



## *Biopatenting and Industrial Policy Discourse: Decoding the Message of Biomedica on the Limits of Agents and Audiences*

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**ABSTRACT (EN):** Patent law has yet to recognize the agency of multiple creators acting jointly with so-called inventors. It operates on the romantic myth of individual creation, ignoring the agency of plants, animals, people, and their genetic substrates. Invention is, according to the law, a singular deliberative act completed in isolation. The legal doctrine of “products of nature” provides only a partial challenge to the legitimacy of biopatent claims and is contingent on human agency for meaning. In Canada, the Supreme Court has recognized the agency of non-humans with its concern over “reproducibility” of mice in the Harvard mouse case and has used this understanding to inform its perhaps unduly criticized reasons against the patentability of the oncomouse. A socio-cultural approach to law using actor network theory may inform our understanding of biology and biotechnology as discourse, always in performativity, adaptation, mutation, and translation. It may provide a means to challenge the normative assumptions implicit in claims of legal entitlement to patents in language familiar to the patent bar, paving the way for recognition of the agency of others while helping define the necessary limits on patentability and patent rights in biomedica. An interdisciplinary approach may generate the necessary conceptual shift and create, in the words of Stuart Hall, a critical “moment of collective self-clarification.”

**RÉSUMÉ (FR):** Le droit de la propriété industrielle n’a toujours pas reconnu les capacités d’agir « agency » de nombreux créateurs qui collaborent avec les prétendument inventeurs. Ce droit fonctionne sur la base du mythe ro-

mantique de la création individuelle, ignorant la contribution des plantes, des animaux, des personnes et de leur substrat génétique. En droit, une invention est un acte délibéré singulier achevé de façon isolée. La théorie juridique du « produit de la nature » ne constitue qu'un défi limité à la légitimité des revendications de biobrevetabilité et dépend de l'intervention humaine pour lui donner une signification. Au Canada, la Cour suprême, dans l'affaire de la souris Harvard, a reconnu l'immixtion de facteurs non humains en prenant en considération le problème de la « reproductibilité » des souris et a utilisé cette perspective pour justifier son raisonnement peut-être indûment critiqué pour ne pas breveter la souris. Une approche socioculturelle du droit, recourant à une théorie des réseaux d'acteurs, peut éclairer notre compréhension du discours concernant la biologie et la biotechnologie, toujours en performativité, en adaptation, en mutation, et en traduction. Cela peut donner un moyen de mettre en question les présupposés normatifs implicites dans les revendications de droits aux brevets, dans un langage plus familier aux praticiens en brevets, pour ainsi ouvrir la voie à la reconnaissance de l'apport des autres agents, tout en aidant à définir les limites nécessaires à la brevetabilité et aux droits des brevets en biomédia. Une approche interdisciplinaire peut apporter une réorientation conceptuelle nécessaire et créer, pour reprendre les mots de Stuart Hall, un « moment d'autoclarification collective » critique.

## A. INTRODUCTION

Spring 2012 witnessed a perfect storm in media, a merger of art with life. A science fiction thriller, *Prometheus* was released in theatres and featured two archaeologists on board the *Prometheus* spaceship on a mission to find the “engineers” of the human race. At the same time, the United States Supreme Court (USSC), in *Mayo v Prometheus*,<sup>1</sup> was confronted with the contested scope of ownership claims and doctrinal limits to the legal meaning of “invention” for biotechnology patents (biopatents). Patent law has allowed the appropriation of labour and agency from multiple creators and users acting in collaboration with so-called inventors. Dutfield notes

[w]hether we have God or natural processes alone to thank, much of the difficult work has been done—in many cases millions of years earlier. Putting it in its bluntest terms, genetic engineers are really just free-rid-

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1 *Mayo Collaborative Services v Prometheus Laboratories Inc*, 566 US \_\_ (2012) [*Prometheus*].

ers who tinker half-knowingly with what they have got and actually create nothing that was not there before.<sup>2</sup>

“Invention” is reduced in common law jurisdictions to the mythology of a single creator engaged in a deliberative act of ingenuity. Insofar as courts have upheld the view that life is patentable, the law reinforces the romantic myth of individual creation, and ignores the agency of plants, animals, even human actors in maintaining their genetic and biological substrates. Patent protection is rationalized on the utilitarian view that patents incentivize new inventions that in the long term will lead to welfare gains. As a matter of policy, offering a short-term monopoly is a rational trade-off for encouraging research and development in the life sciences. But, can the claim to inventorship be justified given the unique capacity for life, from whole organisms to the genes coded by deoxyribonucleic acid (DNA), to self-replicate, adapt, and mutate in response to a (host) environment? The mutability of life in a discursive process is known to science and is a central tenet of epigenomics.<sup>3</sup> It features also in the film *Prometheus*.

