention must be one hundred percent reproducible, but it should not be impossible or random in its outcome.<sup>190</sup>

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<sup>176</sup> KOREAN INTELLECTUAL PROPERTY OFFICE, PATENT EXAMINATION GUIDELINES, § 4.1.3.

<sup>177</sup> *Id.*

<sup>178</sup> *Id.* § 4.1.4.

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> *Id.* § 4.1.5.

<sup>182</sup> *Id.* § 4.1.6.

<sup>183</sup> *Id.*

<sup>184</sup> *Id.* § 4.1.7.

<sup>185</sup> *Id.*

<sup>186</sup> *Id.* § 4.1.8.

<sup>187</sup> *Id.*

<sup>188</sup> *Id.*

<sup>189</sup> *Id.* § 4.1.9.

<sup>190</sup> *Id.*

Incomplete inventions are not eligible for patent protection.<sup>191</sup> If the claim lacks a concrete means to solve the problem posed, there is not an invention within the claims.<sup>192</sup>

## 2. *Novelty*

The Korean Intellectual Property Office notes only one explicit exception to patentability under the aegis of novelty: a new use of a known material is patentable as a method, but the material itself is not patentable.<sup>193</sup>

## 3. *Industrial Application*

Similar to the Japan Patent Office, inventions that cannot be commercialized are explicitly excluded from patentability.<sup>194</sup> Inventions that are only for personal use, academic, or experimental purposes are thus unpatentable.<sup>195</sup> However, if the invention covers marketable or tradable subject matter, it overcomes this bar.<sup>196</sup>

Inventions that cannot be implemented are excluded from patentability by failing the test for industrial applicability.<sup>197</sup> The Korean Intellectual Property Office uses the same example as the Japan Patent Office for illustrating this exception: an invention for preventing an increase in UV rays by covering the earth's surface with plastic film lacks industrial applicability, and is thus excluded from patentability.<sup>198</sup>

## 4. *TRIPS Article 27(2) & (3) Exclusions*

Like the Japan Patent Office, the Korean Intellectual Property Office will not grant patents on the practice of medicine because it does not have industrial application, not because of the TRIPS exception.<sup>199</sup> A method for treatment of the human body by surgery or therapy is unpatentable.<sup>200</sup> Treatments with mixed therapeutic and nontherapeutic or cosmetic effects are considered therapeutic, and thus unpatentable.<sup>201</sup> In contrast, medical devices and diagnostic methods practiced on samples removed from the human body are patentable.<sup>202</sup>

Inventions that are likely to contravene public order or morality are unpatentable.<sup>203</sup> The primary use of an invention must be to contravene public order

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<sup>191</sup> KOREAN INTELLECTUAL PROPERTY OFFICE, PATENT EXAMINATION GUIDELINES, § 4.1.10.

<sup>192</sup> *Id.*

<sup>193</sup> *Id.* § 4.1.2.

<sup>194</sup> *Id.* § 5.2.

<sup>195</sup> *Id.*

<sup>196</sup> *Id.*

<sup>197</sup> *Id.* § 5.3.

<sup>198</sup> *Id.*

<sup>199</sup> *Id.* § 5.1.

<sup>200</sup> *Id.*

<sup>201</sup> *Id.* § 5.1.

<sup>202</sup> *Id.*

<sup>203</sup> *Id.* § 6.3.1.

to be excluded from patentability; incidental immoral use, or use in a way other than the invention's original purpose, is not enough to exclude the invention from patentability.<sup>204</sup> Bingo, although used for gambling, is primarily used for entertainment, and is given as an example of an invention that, if claimed properly, is patentable.<sup>205</sup>

Inventions likely to injure public health are excluded from patentability.<sup>206</sup> Like the public morality analysis, the primary use of an invention must be to injure public health for the patent office to invoke this exception.<sup>207</sup> Examiners are directed to weigh the claimed useful benefit against the harm to public health when, in the invention accomplishing its original useful purpose, it produces a result that is harmful to public health.<sup>208</sup>

### *F. Regulations of the Singaporean Patent Office*

Singapore's Examination Guidelines for Patent Applications at the Intellectual Property Office of Singapore Chapter 8 details exclusions from patentability.<sup>209</sup> The Singaporean Patent Office has extensive guidance on how the exclusion of medical patents should be applied, and provides a good case study for the intricacies that arise in administering the prohibition on medical treatment patents.

#### *1. Categories of Invention*

The Singapore Examination Guidelines state that examiners should look at claims to determine if they are an "invention" by "identify[ing] the actual contribution which is made by the claimed subject matter, having regard to the problem to be solved, how the claimed subject matter works, and what its advantages are."<sup>210</sup>

The presentation of information is not considered an invention and is therefore unpatentable.<sup>211</sup> Functional presentations may be patentable, such as the presentation of information in a newspaper that did not obstruct folding.<sup>212</sup> The source code for software isn't patentable, as it is merely information and not a functional presentation.<sup>213</sup>

Discoveries are not inventions under Singaporean patent law.<sup>214</sup> An invention requires that a "patentee must do something more; he must make some addition, not only to knowledge, but to previously known inventions, and must so use his knowledge

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<sup>204</sup> KOREAN INTELLECTUAL PROPERTY OFFICE, PATENT EXAMINATION GUIDELINES, § 6.3.1.

<sup>205</sup> *Id.*

<sup>206</sup> *Id.* § 6.3.2.

<sup>207</sup> *Id.*

<sup>208</sup> *Id.*

<sup>209</sup> EXAMINATION GUIDELINES FOR PATENT APPLICATIONS, INTELLECTUAL PROPERTY OFFICE OF SINGAPORE, 259 (Sing.) (2017).

<sup>210</sup> *Id.* § 8.3.

<sup>211</sup> *Id.* § 8.27.

<sup>212</sup> *Id.*

<sup>213</sup> *Id.*

<sup>214</sup> *Id.* § 8.9.

and ingenuity as to produce either a new and useful thing or result, or a new and useful method of producing an old thing or result.”<sup>215</sup> The discovery of a new property of a material is specifically mentioned as unpatentable, but if the property results in a new use, that use may be patentable because the new use is “something more,” and thus properly an invention.<sup>216</sup>

Natural products are considered discoveries and thus not eligible for patent protection.<sup>217</sup> Materials and microorganisms found in nature aren’t patentable, even if isolated and purified.<sup>218</sup> Uses of the purified materials may be patentable, though.<sup>219</sup> In addition, modifications from the natural form in order to make the natural product more suitable to some use may make the material or organism patentable.<sup>220</sup> Claims directed towards processes that exist in nature are not allowed, but a claim to a specific use of such a process is allowed.<sup>221</sup> For example, the process of producing a beverage by digesting milk using natural proteases is patentable, even if the claim to the process of digesting milk using natural proteases isn’t.<sup>222</sup>

DNA is explicitly noted as an exception to patentability, as its value is only in the information encoded, and deviation from the natural product may represent no more than a chemical curiosity.<sup>223</sup> The resulting protein is also not patentable, as it is a product of nature. However, the process of making the protein is patentable.<sup>224</sup>

Scientific theories and mathematical models are noted to not be inventions.<sup>225</sup> The use of such a theory, if done in a novel, nonobvious, and industrially applicable way, is explicitly patentable, however;<sup>226</sup> reciting the theory and stating “apply it” does not constitute the use of the theory.<sup>227</sup> Therefore, the theory of relativity is not patentable, but the global positioning system which relies on the theory of relativity is patentable.<sup>228</sup>

Aesthetic creations, literary, dramatic, musical, and artistic works are noted to not be inventions, whether they be the mental processes to produce such works or the physical embodiments of the works.<sup>229</sup> Designs which import some function may be patentable, such as improved non-slip patterning.<sup>230</sup>

Schemes, rules, or methods for performing a mental act, playing a game, or doing business are explicitly not considered inventions.<sup>231</sup> These excluded categories include

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<sup>215</sup> EXAMINATION GUIDELINES FOR PATENT APPLICATIONS, INTELLECTUAL PROPERTY OFFICE OF SINGAPORE, § 8.9.