This chapter reviews the 2012 USSC’s *Prometheus* decision regarding patent ineligibility for natural processes and draws some parallels with the Supreme Court of Canada’s (SCC) *Harvard mouse* decision<sup>4</sup> on the patentability of products that result from the *reproducibility* phenomenon in nature. Both decisions imply that the patentees’ claims to entitlement simply cannot be made out. *Harvard* initiates a necessary conceptual shift towards a broader understanding of non-human actor agency in the context of product claims while *Prometheus* serves this function in terms of *natural* processes. The chapter is divided into four parts. Section B examines the *Prometheus* myth as metaphor to help inform our reading of *Prometheus*. Actor Network Theory (ANT) is introduced to register its potential as a theoretical framework. Section C reviews the concept of reproducibility

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2 Graham Dutfield, “Who Invents Life: Intelligent Designers, Blind Watchmakers or Genetic Engineers?” (2010) 5:7 *J Intell Prop L & Practice* 531 at 533.

3 See National Human Genome Research Institute, *Epigenomics Fact Sheet* (7 May 2012), online: National Human Genome Research Institute [www.genome.gov/27532724](http://www.genome.gov/27532724). “Derived from the Greek, epigenome means ‘above’ the genome. The epigenome consists of chemical compounds that modify, or mark, the genome in a way that tells it what to do, where to do it and when to do it. The marks, which are not part of the DNA itself, can be passed on from cell to cell as cells divide, and from one generation to the next.”

4 *Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76 [*Harvard*]; see also Bitá Amani, *State Agency and the Patenting of Life in International Law: Merchants and Missionaries in a Global Society* (Aldershot: Ashgate Publishing Company, 2009).

endorsed by the majority of the SCC as a basis for rejecting patent claims over a higher life organism. Considered through the ANT lens, the concept of *reproducibility* as a basis for determining patentability may be applied to reconsider the law on lower life, genes, and even DNA. Section D examines the historical treatment of DNA, from its origins in the scientific literature as a “discovery” to its subsequent judicial treatment as chemicals, purified and isolated, and therefore patentable. The final stage in our understanding of DNA would be to give legal effect to DNA as biomedica. As we move from the hardware of the knowledge economy to the wetware<sup>5</sup> of the bioeconomy,<sup>6</sup> decoding the message of DNA may help us understand our relationship with non-human actors.<sup>7</sup> Section E returns to the Prometheus metaphor. Modern science reveals we are all chimeras; transgenics comprised of aliens within. Some of these actors are essential to our survival. The impulse towards greater human agency, to colonize and impose proprietary mappings on inner space as the new frontier, may be strong. Yet these boundary-bending “foreign” bodies force us to interrogate the legal concept of discrete interventions as *inventions*, the scope and limits of property, and the concept of what is “human” and, by corollary, what is “nature.” Rather than a piecemeal and incremental approach to the patentability of biological and biochemical claims, a principled understanding is needed to inform doctrinal analyses. This is where interdisciplinarity holds promise.

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5 Dennis Bray, *Wetware: A Computer in Every Living Cell* (New Haven, CT: Yale University Press, 2009). Bray defines wetware as “the sum of all the information-rich molecular processes inside a living cell . . . Cells are built of molecules that interact in complex webs, or circuits . . . The computational units of life — the transistors, if you will — are its giant molecules, especially proteins. Acting like miniature switches, they guide the biochemical processes of a cell this way or that. Linked into huge networks they form the basis of all of the distinctive properties of living systems” at x.

6 Matthew Herder & E Richard Gold, “Intellectual Property Issues in Biotechnology: Health and Industry” Report delivered at the Third Meeting of the Steering Group of the OECD International Futures Project on the Bioeconomy to 2030: Designing a Policy Agenda, Paris (7–8 February 2008).

7 See, for example, Feris Jabr, “Microbial Mules: Engineering Bacteria to Transport Nanoparticles and Drugs” (2012) 306:6 *Scientific American* 20, reporting on research taking non-pathogenic *Escherichia coli* and saddling it with beads, rods, and crescents made from nickel and tin coated in gold that is heated by infrared light to destroy surrounding diseased tissue. Other projects are focused on engineering bacteria to deliver medical packages directly to diseased cells.

## B. PROMETHEUS AND THE ORIGIN OF ORIGIN STORIES

What can *Prometheus* teach us? Stories of creation or evolution are origin stories. Origin stories are authorship<sup>8</sup> stories, born from the normative narrative of those who give expression to an articulation that claims sovereignty over competing narratives and interpretations. According to Leeming,

[h]uman beings have traditionally used stories to describe or explain things they could not explain otherwise . . . . In this sense, myth is related to metaphor, in which an object or event is compared to an apparently dissimilar object or event in such a way as to make its otherwise inexplicable essence clear . . . to read a culture's myths is to glean information about that culture . . . . In a real sense, the world reveals its inner self through its common mythology.<sup>9</sup>

Semiotics<sup>10</sup> helps explain how each (re)iteration of Prometheus as myth and metaphor captures and modifies its social meaning, encoding a new narrative to be decoded by the audience. Prometheus is credited with creating humanity (from clay) and Zeus for punishing him, but who authors Prometheus? Leeming tells us that

[a] question that inevitably arises in connection with mythology is that of authorship. Who wrote the myths or, more accurately, who first told them? Almost invariably the answer must be the people themselves. The myth, like its close relative the fairy tale, has its origins in the collective "folk" mind.<sup>11</sup>

When we seek to locate an individual author, we run into trouble as "[p]ower and authorship fabricate reality."<sup>12</sup> It is axiomatic in western intellectual

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8 See, for example, Michel Foucault, "What is an Author" in Josué V Harari, ed, *Textual Strategies: Perspectives in Post-Structuralist Criticism* (New York: Cornell University Press, 1979) at 141. Foucault asserts that the idea of an atomistic author as the "sole creator" of unique works is a relatively recent invention; see also Martha Woodmansee & Peter Jaszi, eds, *The Construction of Authorship: Textual Appropriation in Law and Literature* (Durham: Duke University Press, 1994).

9 David Adams Leeming, *The World of Myth: An Anthology* (New York: Oxford University Press, 1990) at 3–6.

10 See, for example, Susan W Tiefenbrun, "Semiotic Definition of Lawfare" (2011) 43 Case W Res J Int'l L 29, wherein the author defines semiotics as "the exchange between two or more speakers through the medium of coded language and convention" at 32 [footnotes omitted].

11 Leeming, above note 9 at 6–7.

12 Donna J Haraway, *Simians, Cyborgs, and Women: The Reinvention of Nature* (New York: Routledge, 1991) at 74.

property law that whoever tells the tale owns it. And, what of the contribution of “others”?

The politics of ownership and control are an integral part of media studies but also attract much scrutiny in intellectual property literature, where the law is sometimes seen as having independent agency in meaning (myth) making:<sup>13</sup> treating corporations as persons and life as proprietary “invention.” The law prioritizes the patent as readable text and so recognizes the agency of some actors, inventors in patent law, while alienating the “other” whose voiceless agency renders them invisible as actants in the law. But who is an inventor and what is an “invention”?

The relationship between law and science is political.<sup>14</sup> The USSC in a 5-4 split decision in *Diamond v Chakrabarty* found living micro-organisms patentable as a “nonnaturally occurring manufacture or composition of matter — a product of human ingenuity.”<sup>15</sup> The focus was not so much on life as patentable subject matter *per se* but on human agency. That “anything under the sun that is made by man”<sup>16</sup> is patentable — reflects the view that no distinction is to be drawn on the basis of whether the claim extends to the living or inanimate.

*Beineke v USPTO*<sup>17</sup> addressed whether discovered superior oak trees, each over 100 years old, were patentable. Plants and animals have long been patentable in the United States.<sup>18</sup> Yet, the Federal Circuit upheld the Patent Office’s rejection of the claims on the basis that these were unpatent-

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13 Leeming, above note 9. The term “myth” may be understood as “a generally accepted belief unsubstantiated by fact” at 3.

14 For example, the characterization of Ephedra, now banned, as a natural substance rather than as a drug situated its use as a weight loss supplement outside the need for FDA approval. Over 800 law suits were later launched on the view that use of Ephedra use led to heart attacks and strokes; see Hon Jed S Rakoff, “Science and the Law: Uncomfortable Bedfellows” (2008) 38 Seton Hall L Rev 1379, online: Seton Hall <http://38.113.83.199/Students/academics/journals/law-review/Issues/archives/upload/Rakoff-final.pdf>.

15 *Diamond v Chakrabarty*, 447 US 303 (1980).

16 *Ibid* at 309, citing S Rep No 1979, 82d Cong, 2d Sess, 5 (1952).

17 *Beineke v USPTO*, 12-580 (2012) [*Beineke*], online: Justia <http://docs.justia.com/cases/federal/appellate-courts/cafc/11-1459/11-1459-2012-08-06.pdf>; petition for writ of certiorari (5 November 2012) denied by the US Supreme Court, 19 February 2013, online: US Sup Ct [www.supremecourt.gov/Search.aspx?FileName=/docketfiles/12-580.htm](http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/12-580.htm).