<sup>216</sup> *Id.* § 8.10.

<sup>217</sup> *Id.* § 8.14.

<sup>218</sup> *Id.* § 8.12.

<sup>219</sup> *Id.*

<sup>220</sup> *Id.* § 8.14.

<sup>221</sup> *Id.* § 8.15.

<sup>222</sup> *Id.*

<sup>223</sup> *Id.* § 8.15.

<sup>224</sup> *Id.*

<sup>225</sup> *Id.* § 8.17.

<sup>226</sup> *Id.* § 8.19.

<sup>227</sup> *Id.* § 8.21.

<sup>228</sup> *Id.* § 8.18.

<sup>229</sup> *Id.* § 8.22.

<sup>230</sup> *Id.* § 8.23.

<sup>231</sup> *Id.* § 8.25.

teaching methods and methods for design, but a method for design plus a manufacturing step may be patentable.<sup>232</sup>

## 2. *Nonobviousness*

The mere combination of isolated and purified natural products with known materials does not grant patentability unless the combination goes beyond just putting the combination together, and results in a specific useful application.<sup>233</sup>

## 3. *Industrial Application*

A claim to subject matter that is contrary to established physical laws is unpatentable.<sup>234</sup> Perpetual motion machines have no industrial applicability, and so are excluded from patentability.<sup>235</sup>

## 4. *TRIPS Article 27(2) & (3) Exclusions*

Singapore has a very detailed explanation of exceptions under the patentability exclusion for medical use. Methods of medical treatment practiced on the human or animal body are excluded from patentability under the rationale that they are not industrially applicable.<sup>236</sup> All methods of therapy are excluded from patentability, including preventative treatment, vaccines, any methods to alleviate disease symptoms, any curative treatment, and any veterinary treatment of a diseased or injured animal, including prophylactic and immunotherapeutic treatment.<sup>237</sup> If it is possible to establish a direct link between the method and the disease being cured, prevented, or alleviated under either western medical standards or traditional Chinese medicine, the method is expressly excluded from patentability.<sup>238</sup> Methods that result in the death of the subject, such as the given example of a method for the sacrifice of laboratory animals, are patentable because they are not therapeutic.<sup>239</sup> Dual-use technologies can be patented so long as the claim doesn't encompass therapeutic use.<sup>240</sup> Thus, The Intellectual Property Office of Singapore gives the example of using a certain molecule to prevent the coagulation of blood would not be allowed due to the therapeutic uses of the molecule, but if the claim was restricted to the use of the molecule to prevent the coagulation of blood for storage or collection in a blood bank,

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<sup>232</sup> EXAMINATION GUIDELINES FOR PATENT APPLICATIONS, INTELLECTUAL PROPERTY OFFICE OF SINGAPORE, § 8.26.

<sup>233</sup> *Id.* § 8.14.

<sup>234</sup> *Id.* § 8.31.

<sup>235</sup> *Id.*

<sup>236</sup> *Id.* § 8.33.

<sup>237</sup> *Id.* § 8.37.

<sup>238</sup> *Id.* § 8.38.

<sup>239</sup> *Id.* § 8.49.

<sup>240</sup> *Id.* § 8.44.

the claim would be allowed.<sup>241</sup> Methods of abortion are noted as explicitly unpatentable under the aegis of medical treatment, not on public policy grounds, even though methods of abortion do not fall within the definition of therapy used for the rest of the section.<sup>242</sup>

Singapore has special statutory provisions for first and second medical use of compositions of matter to allow patents for methods using known compounds for therapeutic purposes.<sup>243</sup> These provisions allow for both composition and method patents for pharmaceuticals when the method patents would be otherwise barred by the blanket ban on patents on therapies.

Methods of surgery on humans or animals are explicitly not patentable.<sup>244</sup> To qualify as a method of surgery, the claim must cover the kind of interventions which represent the core of the medical profession's activities.<sup>245</sup> Method for cosmetic ear piercing or a method of tattooing are patentable because they do not require the application of medical skill or knowledge.<sup>246</sup> The treatment of samples after they have been removed from the body and won't be returned to the same body is patentable;<sup>247</sup> dialysis is not patentable because the blood is returned to the same body.<sup>248</sup>

Methods to increase the economic value of livestock through increased meat, eggs, milk, or other improvements may be patentable.<sup>249</sup> However, these claims must be limited to non-therapeutic uses to be patentable.<sup>250</sup> If the increased meat yield comes either as a direct result of increased health because of the therapeutic use of the method, or there is an incidental therapeutic use, the claim is unpatentable.<sup>251</sup>

Diagnostic methods practiced on the human or animal body are unpatentable.<sup>252</sup> The Intellectual Property Office of Singapore defines diagnosis as four steps leading toward the identification of a condition:

1. The examination and collection of data;
2. Comparison of the data with normal values;
3. Recording any deviation from the norm; and finally,
4. Attributing the deviation to a particular clinical picture.<sup>253</sup>

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<sup>241</sup> EXAMINATION GUIDELINES FOR PATENT APPLICATIONS, INTELLECTUAL PROPERTY OFFICE OF SINGAPORE, § 8.84

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

<sup>243</sup> *Id.* § 8.111.

<sup>244</sup> *Id.* § 8.33.

<sup>245</sup> *Id.* § 8.52.

<sup>246</sup> *Id.* § 8.53.

<sup>247</sup> *Id.* § 8.91.

<sup>248</sup> *Id.* § 8.90.

<sup>249</sup> *Id.* § 8.72.

<sup>250</sup> *Id.*

<sup>251</sup> *Id.* §§ 8.73, 8.74.

<sup>252</sup> *Id.* § 8.92.

<sup>253</sup> *Id.* § 8.93.

Any method that accomplishes these steps is unpatentable.<sup>254</sup> However, the Intellectual Property Office of Singapore notes that if a diagnostic method is carried out on a dead human or dead animal body, it is patentable.<sup>255</sup> Fitness tests and other methods for determining general health, but not a specific pathological condition, are patentable.<sup>256</sup>

Singapore bans the patenting of morally objectionable claims.<sup>257</sup> Claims may be rejected as morally objectionable if they encompass one of the prohibited activities of the Human Cloning and Other Prohibited Practices Act (“HCOPPA”),<sup>258</sup> or the Human Biological Research Act (“HBRA”).<sup>259</sup> These laws prohibit on ethical grounds the cloning of humans or the development of a human embryo outside of a woman for more than fourteen days, among other acts relating to the treatment of human embryos.<sup>260</sup> Claims to methods of producing human stem cell lines are generally allowable,<sup>261</sup> as are claims to genetically modified organisms or transgenic organisms.<sup>262</sup>

### *G. Regulations of the United States Patent and Trademark Office*

United States patent law subject matter eligibility is codified in 35 U.S.C. § 101, and gives inventors of “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, [the right to] obtain a patent therefor, subject to the conditions and requirements of this title.”<sup>263</sup> Compared to the other patent regulations analyzed so far, the United States has very few explicit exceptions to patentability.

#### *1. Categories of Invention*

The United States Patent and Trademark Office (“USPTO”) Manual of Patent Examining Procedure Section 2104 outlines how the USPTO deals with the question of what constitutes an invention.<sup>264</sup> The USPTO uses a two-step procedure: first, is the claim directed towards one of the categories of statutory exceptions; second is the claim directed towards one of judicially recognized exceptions to patentability.<sup>265</sup>

The four statutory categories are process, machine, manufacture, and composition of matter.<sup>266</sup> A process is an act or series of steps.<sup>267</sup> A machine is “a concrete thing,

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<sup>254</sup> EXAMINATION GUIDELINES FOR PATENT APPLICATIONS (Sing.) § 8.94.

<sup>255</sup> *Id.* § 8.95.

<sup>256</sup> *Id.* § 8.108.

<sup>257</sup> *Id.* § 8.185.

<sup>258</sup> *Id.* § 8.194.

<sup>259</sup> *Id.* § 8.200.

<sup>260</sup> *Id.* § 8.198.

<sup>261</sup> *Id.* § 8.199.

<sup>262</sup> *Id.* § 8.203.

<sup>263</sup> 35 U.S.C. §101 (2012).

<sup>264</sup> MPEP § 2104.

<sup>265</sup> *Id.*

<sup>266</sup> MPEP § 2106; 35 U.S.C. § 101.

<sup>267</sup> MPEP § 2016; *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972).

consisting of parts, or of certain devices and combination of devices.<sup>268</sup> A manufacture is “an article produced from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand labor or by machinery.”<sup>269</sup> Finally, a composition of matter is “all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids, for example.”<sup>270</sup> Examples of subject matter that, without more, is outside these four defined categories are propagating electromagnetic signals, a legal contractual agreement, a computer program, and an arrangement of printed matter.<sup>271</sup>

If the claim fits into one of the statutory categories, a patent may not be issued if the subject matter wholly embraces a judicial exception without adding significantly more.<sup>272</sup> The judicial exceptions include laws of nature, natural phenomenon, abstract ideas, scientific principles, mental processes, and disembodied mathematical algorithms and formulas.<sup>273</sup> The judiciary has theorized that such “manifestations of laws of nature’ are ‘part of the storehouse of knowledge,’ ‘free to all men and reserved exclusively to none.’”<sup>274</sup> Therefore, both a mineral found in the earth and  $E=mc^2$  are not inventions under United States patent law. Until recently, the USPTO recognized isolated and purified natural products as inventions, but this has been overturned by *Association for Molecular Pathology v. Myriad Genetics*,<sup>275</sup> which held that DNA isolated and purified is unpatentable as a product of nature.<sup>276</sup> The USPTO has extended this reasoning to hold all natural products are unpatentable even if isolated and purified without a showing of markedly different properties from the natural form.<sup>277</sup>

## 2. Industrial Application

The United States uses the term “useful” to describe the necessity of industrial application for inventions, and explains the requirements for utility in Section 2107.<sup>278</sup> The USPTO requires that a claim have specific and substantial utility to be patentable.<sup>279</sup> Specific utility means a present definite use for the invention and substantial utility means it has a real world use.<sup>280</sup> Examples of inventions which fail this test are methods for treating an unspecified disease, or an intermediate molecule

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<sup>268</sup> MPEP § 2106; *Burr v. Duryee*, 68 U.S. (1 Wall.) 531, 570 (1864).

<sup>269</sup> MPEP § 2106; *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>270</sup> MPEP § 2106; *Chakrabarty*, 447 U.S. at 308.

<sup>271</sup> MPEP § 2106 (2018).

<sup>272</sup> MPEP § 2106; *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014).

<sup>273</sup> MPEP § 2106; *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 218 (2014).

<sup>274</sup> MPEP § 2106; *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

<sup>275</sup> MPEP § 2106.

<sup>276</sup> *Id.*

<sup>277</sup> Memorandum from Robert W. Bahr, Deputy Commissioner, United States Patent and Trademark Office, to Patent Examining Corps on Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant’s Response to a Subject Matter Eligibility Rejection (May 4, 2016) (on file with the USPTO).

<sup>278</sup> MPEP § 2107.

<sup>279</sup> *Id.*

<sup>280</sup> *Id.*

in a chemical synthesis with no use except to get to the end product.<sup>281</sup> Inventions asserting utility for the treatment of human or animal disorders must identify some specific usefulness by identifying any pharmacological activity to pass this bar.<sup>282</sup>

The USPTO will not issue a patent for wholly inoperative inventions, inventions that claim incredible utility, or to inventions which contravene laws of nature.<sup>283</sup> Therefore, no patents will be issued to perpetual motion machines.<sup>284</sup>

### 3. TRIPS Article 27(2) & (3) Exclusions

The Leahy-Smith America Invents Act (“AIA”) changed United States patent law to exempt human organisms from patentability.<sup>285</sup> The USPTO had until the AIA issue patents on human genes,<sup>286</sup> human stem cells, and transgenic animals, but had not issued patents on claims directed towards human embryos, fetuses, or human organisms.<sup>287</sup> This change in law codified the existing practice and the USPTO continues to issue patents on stem cells and transgenic animals.

## III. COMMONALITIES AND DIFFERENCES IN NATIONAL PATENTABILITY EXCEPTIONS

### A. Categories of Invention

Patent offices the world over have come to a somewhat unified understanding of what exclusions there should be in order to define categories of invention. Generally, discoveries, scientific principles, and mathematical equations are explicitly excluded from patentability. These exclusions reflect the idea that the patent monopoly should not be used to preclude the use of the foundational building blocks of innovation. If a scientist discovers a new principal of physics, they must bring some concrete benefit to society in the form of a tangible invention using the new principal in order to be rewarded for their discovery. Likewise, purely mental processes are excluded from patentability by most patent offices because they are the “basic tools of scientific and technological work.”<sup>288</sup>

The fine arts are excluded from the definition of an invention, either explicitly or implicitly, save for Canada, where they are seen as industrially inapplicable.<sup>289</sup>

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<sup>281</sup> MPEP § 2107.01.