18 *JEM Ag Supply v Pioneer Hi-Bred International*, 534 US 124 (2001); “Transgenic non-human mammals,” US Patent No 4736866 (22 June 1984); but see *Ex Parte Latimer*, 1889 Dec Com Pat 123, rejecting the application over a fibre found in pine tree needles and not known in the prior art as “invention”; see *Parker v Flook*, 437 US 584 (1978) [*Flook*], where it was held that “[e]ven though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the

able discoveries of products of nature. The Court found no evidence to support the patentee's claim; the trees were not, from inception, created or contributed to by "human activity."<sup>19</sup> The Court also found that "the statute required some "exercise of the inventive faculty"<sup>20</sup> and that this view was consistent with *Chakrabarty*. *Chakrabarty's* distinction between the natural and non-natural was affirmed as the central question in this case. Yet, law is as much a social construct, an artifact of cultural production — a myth — as the nature it seeks to govern.

At issue in *Mayo v Prometheus*,<sup>21</sup> were the contested patents of Prometheus Laboratories relating to the use of thiopurine drugs to treat autoimmune diseases. These drugs were metabolized by the ingesting body differently, producing variable levels of metabolites that must be "read" and measured before the medication is adjusted by the doctor overseeing treatment: "[t]he patent claims at issue here set forth processes embodying researchers' findings that identified these correlations with some precision . . . . The patent claims seek to embody this research in a set of processes."<sup>22</sup>

Did Prometheus Laboratories invent this process? Prometheus, as exclusive licensee of the contested patents, sold the diagnostic blood tests embodying the processes to Mayo Clinic et al. In 2004, Mayo announced its intention to use and sell its own tests, with higher metabolite metrics for determining toxicity. The District Court found that Mayo's tests were infringing; the toxicity levels were too similar to those of Prometheus to be considered different tests. Based on the claim language, the Court also endorsed Prometheus' view that the medical expert using the Mayo test could also violate the patent even if no change was made in treatment decisions after test results.<sup>23</sup> Summary judgment was granted to Mayo, however, on the basis that "the patents effectively claim natural laws or natural phe-

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discovery of such a phenomenon cannot support a patent *unless* there is some *other inventive concept* in its application" at 594 [emphasis added].

19 *Beineke*, above note 17 at 4.

20 *Ibid* at 9. The 35 USC § 161 provides that "[w]hoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings" may be eligible for a plant patent. The Federal Circuit rejected the patent, finding "no indication in the text of the amendments or in the legislative history that Congress intended to ignore the longstanding view that, to be patentable, a new and distinct invention (including a new and distinct plant) must be the product or result of man and his inventive efforts" at 18.

21 *Prometheus*, above note 1.

22 *Ibid* at 5.

23 *Ibid* at 6.

nomena — namely the correlations . . . — and so are not patentable.”<sup>24</sup> The Federal Circuit reversed on appeal and found that the patents claimed more than natural correlations. The process claims specify the steps of administering the drug to a patient and determining the resulting metabolite level. These steps were said to involve the transformation of the human body or of blood taken from the body. “Thus, the patents satisfied the Circuit’s ‘machine or transformation test.’”<sup>25</sup> The USSC granted Mayo’s petition for *certiorari* and vacated the judgment, remanding the case for reconsideration in light of *Bilski*,<sup>26</sup> which had clarified that the “machine or transformation test,” although helpful, was not definitive of patent eligibility. The Federal Circuit on remand reaffirmed its earlier decision that the patent claims “do not encompass laws of nature or pre-empt natural correlations.”<sup>27</sup> Mayo filed another petition for *certiorari* which was granted. In a unanimous decision the USSC held that the process claims were not patent eligible:

Prometheus’ patents set forth laws of nature — namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm . . . . While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body — entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.<sup>28</sup>

Implicit in the rationale for patent ineligibility is the recognized difficulty of claiming inventorship where the level of human agency is insufficient to warrant a twenty year grant of exclusive rights.<sup>29</sup> When phrased in relation to the laws of nature, the distinction may appear arbitrary; from the lens of agency, it becomes principled. That is, we might move beyond the

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24 *Ibid* at 7.

25 *Ibid*.

26 *Bilski v Kappos*, 561 US \_\_ (2010) [*Bilski*].

27 *Ibid* at 8.

28 *Prometheus*, above note 1 at 8.

29 *Ibid*. Citing *Flook*, above note 18 and *Bilski*, above note 26, Justice Breyer, writing for the Court found that the authorities “insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an ‘inventive concept,’ sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself” at 3.



“natural/non-natural” distinction in *Chakrabarty* to the analysis of what is “man-made.”