<sup>282</sup> MPEP § 2107.03.

<sup>283</sup> MPEP § 2107.01.

<sup>284</sup> *Id.*

<sup>285</sup> MPEP § 2105; Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).

<sup>286</sup> *But see* Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 590-591 (2013).

<sup>287</sup> MPEP § 2105; 157 CONG. REC. E1177-04, E1180 (daily ed. June 23, 2011) (testimony of Representative Dave Weldon previously presented in connection with the Consolidated Appropriations Act, 2004, Public Law 108-199, 634, 118 Stat. 3, 101, (later resubmitted with regard to the AIA); see 149 Cong. Rec. E2417-01).

<sup>288</sup> Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

<sup>289</sup> CANADIAN INTELLECTUAL PROPERTY OFFICE, MANUAL OF PATENT OFFICE PRACTICE §12.03.07 (Can.) (2017).

Inventing, although creative work, is thought to require different incentives than the pure creative exercise of artists.<sup>290</sup> The goal of a patent system is to encourage repeated innovation, which requires building on the ideas and implementations of previous inventions.<sup>291</sup> This iterative process requires different incentives to function correctly than the fine arts, which are given protection suited to the needs of fostering the arts under the auspices of copyright law.<sup>292</sup>

Computer systems untethered to specific machines or processes are generally considered to be a mere list of orders or instructions untethered from an inventive activity and so not offered patent protection.<sup>293</sup> As TRIPS notes, computer programs can be covered by copyright,<sup>294</sup> in recognition of the creative nature of writing the program. Because artful claim drafting can fit a claim for a computer program into the requirements for a process claim, most countries have explicitly excluded computer programs from patentability.

Frivolous or incredible inventions are the final, generally-accepted exclusions from patentability. Perpetual motion machines or claims to compounds that cure death are so outside the bounds of what is considered scientifically plausible that they do not fulfill the patent bargain of disclosing new innovations. Additionally, patent offices don't want to spend the resources dealing with a deluge of spurious inventions and so have a blanketed prohibition against this kind of subject matter.<sup>295</sup> Some countries deal with these incredible inventions by ruling that they lack industrial applicability instead of saying that they are not inventions, but the end result is the same.

In contrast to these agreed-upon norms, countries have come do different conclusions to the question of if a skill is patentable. South Korea and Japan both explicitly exclude skill acquired through personal experience.<sup>296</sup> They hold that personal skill lacks a sufficient technical idea to render it an "invention." These countries feel that describing a better method of throwing a ball is of insufficient importance to give a patent monopoly. Other countries do not attach a specific minimum technical requirement to qualify for inventions, and so methods relating to personal skill are inventions.<sup>297</sup>

### *B. Novelty*

Countries have very few listed specific exceptions to the requirements of novelty. India and South Korea list specific exceptions that are covered in more general terms in other country's patent laws.<sup>298</sup> The requirements of novelty dictate the claim not

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<sup>290</sup> *What is Intellectual Property*, WIPO, [http://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo\\_pub\\_450.pdf](http://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo_pub_450.pdf) (last visited Mar. 27, 2019).

<sup>291</sup> Suzanne Scotchmer & Jerry Green, *Novelty and Disclosure in Patent Law*, 21 RAND J. ECON. 131, 133 (1990).

<sup>292</sup> *Id.*

<sup>293</sup> See *supra* Part II.E.1.

<sup>294</sup> TRIPS Art. 10.

<sup>295</sup> Gene Quinn, *The Patent Law of Perpetual Motion*, IPWATCHDOG, <http://www.ipwatchdog.com/2011/10/11/the-patent-law-of-perpetual-motion/id=19828/> (last visited Mar. 27, 2019).

<sup>296</sup> See *supra* Part II.D.2, Part II.E.1.

<sup>297</sup> U.S. Patent No. 5,280,906 (issued Jan. 25, 1992).

<sup>298</sup> See *supra* Part II.C.2.

cover things already available to the public. Therefore, as the exceptions that Japan and South Korea list point out, a new use of a known material is patentable, even if the material itself is not patentable again.

The EPO,<sup>299</sup> Japan,<sup>300</sup> and South Korea<sup>301</sup> all allow patents on isolated and purified natural products, even if the chemical structure of the product is identical to that which exists in nature. Until recently the United States also recognized this isolated and purified exception to the novelty rule on the basis that even if the chemical structure is not novel, the isolated and purified form of it was a novel state and thus worthy of patent protection.<sup>302</sup> Furthermore, it was worth the cost to society of a patent grant to incentivize research into compounds from the natural world, and so this less-strict application of the novelty requirement was acceptable. Due to the Supreme Court's recent ruling in *Association for Molecular Pathology v. Myriad*,<sup>303</sup> the United States has joined Singapore in excluding isolated and purified natural products from patentability.

India is the only country to specifically exclude traditional knowledge from patentability due to it not being novel. Traditional knowledge may be excluded from patenting under novelty considerations if the claim is entirely known, but India specifies this as a listed exemption to patentability. The implications of traditional knowledge on patentability have been a topic at WIPO, and WIPO has cautioned against granting patents that are not novel or nonobvious in light of traditional knowledge.<sup>304</sup>

### C. Nonobviousness

Similar to novelty, countries have very few listed specific exceptions to the requirements of nonobviousness, and those that are listed are generally covered by other countries' more general nonobviousness rules. For example, India specifically exempts combinations of components or independent machines where the resulting properties do not produce results that are different than an admixture of the components. This is the same result that would be obtained by applying the rules of nonobviousness to the situation in other countries absent a specific exclusion.<sup>305</sup> Singapore includes an exclusion for a mixture containing isolated and purified natural products that similarly fits within the purview of obviousness analysis in other countries. Isolated and purified natural products are not patentable in Singapore, and the Singaporean patent regulations exclude a mixture of natural product with non-

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<sup>299</sup> See *supra* Part II.B.2.

<sup>300</sup> See *supra* Part II.D.1.

<sup>301</sup> See *supra* Part II.E.1

<sup>302</sup> See *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911).

<sup>303</sup> *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 596 (2013).

<sup>304</sup> *Recognition of Traditional Knowledge within the Patent System, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore*, WIPO (Sept. 18, 2008), [https://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_13/wipo\\_grtkf\\_ic\\_13\\_7.pdf](https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_13/wipo_grtkf_ic_13_7.pdf).

<sup>305</sup> See MPEP § 2144.06.

natural materials from patentability unless the admixture produces some result besides that which would be expected from the combination of the components.<sup>306</sup>

#### *D. Industrial Application*

In the patent bargain, there must be some exchange for the patent monopoly, some benefit that the invention can bring to the public. This fundamental requirement is seen in the limited exceptions the studied nations give to the requirement of usefulness or industrial applicability. However, the theories that countries use to obtain this balance are vastly different in background. These different backgrounds mean that if the standard of industrial applicability is applied with rigor, there could be vastly different outcomes for the same invention. In practice, countries maintain the industrial applicability standard as a very low bar,<sup>307</sup> so only edge cases provide different outcomes for patentability analysis. However, there is one edge case that bears examination: must the invention be commercializable?