*Prometheus* and *Harvard* happened to draw the right line, but without a more stable underpinning, such decisions are vulnerable to the composition of the bench,<sup>30</sup> and so *eternally* contingent<sup>31</sup> on the particular subjectivities of individual judges when reading “nature” as the subtext of the patent text. So much depends on language for “preferred readings”<sup>32</sup> and dominant meanings of patent texts. Dominant or preferred meanings, insofar as they are ideological, function to transform the real into the imaginary,

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30 In *Bowman v Monsanto Co*, No. 11-796, writ for *certiorari* granted by the US Supreme Court (5 October 2012), the Federal Circuit rejected the farmer’s claim to his right to save commodity seeds purchased from a grain elevator that embodied the glyphosate resistance of Monsanto’s Roundup Ready patented soybean variety, finding that to apply the “first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder.” Matthew Alan Chivvis, Rachel Krevans, & Michael R Ward, “Sound the Alarm? — The Supreme Court’s Renewed Interest in Life Sciences Patents Could Create Additional Hurdles Across the Field” (16 November 2012), online: Morrison & Foerster [www.mofo.com/files/Uploads/Images/121116-Life-Sciences-Patents.pdf](http://www.mofo.com/files/Uploads/Images/121116-Life-Sciences-Patents.pdf). Chivvis, Krevans, & Ward conclude that the USSC’s decision to review the Federal Circuit’s decision “suggest[s] that the Court is unhappy with the Federal Circuit’s articulation of the law in this area.” On 13 May 2013, the USSC affirmed that the doctrine of exhaustion only limits the patentees rights to the particular article sold and does not apply to allow farmers to harvest patented plant seed from a legitimately acquired plant for future replanting without the permission of the patentee: see *Bowman v Monsanto*, 569 US \_\_\_ (2013), online: [www.supremecourt.gov/opinions/12pdf/11-796\\_c07d.pdf](http://www.supremecourt.gov/opinions/12pdf/11-796_c07d.pdf).

31 Quentin Meillassoux, “Iteration, Reiteration, Repetition: A Speculative Analysis of the Meaningless Sign” (20 April 2012), translated by Robin Mackay, online: [http://cdn.shopify.com/s/files/1/0069/6232/files/Meillassoux\\_Workshop\\_Berlin.pdf?100796](http://cdn.shopify.com/s/files/1/0069/6232/files/Meillassoux_Workshop_Berlin.pdf?100796). “The contingency of which we speak is speculative, not physical. It designates the possible being-otherwise of every entity, even entities that cannot be modified by any human means” at 36.

32 Stuart Hall, “Encoding/Decoding” in Stuart Hall et al, eds, *Culture, Media, Language* (London: Hutchinson, 1980) at 128. Hall writes that “[a]ny society/culture tends, with varying degrees of closure, to impose its classifications of the social and cultural and political world. These constitute a *dominant cultural order*, though it is neither univocal nor uncontested. This question of the ‘structure of the discourses in dominance’ is a crucial point. The different areas of social life appear to be mapped out into discursive domains, hierarchically organized into *dominant* or *preferred meanings* . . . [W]e say ‘dominant’ because there exists a pattern of ‘preferred readings’; and these both have the institutional/political/ideological order imprinted in them and have themselves become institutionalized” at 134 [emphasis in original][footnote omitted].

“History into Nature.”<sup>33</sup> What then is *nature*?<sup>34</sup> Can the reductive dichotomy between nature and culture be sustained any longer?

Stengers, in discussing the natural versus the supernatural, contends that the distinction “relies on a disastrous definition [of] the ‘natural,’ namely: that which Science will eventually explain.”<sup>35</sup> And, what is to come *after* nature? Bruno Latour observes “there is no way to devise a successor to nature, if we do not tackle the tricky question of *animism* anew.”<sup>36</sup> One can contest the idea of nature as stasis; “*always already assembled*, since nothing happens but what comes from before.”<sup>37</sup>

Thus, the main issue in biopatent cases can be seen as an issue of animism/inanimism understood more technically through the ANT lens:

[A]lthough every state of affairs deploys associations of *mediators*, everything is supposed to happen as if only chains of purely passive *intermediaries* were to unfold. Paradoxically, the most stubborn realism, the most rational outlook is predicated on the most unrealistic, the most contradictory notion of an *action without agency*.<sup>38</sup>

Latour is one of the founders of ANT. John Law, another founder, contends that ANT “may be understood as a *semiotics of materiality*.”<sup>39</sup> ANT was originally “developed by sociologists of science as a response to the methodological and theoretical dilemmas these scholars encountered as they explored how scientists produced and circulated scientific facts.”<sup>40</sup>

ANT theory “insists that performance creates the relations and the objects/people/actants constituted by these relationships. Networks and actors do not exist prior to performance, but are constituted by perform-

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33 Roland Barthes, “Myth Today” in Roland Barthes, *Mythologies*, translated by Annette Lavers (New York: Hill & Wang, 1984) at 10.

34 See, for example, Eduardo Kac, ed, *Signs of Life: Bio Art and Beyond* (Cambridge: Massachusetts Institute of Technology, 2007) [Kac, *Signs of Life*].