Canada rejects inventions that do not solve a practical problem as industrially inapplicable. This is in contrast to Japan and South Korea, who reject inventions that are commercially inapplicable, and the United States, which rejects inventions that do not have specific and substantial utility. How these different philosophies manifest is evident in the exceptions to patentability each country lists.

As Canada is looking for the solution to a practical problem, inventions which are merely incidental to solving a problem, such as a novel aesthetic feature on a machine that does not impact the functioning of the machine, are listed as specific exclusions to patentability. This approach blends the analysis of categories of invention and industrial applicability together by holding these disembodied improvements to something other than solving a problem are inventions, just not patentable inventions. The typical definition of invention involves solving a problem, and so this blended approach to industrial applicability can be viewed as more of a restatement of the categories of inventions.

Canada's blended invention-industrial applicability approach is similar to the United States' approach, where the invention must have specific and substantial utility. Like Canada, a patentable invention in the United States must identify something that the invention is doing, some problem it is solving. This requires that the applicant identify some present real-world problem (satisfying substantial utility) and make a claim that the invention is remedying it (satisfying specific utility). Therefore, as the United States Manual of Patent Examining Procedure points out, a patent can't be granted on a molecule to be used as a drug without identifying what condition the molecule is supposed to ameliorate. These standards, although worded differently and illustrated with different exclusions, are merely an extension of the question of what is an "invention," and, as such, both countries come to similar conclusions on patentability.

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<sup>306</sup> INTELLECTUAL PROPERTY OFFICE OF SINGAPORE, EXAMINATION GUIDELINES FOR PATENT APPLICATIONS, § 8.31 (Sing.) (2017).

<sup>307</sup> See, e.g., Julie Desrosiers & Michael Shortt, *Supreme Court Rejects the "Promise of the Patent" Redefines Canada's Patent Utility Requirement*, FASKEN, <https://www.fasken.com/en/knowledgehub/2017/07/intellectualpropertybulletin-20170704> (last visited Mar. 27, 2019).

India lists no specific examples of inventions that are unpatentable due to industrial applicability, but does require that the invention “is capable of being made or used in an industry.”<sup>308</sup> The Indian Patent Office takes a stance on industrial applicability similar to the United States: a general statement that the compound “may be useful in treating unspecified disorders, or that the compound has ‘useful biological’ properties”<sup>309</sup> is insufficient industrial applicability, but if *some* use is identified, the patent office will not reject the claim on these grounds. Singapore takes a nearly identical tact to India but lists the specific example of perpetual motion machines as lacking industrial applicability.

In contrast to Canada, the United States, India, and Singapore, Japan and South Korea require inventions to be commercializable. This is expressed in the listed exceptions: inventions which are only for personal use, academic use, or experimental purposes are unpatentable. This definition extends industrial applicability beyond a refinement of defining an invention but mandates that an invention must be useful in commerce. Therefore, inventions which pass the utility bar in the United States may not fulfill the requirements for industrial applicability in Japan and South Korea.<sup>310</sup> An invention that may fall foul of this industrial application requirement would be a transgenic mouse useful for research into neurotransmitter properties in humans.<sup>311</sup> The applicant must argue that there is some industrial application to this mouse outside of the research context, a bar that would be hard to surmount.

An interesting view into the interplay of the standard for invention and patentability is seen in how Canada and Japan handle cosmetology. Canada says explicitly that methods of cosmetology are not inventions, and thus not patentable because they are a fine art. Canada therefore does not reach the question of if advances in cosmetology are the solution to practical problems. Japan, on the other hand, does not have an express prohibition on inventions in the fine arts, and expressly allows patents on cosmetology methods such as a method of weaving hair due to its applicability in the beauty industry, which Japan sees as sufficient commercial application.

In interpreting the requirement for industrial applicability, two camps have developed. One, composed of Canada, the United States, India, and Singapore, has a very low standard of industrial applicability, using this criterion as a second check on categories of invention. Japan and South Korea treat industrial applicability as an actual requirement, mandating a showing of commercializability that far exceeds anything other countries ask for. Japan and South Korea thus don’t provide public incentives for research into technologies that do not bring profit but may bring other benefits to society, such as research tools; on the other hand if these technologies are developed, Japan and South Korea allow for more widespread dissemination due to the lack of patent protection. However, if it turns out there is later discovered a commercial use, the initial inventor cannot capture the benefit of that development. This approach is in contrast to the United States’ approach, which allows patents on research tools

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<sup>308</sup> THE OFFICE OF CONTROLLER GENERAL OF PATENTS, DESIGNS, AND TRADEMARKS, MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE, § 08.03.04 (India) (2010).

<sup>309</sup> MPEP § 2107.01.

<sup>310</sup> Jay Erstling, *Korea’s Patent Policy and Its Impact on Economic Development: A Model for Emerging Countries?*, 11 SAN DIEGO INT. L.J. 441, 450 (2010).

<sup>311</sup> See, e.g., U.S. Patent No. 5,932,780 (issued Aug. 3, 1999).

but has a relatively liberal experimental use exception to patent infringement.<sup>312</sup> This allows the inventor to capture the benefit of their invention commercial activity, even if it is unknown at the time of application, without precluding basic research. In the United States, the inventor of a currently commercially useless invention must make the decision of if the patent office fees are worth the chance to capture future commercial uses; in Japan and South Korea the inventor has this choice made for them, and is thus incentivized to maintain the invention as a trade secret until a commercial use is found. This model of granting patents on commercially inapplicable inventions, coupled with a liberal experimental use exception, would give inventors the agency to decide if the benefits of farsighted research outweigh the costs, and thus spur speculative innovation more broadly into technology that is currently commercially inapplicable and promote earlier disclosure to the public, compared to a system where the inventor must find a commercial application themselves before a patent could be granted.

### *E. TRIPS Article 27(2) & (3) Exclusions*

#### *1. Public Morality*

Most countries studied in this Article have some patentability exception for public morality, but the scope of the exception differs significantly. Canada lacks any sort of exception for inventions which offend public morality. Some of the most likely inventions to offend, such as patents on transgenic humans, human embryos, or human fetuses, are covered by Canada's prohibition on patenting higher life forms. Patents on embryonic stem cell lines, and methods of producing them, are mentioned as statutory subject matter, and are patentable in Canada. The United States does not have a statutory prohibition against patenting higher life forms, but does have an explicit prohibition on issuing patents for human embryos, fetuses, or organisms. There is no prohibition on patenting human stem cells. Likewise, Singapore bans the patenting of humans and human cloning, but does so by prohibiting on ethical grounds any conduct that is prohibited by two other national laws about human biological research. Therefore, with regard to patents on humans in any stage of development, Canada, the United States, and Singapore achieve generally the same result by different means.

The Japanese Patent Office has a broader prohibition on patents for amoral inventions, but cautions that it is to be applied sparingly, and not just because the invention is illegal to use under Japanese law. In addition to the prohibitions on humans that Canada and the United States enforce, Japan also will not issue a patent on methods whose only purpose is to harm, such as a method to brutally massacre humans. The EPO has similar statutory language as Japan, but takes a broader stance on the prohibition of issuing patent on public morality grounds. EPO regulations prohibit patenting inventions whose commercial exploitation would be harmful to

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<sup>312</sup> Ted Hagelin, *The Experimental Use Exceptions to Patent Infringement*, NYSTAR RESEARCH REPORT (Sept. 2008), <http://nysstlc.syr.edu/wp-content/uploads/2014/09/NYSTAR-The-Experimental-Use-Exemptions-to-Patent-Infringement-Fall-2005.pdf>.

public morality, such as methods of cloning human beings or the use of human embryos for commercial purposes.

The South Korean Patent Office excludes more inventions from patentability than the EPO. Incidental amoral use isn't a bar, but South Korea would ban an invention if the invention's intended use was gambling. Given the examples the EPO provided for unpatentable amoral inventions, South Korea's ban on inventions for gambling is likely a lower bar than the EPO would invoke.

India has the most expansive nationalization of TRIPS Article 27(2), incorporating it verbatim into its national regulations. It also lists the most expansive roster of examples of prohibited inventions, from burglary tools to terminator gene technology. The inclusion of terminator gene technology, a method by which farmers are required to re-buy genetically modified seeds from the manufacturer instead of replanting them, is unique to India. There is significant debate about the ethics of terminator gene technology, especially when applied to food crops,<sup>313</sup> but the prohibition on granting a patent does not otherwise outlaw the technology, which in the end may make it more widespread in India. Interestingly, given India's broad prohibitions, there are no concrete examples of innovations that are unpatentable due to their harm the environment.

## 2. *Diagnostic, Therapeutic, or Surgical Methods*

All countries studied exclude from patentability, either de facto or de jure, patents on medical treatment of humans, although the scope of this prohibition varies. The United States has the most permissive regime, having no exceptions to the granting of patents on diagnostic, therapeutic, or surgical methods. However, 35 USC 287(c) immunizes health care professionals and related institutions from infringement of patents for medical or surgical (but not diagnostic) activities.<sup>314</sup> Therefore, patents on medical techniques on humans do not grant a monopoly because they give no ability to restrain infringement by the only users of the methods on humans. Thus, although the United States does not have a ban on granting patents on medical methods for humans, it has a de facto ban because of their uselessness as a monopoly for the inventor.

Canada excludes methods of therapy or surgery on living humans from patentability, but does not ban patents on methods of diagnosis. This is in contrast to the EPO, Japan, South Korea, India, and Singapore, who ban patents on diagnostic, therapeutic, and surgical methods. The EPO bases these exclusions on the notion that medical methods are not inventions, while Japan, South Korea, and Singapore state that such methods are not industrially applicable, and thus unpatentable. The end result of this logic though is virtually identical: methods to "cure, prevent or ameliorate an ailment or pathological condition, or treat a physical abnormality or deformity"<sup>315</sup>

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<sup>313</sup> *What's the Controversy over GMOs and "Terminator" Seeds?*, GENETIC LITERACY PROJECT, <https://gmo.geneticliteracyproject.org/FAQ/whats-controversy-gmos-terminator-seeds/> (last visited Mar. 27, 2019).

<sup>314</sup> Kevin E. Noonan, *Do Diagnostic Method Claims Fall under the Safe Harbor of 35 U.S.C. § 287(c)?*, PATENTDOCS (Apr. 11, 2012, 11:07 PM), <http://www.patentdocs.org/2012/04/do-diagnostic-method-claims-fall-under-the-safe-harbor-of-35-usc-287c.html>.

<sup>315</sup> CANADIAN INTELLECTUAL PROPERTY OFFICE, MANUAL OF PATENT OFFICE PRACTICE §17.03.01 (Can.) (2017).

are all outside of the scope of patent protection. Canada explicitly allows methods of treatment for non-pathological conditions, such as aging and hair loss, and although the EPO is not explicit in its allowance of such methods, has issued patents for methods of treatment of non-pathological conditions.<sup>316</sup>

Despite disparate implementation measures and levels of detail on what exactly counts as a method of therapy or surgery, the countries this Article studied are uniform in their prohibition on patents on human medical methods. The United States and Canada are unique among the countries studied in granting enforceable patents on medical diagnostic testing methods for humans, although there is some public and legal debate on whether this practice should continue.<sup>317</sup> Although this debate could go either way, the policy rationales behind banning therapeutic and surgical patents seem to extend neatly to cover diagnostic methods, as innovations in diagnostic methods “do not require the midwifery of patent law.”<sup>318</sup> Therefore this Article argues that, in the production of a new Article 27, diagnostic methods should join therapeutic and surgical methods as unpatentable inventions in Canada and the United States. Although this change would not be popular with the creators of diagnostic methods, the expansion and harmonization of patent coverage in other areas throughout the world would be sufficient tradeoff for the biotechnology industry to find the trade palatable.

### 3. *Animals*

Even if a country prohibits patenting medical techniques on humans, does this ban apply to patents on those same techniques in animals? This is a more difficult policy question because there is public good that comes from increased agricultural yield, and incentivizing innovation in the livestock sector would be a use of patent policy. The countries studied in this Article have come to vastly different conclusions on this question. India takes the strictest approach, excluding methods of diagnosis, therapy, or surgery on non-humans, as well as methods that increase the economic value of animals or their products. In contrast, Canada and Singapore exclude methods of diagnosis, therapy, and surgery on animals, but hold that nontherapeutic methods of increasing livestock productivity are patentable. The EPO likewise excludes such medical methods on animals from patentability, but is silent on the issue of nontherapeutic increasing of livestock productivity.

In contrast to these countries’ regimes, Japan and South Korea state that patents on medical methods animals are allowable if humans explicitly disclaimed.<sup>319</sup> The United States, like medical methods for humans, has no prohibitions on patenting medical methods for animals. Unlike human medical method patents though, there is no parallel immunization of veterinarians like 35 USC § 287(c).

Therefore, like industrial applicability, the world has broken into two camps. There is a strong moral argument that the treatment of human maladies shouldn’t be

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<sup>316</sup> European Patent No. 1,135,094 B1 (issued Nov. 3, 2009).

<sup>317</sup> See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012); see also Noonan, *supra* note 314.

<sup>318</sup> 142 Cong. Rec. S12023 (1996) (Remarks of Senator Frist).

<sup>319</sup> See *supra* Part II.D.III, II.E.4.

an industrial enterprise, but the argument that the production of better, healthier, more productive livestock is not a moral industry is weaker, given the historical precedent.<sup>320</sup> Farmers will always try to improve their livestock due to the economic incentives to do so; the question countries must ask themselves is what form of intellectual property protection should be offered for these improvements. If patents are not offered on methods of medicine on animals, farmers will be incentivized to utilize trade secret protection to maintain their competitive edge. Thus, the question of animal medical method patents should be phrased as “does the disclosure mandated by patents and the subsequent development of the science of the treatment of livestock outweigh the marginal societal cost between the patent monopoly and the de facto monopoly of keeping the innovation a trade secret.” This is the fundamental reason that the patent system exists: society has judged the price paid to give a monopoly is worth far less than the benefits received by follow-on innovation. In addition, follow-on innovation is not limited to animals: in countries that ban patents on human medical methods, disclosed advances in animal medical methods can be utilized as a starting point for innovations in human medicine. This benefit should more than outweigh the marginal difference in costs between the patent monopoly and the trade secret monopoly.