35 Isabelle Stengers, “Reclaiming Animism” 36 *e-flux* (July 2012), online: e-flux [www.e-flux.com/journal/reclaiming-animism/](http://www.e-flux.com/journal/reclaiming-animism/).

36 Bruno Latour, “An Attempt at a ‘Compositionist Manifesto’” (2010) 41:3 *New Literary History* 471 at 481 [emphasis in original].

37 *Ibid* at 482 [emphasis in original].

38 *Ibid* [emphasis in original].

39 See John Law, “After ANT: Complexity, Naming and Topology” in John Law & John Hassard, eds, *Actor Network Theory and After* (Oxford: Blackwell, 1999) at 4 [emphasis in original].

40 Ilana Gershon, “Bruno Latour (1947–)” in Jon Simons, ed, *From Agamben to Žižek: Contemporary Critical Theorists* (Edinburgh: Edinburgh University Press, 2010) at 161.

ance.”<sup>41</sup> From this critical lens we begin to appreciate how other doctrines of patent law may be conceptually incomplete in the biotechnology context. They cannot adequately deal with the rupture to the legal claim of title that biological matter introduces. The law should not sanction appropriations from “nature” not least because the conceptual view of nature as a separate entity from man who claims sovereignty over it is no longer tenable. Sometimes nature is seen as co-optor of the agency of other actors.<sup>42</sup> More often, nature is an effective co-author/co-inventor, and sometimes intended collaborator, in a complex performance of discursive agencies called Life.<sup>43</sup> ANT’s recognition of these activities and agencies will force patent law to reconsider the doctrinal limits to the patentee’s claim as “owner.” In short, ANT asks us to consider the subtle difference between concluding: “these are not *inventions*” and “even if these are *inventions*, they are not *yours* alone.”

The distinction between author/creator/inventor and owner is fundamental in IP law.<sup>44</sup> Recent changes to US patent law further entrench the distinction between human agents/inventors and owners of such claimed inventions:

Metaphysically, the rules serve to crystallize the US patent system’s *shift in focus* away from inventors and toward corporate owners . . . . Up to now, corporations were never considered patent applicants. Rather, inventors were the applicants. Even when the ultimate rights were owned by a corporate entity, the USPTO still focused on the inventors as the patent applicants. Under the new rules . . . the status of “patent applicant” will no longer be keyed to inventorship but instead ownership. Thus, any juristic entity who can show a proprietary interest will be permitted to file and prosecute a patent application *as the patent applicant* . . . .<sup>45</sup>

If non-human, non-living manufactured corporate actors can find representation in the judicial world as juristic persons, why not other non-hu-

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41 *Ibid* at 166.

42 Robert H Carlson, *Biology is Technology: The Promise, Peril, and New Business of Engineering Life* (Cambridge: Harvard University Press, 2010) at 1.

43 See, for example, Eduardo Kac, “Life Transformation — Art Mutation” in Kac, *Signs of Life*, above note 34 at 164 [Kac, “Life Transformation”].

44 See Dennis Crouch, “AIA Shifts USPTO Focus from Inventors to Patent Owners” *PatentlyO* (14 August 2012), online: PatentlyO [www.patentlyo.com/patent/2012/08/aia-shifts-usptos-focus-from-inventors-to-patent-owners.html](http://www.patentlyo.com/patent/2012/08/aia-shifts-usptos-focus-from-inventors-to-patent-owners.html).

45 *Ibid* [emphasis in original]; it is worth noting that while Canada is a first to file system, until recent patent reform, the US had a first to invent system.

man yet animate actants? Performance artists and common lay-persons<sup>46</sup> challenge any inclination for conflation in the law's asymmetrical recognition of labour and agency. They seem to recognize, as Latour has, that "[i]t is inanimism that is the queer invention: an agency without agency constantly denied by practice."<sup>47</sup>

In *Prometheus*, the USSC asked: "[D]o the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?" The three step process recited in the claims,

tells doctors interested in the subject about the correlations that the researchers discovered. In doing so, it recites an "administering" step, a "determining" step, and a "wherein" step. These additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim.<sup>48</sup>

In reading the claims, the Court speaks directly to the issue of audience:

[T]he "administering" step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs. That audience is a pre-existing audience; doctors used thiopurine drugs to treat patients suffering from autoimmune disorders long before anyone asserted these claims.<sup>49</sup>

The Court, in examining the "wherein" clauses, concludes that these "simply tell a doctor about the relevant natural laws."<sup>50</sup> The Court recognizes that there is a discourse — "these clauses tell the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decision-making."<sup>51</sup>

Through their use of language in claims drafting, patent lawyers and agents inscribe new texts on the "state of nature." Judges adjudicating such

46 See, for example, patent GB Application No 0000180.0 (5 January 2000) (application terminated 9 March 2001). Donna MacLean, a British waitress and poet, applied to patent herself, claiming she had reinvented herself, was new, useful, and non-obvious; see: Bita Amani & Rosemary J Coombe, "The Human Genome Diversity Project: The Politics of Patents at the Intersection of Race, Religion, and Research Ethics" (2005) 27:1 Law & Pol'y 152 at 159.