#### 4. *Plants and Animals Other Than Microorganisms*

TRIPS Article 27(3)(b) allows countries to exclude plants, animals, and essential biological processes for their production from patentability, but if a country will not issue utility patent protection for plants it must have an effective sui generis system for protecting innovations into plant varieties. Canada, the EPO, and India explicitly exclude plants from utility patents and have a system of “plant patents,” whereas Japan,<sup>321</sup> South Korea,<sup>322</sup> and Singapore<sup>323</sup> do not explicitly exclude plants from protection in their manuals of patent examining procedure, but have sui generis systems for issuing “plant patents.” The treatment of plants is an area of relative conformity in the policies implemented.

Canada, and India prohibit granting patents on animals or other multicellular life. Japan, South Korea, Singapore, and the United States all permit patents on these higher life forms so long as the other statutory requirements are met. The EPO grants patents on transgenic animals by defining animal varieties to not encompass lab-created animals.<sup>324</sup> There has been significant amounts of scholarship on whether

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<sup>320</sup> See, e.g., Amelie Scheu et al., *The Genetic Prehistory of Domesticated Cattle from Their Origin to the Spread Across Europe*, 16 BMC GENETICS 15, 4 (2015).

<sup>321</sup> See Muriel Lightbourne, *Plants and Intellectual Property Rights in the US, Japan, and Europe*, IIP BULLETIN, [https://www.iip.or.jp/e/e\\_summary/pdf/detail2004/e16\\_11.pdf](https://www.iip.or.jp/e/e_summary/pdf/detail2004/e16_11.pdf) (last visited Mar. 27, 2019).

<sup>322</sup> *IP Protection in South Korea*, AUSTRALIAN GOV'T (Mar. 22, 2016), <https://www.ipaustralia.gov.au/understanding-ip/taking-your-ip-global/ip-protection-south-korea>.

<sup>323</sup> *Plant Varieties Protection*, INTELL. PROP. OFF. OF SINGAPORE, <https://www.ipos.gov.sg/understanding-innovation-ip/other-ips/plant-varieties-protection> (last visited Mar. 27, 2019).

<sup>324</sup> Bioethics and Patent Law: The Case of the Oncomouse, *WIPO MAG.* (June 2006), [http://www.wipo.int/wipo\\_magazine/en/2006/03/article\\_0006.html](http://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html).

animal patents are worthwhile to society,<sup>325</sup> but the general conclusion has been that genetically modified animals are of such importance to research, and constitute such a worthwhile inventive activity that patent protection should be granted. A revised Article 27 should incorporate this understanding to provide worldwide protection for the next generation of groundbreaking oncomouse<sup>326</sup> development.

#### F. Other Exclusions

India is the only country that has express exceptions to patentability that go beyond the enumerated categories in TRIPS. The Indian patent office explicitly excludes methods of agriculture and horticulture from patentability.<sup>327</sup> TRIPS Article 27(2) allows exclusions to patentability to protect human life, and India's large subsistence agricultural sector is a key factor in preventing widespread starvation on the subcontinent. However, TRIPS does not allow an exclusion to patentability for life-saving pharmaceutical compounds under 27(2). The second most prevalent cause of death in India is diarrheal disease, a host of illnesses that can be treated by modern medicine if it is available.<sup>328</sup> India has granted patent protection to some of the most promising ant diarrheal medications and not exempted them under 27(2).<sup>329</sup> Although malnutrition is the leading cause of death and disability in India,<sup>330</sup> it would not be a clear argument that advances in agricultural technology should be exempt from patentability under 27(2) if clearly life-saving drugs are not.

The Indian Patent Office will not issue utility patents on the topography of integrated circuits,<sup>331</sup> but these designs are otherwise protected under the Semiconductor Integrated Circuit Lay-out Designs Act of 2000.<sup>332</sup> Like the parallel tracks of design and utility patents in other countries, India has chosen to bifurcate its patent laws, and if comparable protection is offered this would likely not be a violation of TRIPS Article 27. However, the Integrated Circuit Lay-out Designs Act is a registration system and not an examination system, and protection is limited to ten years from filing.<sup>333</sup> However, TRIPS Article 35 mandates countries provide protection for integrated circuit topographies, but does not mandate that these protections fall

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<sup>325</sup> See, e.g., Elisabeth T. Jozwiak, *Worms, Mice, Cows and Pigs: The Importance of Animal Patents in Developing Countries*, 14 NW. J. INT'L L. & BUS. 620 (1994); Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS 399 (1988).

<sup>326</sup> Fiona Murray, *Patenting Life: How the Oncomouse Patent Changed the Lives of Mice and Men*, in MAKING AND UNMAKING INTELLECTUAL PROPERTY: CREATIVE PRODUCTION IN LEGAL AND CULTURAL PERSPECTIVE (Mario Biagioli, Peter Jaszi & Martha Woodmansee eds., 1st ed. 2011).

<sup>327</sup> OFFICE OF CONTROLLER GENERAL OF PATENTS, DESIGNS, AND TRADEMARKS, MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE § 08.03.05.07 (India) (2010).

<sup>328</sup> *Global Health – India*, CDC, <https://www.cdc.gov/globalhealth/countries/india/pdf/India-Factsheet-p.pdf> (last visited Mar. 27, 2019).

<sup>329</sup> India Patent No. 259137 (issued Feb. 27, 2014).

<sup>330</sup> *India*, INSTITUTE FOR HEALTH METRICS AND EVALUATION, <http://www.healthdata.org/india> (last visited Mar. 27, 2019).

<sup>331</sup> OFFICE OF CONTROLLER GENERAL OF PATENTS, DESIGNS, AND TRADEMARKS, MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE § 08.03.05.14 (India) (2010).

<sup>332</sup> The Semiconductor Integrated Circuits Layout Design Act, (India) (2000), [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=128089](http://www.wipo.int/wipolex/en/text.jsp?file_id=128089) (last visited Mar. 27, 2019).

<sup>333</sup> *Id.*

under the umbrella of Article 27. Therefore, India's sui generis system of protection may be in compliance with its TRIPS obligations, even though such topographies are carved out of utility patents.

#### IV. CONCLUSION: CURRENT DISPUTES AND POTENTIAL RESOLUTIONS

In the analysis of the manuals of patent examining procedure, this Article argues that there are areas where TRIPS Article 27 needs to be either refined, applied, or revised. First, the definition of industrial applicability needs to reflect the actual practice of the majority of states, and to not bar non-commercial but useful inventions from patenting. Second, member nations should strike the allowance for prohibiting patents on non-human higher life forms. Third, TRIPS should be revised to include specific permission for countries to set up sui generis patent systems for integrated circuit topographies, similar to the current carve-out for plants. Fourth, TRIPS should address the immunization against infringement of certain patents to restrict such immunity to accomplish the aims of TRIPS. Finally, the international community should pressure India to comply with its TRIPS obligations and issue patents on methods of agriculture.