47 Latour, above note 36 at 482–83.

48 *Prometheus*, above note 1 at 9.

49 *Ibid.*

50 *Ibid.*

51 *Ibid.*

cases may be more competent and comfortable reading the patent text than its underlying science, but the exercise of reading law is complicated by the reading of the science.<sup>52</sup> In *Prometheus*, the USSC held unanimously that the patent text as written could not be interpreted to support the claim of patentability:

Our conclusion rests upon an examination of the particular claims before us in light of the Court’s precedents. Those cases warn us against interpreting patent statutes in ways that make patent eligibility “depend simply on the draftsman’s art” without reference to the “principles underlying the prohibition against patents for [natural laws]” . . . . If a law of nature is not patentable, then neither is a process reciting a law of nature unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.<sup>53</sup>

According to the judgment, the combination of these three steps in order “adds nothing to the laws of nature that is not already present when the steps are considered separately.”<sup>54</sup> *Prometheus* is to be applauded and coheres with *Harvard* where even the “added” contribution of the scientists who “engineered” the mouse was not enough to create sovereignty over “nature.”<sup>55</sup>

### C. LIFE IN PERFORMANCE: THE REPRODUCIBILITY PHENOMENA

The SCC’s finding that a mouse genetically modified to carry a cancer-causing gene was patent-ineligible was highly controversial and set Canada apart from other common law jurisdictions. The Court found that while bacteria and yeasts were patentable, non-human higher life, namely plants and animals, were not. The oncomouse was neither a manufacture nor a composition of matter within the definition of “invention.” Of key

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52 Philip J Hanes, “The Advantages and Limitations of a Focus on Audience in Media Studies” (April 2000), online: [www.aber.ac.uk/media/Students/pph9701.html](http://www.aber.ac.uk/media/Students/pph9701.html). “[A] text does not have a single meaning but rather a range of possibilities which are defined by both the text and by its audiences. The meaning is not in the text, but in the *reading*” [emphasis in original], quoting Hart (1991, 60).

53 *Prometheus*, above note 1 at 3 and 8–9.

54 *Ibid* at 10.

55 *Harvard*, above note 4.

concern was the patentee's lack of control over the reproducibility of the mouse.

At trial, Nadon J found that:

the question of reproducibility is related to the scope of the respondent's invention . . . [B]ecause the respondent is . . . claiming . . . the entire mammal, and the respondent has not made any claims to even minor control over any aspect of the mammal except the presence of the transgene, [thus] the respondent can make no claim to being able to reproduce the mammal at will by doing anything other than ordinary breeding.<sup>56</sup>

Justice Rothstein, for the Court of Appeal, found the oncomouse patentable, holding:

The definition of "invention" in the *Patent Act* does not expressly exclude discoveries that follow the laws of nature. It would thus appear that the reason creations or discoveries that *only* follow the laws of nature do not meet the requirements of patentability is because they are not considered new and unobvious. Rather, such creations or discoveries are considered to have existed and only to have been uncovered by man. Something more is required for patentability, namely, a non-naturally occurring "composition of matter" arising from the application of inventiveness or ingenuity.<sup>57</sup>

The distinction between unpatentable discoveries and patentable inventions was valid and remains undisturbed by the SCC decision that overturned Rothstein J's finding. In the SCC's summary of the appeal decision, it was noted that Rothstein J had

also disagreed with the Commissioner's approach of dividing the invention into two phases on the basis that, once it is accepted that most inventions involve the laws of nature, "there can be no valid basis for splitting an invention between the portion that is the result of inventive ingenuity and the portion that is not."<sup>58</sup>

Was the human ingenuity in this case enough to support a patent claim over the *whole* animal? Claim 1 was even more ambitious in staking claim to all transgenic *mammals*. Though the Harvard scientists who "made" the

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56 *Ibid* at para 134.

57 *Harvard College v Canada (Commissioner of Patents)*, [2000] 4 FC 528 (CA) at para 126 [emphasis in original].