##### *A. Harmonize the Interpretation of Industrial Applicability.*

The exclusions to patentability under the guise of industrial applicability should be harmonized to create uniform incentives for innovation. As discussed in Section III, there are two primary camps in the understanding of what it means to be industrially applicable. First, the United States, Canada, India, and Singapore all treat industrial applicability as an extension of defining what counts as an invention - something has to have some use to be truly called an "invention." Japan and South Korea though extend industrial applicability to a stand-alone requirement of commercial utility. This focus on commerce unwisely excludes significant areas of technological innovation, and a wise use of immunization for non-commercial infringement would minimize the harm these patents could cause to research while still reaping the innovation incentives.<sup>334</sup> Inventors should be the ones to decide if the potential commercial profits they can capture exceed the costs of filing and enforcing their patent. The use of over-narrow definitions of industrial applicability by Japan and South Korea go beyond enforcing allowed exclusions to patentability, and reflect an overbroad view of what should not be patented for the public good. These same protections can be served by immunizing certain actors from infringement without excluding whole areas of technological but non-commercial research from the patent apparatus.

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<sup>334</sup> See, e.g., Kevin Iles, *A Comparative Analysis of the Impact of Experimental Use Exemptions in Patent Law on Incentives to Innovate*, 4 NW. J. TECH. & INTELL. PROP. 61, 63 (2005); Vihar R. Patel, *Are Patented Research Tools Still Valuable? Use, Intent, and A Rebuttable Presumption: A Proposed Modification for Analyzing the Exemption from Patent Infringement Under 35 U.S.C. S 271(e)(1)*, 47 IDEA 407, 427 (2007); Alicia A. Russo & Jason Johnson, *Research Use Exemptions to Patent Infringement for Drug Discovery and Development in the United States*, 5 COLD SPRING HARB. PERSPECT. MED. 1 (2015).

*B. Non-human Higher Life Forms Should Be Patentable.*

As argued earlier, Canada and India's exclusion of higher life forms from patentability is an outlier. There was significant debate over whether the Harvard oncomouse was patentable at the turn of the century, but the Canadian Supreme Court articulated that the public policy arguments could not overcome the language of the statute.<sup>335</sup> Sound public policy shows even more strongly now than it did in 2001 how patents on genetically modified organisms promote useful research and development, and most countries have recognized this. The prohibition against patenting higher life forms is currently allowed by TRIPS, which was negotiated in the early years of viable genetically modified higher life forms. A revision of TRIPS should reflect the new understanding of the usefulness of genetically modified higher life forms. This will require updating of national laws to draw the line between the newly patentable non-human, and the still universally unpatentable human higher life forms. Given the consensus that humans should not be patentable, the updates required to ensure that humans remain unpatentable should be politically palatable.

*C. Specific Carve-Outs, Like Plant Patents for Functional Designs*

India has a creative solution to the gap between utility patents and design patents in providing a sui generis system of intellectual property protection for the functional design of integrated circuit topographies. Traditional design patent law does not protect such functional designs, but the innovation embodied in these inventions is something worth capturing by the patent system to allow for disclosure and spur follow-on innovations. The United States also attempted to implement a similar system, although its effectiveness is in debate.<sup>336</sup> Explicitly allowing for direct protection on these designs in a sui generis system is a good way to reconcile some of the problems shoehorning them into either design or utility patent systems would cause, and is the path that countries are taking absent any international agreement. Such a carve-out should be explicitly allowed by TRIPS for functional designs in order to facilitate this expansion of intellectual property protection into the gap between design and utility patents.

*D. The Rules for Immunization Against Infringement Should Be Codified.*

Imagine the United States felt like promising foreign solar panel technology was being restricted by unpracticed patents. How could the United States encourage commercialization? One option would be to cancel the patents and refuse to issue any more patents on solar panel technology, a clear TRIPS violation. A second option, one

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<sup>335</sup> See Anwar N. Khan, *Canadian Researchers and Patenting of Higher Life*, 33 J.L. & EDUC. 63, 65-66 (2004).

<sup>336</sup> See Leon Radomsky, *Sixteen Years After the Passage of the U.S. Semiconductor Chip Protection Act: Is International Protection Working?*, 15 BERKELEY TECH. L.J. 1049 (2000).

that is explored in depth elsewhere,<sup>337</sup> is to force a compulsory license on the patent holder, giving compensation, but freeing the technology for use. A third method of accomplishing this goal is the parallel to the United States' implementation of a ban on medical method patents and research tool patents: immunize those most likely to infringe from liability. This is not prohibited by TRIPS, and functions as a de facto implementation of option one above.

However, as seen in the analysis of industrial applicability and the exclusion of medical technologies, immunization against infringement can serve as an important tool in national patent offices' kit to promote innovation without restricting use of technology for the public good. In the United States, if an inventor wants to pursue research into transgenic organisms thinking that there will be additional uses outside of the research tool context, society benefits if one is discovered via the commercial exploitation — the benefits of which the inventor captures due to the patent — but also benefits via the disclosure if a commercial application isn't discovered. Contrast this to the situation where an inventor knows that no patent will be issued until a commercial use is identified — the inventor will keep the knowledge a trade secret out of fear that they will not be able to get a patent later due to novelty concerns, if they pursue the research at all. Therefore, immunization of key users gives national patent offices the flexibility to grant patents that may otherwise hinder the development of society, and gives inventors the agency to pursue research into possible dual-use technologies.

While this strategy of patents plus immunization may be an ideal implementation of allowed exclusions to patentability to allow inventors to capture any non-prohibited subject matter on dual-use claims, it presents a significant opportunity of misuse. Explicit language in TRIPS to prevent this workaround except in enforcement of allowed TRIPS prohibitions would forestall any attempt to honor the law, but not the spirit of TRIPS. This would still allow nations to have the freedom to shape their patent law within the spirit of TRIPS, but not undercut the agreement.

### *E. Agriculture*

India's prohibition of agricultural method patents is unique and seems to contradict Article 27(1)'s mandate that patents be "enjoyable without discrimination as to . . . the field of technology." This Article argues that this prohibition is also unwise on policy grounds, as it discourages the dissemination of agricultural knowledge due to the increased reliance on trade secrecy. Therefore, work needs to be done to bring India into compliance with its TRIPS obligations for the good of agricultural research and development, and by extension, the people relying on increases in food yield to survive an increasing tumultuous climate.

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<sup>337</sup> See, e.g., Charlene A. Stern-Dombal, *Tripping over Trips: Is Compulsory Licensing Under Ebay at Odds with U.S. Statutory Requirements and Trips?*, 41 SUFFOLK U. L. REV. 249, 250 (2007); Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 NW. J. INT'L L. & BUS. 666, 667 (1988).