58 *Harvard*, above note 4 at para 139.

mouse demonstrated inventive faculty, theirs was not the sole contribution to the existence of the mouse; why should it be credited as such? This is the “reproducibility” problem the Court grappled with:

[T]he Commissioner determines that there are two distinct phases. The first phase involves the preparation of the genetically engineered plasmid. The second involves the development of a genetically engineered mouse in the uterus of the host mouse. The Commissioner concluded that while the first phase is controlled by human intervention, in the second phase it is the laws of nature that take over to produce the mammalian end product. He was therefore unwilling to extend the meaning of “manufacture” or “composition of matter” to include a non-human mammal. In his view, *the inventors do not have full control over all of the characteristics of the resulting mouse, and human intervention ensures that reproducibility extends only so far as the cancer-forming gene.*<sup>59</sup>

The material distinction for patentability in Canadian law is now between higher and lower life. But, can lower life remain patentable applying the *reproducibility* analysis as a test for agency? Any affirmation of the patentability of lower life was *obiter* since the issue was not before the Court. The Court’s reasoning, however, invites us to revisit the arbitrary line between higher and lower life<sup>60</sup> with a less arbitrary (ANT) framework. Despite any judicial urge to converge with legal norms of other jurisdictions that hold higher life patentable, the SCC’s analysis recognizes that not all labour and agency ought to be legally rewarded with title. The distinction between higher and lower life was rendered moot after the SCC majority decision in *Schmeiser*, where unpatentable higher life embodying the patented subcomponent was found to be an infringing use.<sup>61</sup> According to Haraway,

patent status reconfigures an organism as a human invention, produced by mixing labor and nature as those categories are understood in Western

59 *Ibid* at para 130 [emphasis added].

60 See *Re Application of Abitibi Co* (1982), 62 CPR (2d) 81 (Pat App Bd), where the claim was for both product and processes that resulted from new mixed fungal yeast culture. The fungi were isolated and subjected to increasing concentrations of sulphites and nutrients, surviving yeast were functionally adapted to consume and digest paper mill waste product. The Patent Commissioner accepted the Patent Board’s recommendation to allow the claims over these micro-organisms as invention so long as they could be recreated uniformly on large scale and at will.

61 *Monsanto Canada v Schmeiser*, 2004 SCC 34; see also Amani, above note 4 at ch 3.

law and philosophy, patenting an organism is a large semiotic and practical step toward blocking nonproprietary and nontechnical meaning from many social sites — such as labs, courts, and popular venues.<sup>62</sup>

Common law jurisdictions may well have the most experience in determining where to draw the lines between unpatentable discoveries and patentable inventions<sup>63</sup> but the determination is “both fuzzy and arbitrary.”<sup>64</sup> The remaining question is whether DNA could be patentable under an ANT lens. As Dutfield aptly states, “[n]o legal distinction is scientifically trustworthy.”<sup>65</sup>

#### **D. LAW, SCIENCE, AND BIOMEDIA: CODE, CHEMICALS, AND COMMUNICATION**

The discovery of the double helix structure of DNA in 1953 by James Watson and Francis Crick and the subsequent development of mapping technologies were essential for the advancements made in molecular genetics and the intensification of the biotechnology industry.<sup>66</sup> Watson and Crick “appropriate[d] the metaphors of ‘information’ and ‘coding’ to describe their elucidation of the structure of DNA.”<sup>67</sup> The “coding problem” became a central concern for molecular biology.<sup>68</sup> The metaphors stuck<sup>69</sup> as DNA paved the way for subsequent decryption projects, as the Human Genome Project (HGP), Human Genome Diversity Project, and the HAPMAP project.<sup>70</sup> DNA

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62 Donna J Haraway, *Modest\_Witness@Second\_Millennium.FemaleMan@\_Meets\_Oncomouse™: Feminism and Technoscience* (New York: Routledge, 1997) at 82.

63 Dutfield, above note 2 at 531.

64 David Vaver, *Intellectual Property Law: Copyright, Patents, Trade Marks*, 2d ed (Toronto: Irwin Law, 2011) at 294.

65 Dutfield, above note 2 at 539–40.

66 Carlson, above note 42 at 10, citing examples such as farming, breeding, biofuel production and bioremediation, etc.

67 Eugene Thacker, *Biomedica* (Minneapolis: University of Minnesota Press, 2004) at 146.

68 *Ibid.*

69 Kevin Davies, *Cracking the Human Genome: Inside the Race to Unlock Human DNA* (New York: The Free Press, 2001).

70 The HGP, an international public collaborative scientific research project launched in 1988, met with private competition from Craig Venter, an abdicator from the project. The completion of the mapping was announced in 2003. Already more than 4,000 of the approximately 24,000 genes had been claimed in US patents. See generally Amani, above note 4.



gave new legitimacy for the use of science in the law,<sup>71</sup> importing a certain indisputability, authority, and complexity into the law while simultaneously mediating its relationship with science. In some areas, such as the use of DNA in the criminal context, we listen to the claims of science regarding what DNA *communicates* as informational code<sup>72</sup>—even if our reception of the message is flawed or leads to unsupported genetic determinism, errors in human translation, and potential manipulation. As one judge put it, “[l]ike aliens from outer space, then, science has invaded the courtroom . . . . Nevertheless, judges frequently find it difficult, and sometimes bewildering, to come to grips with science . . . .”<sup>73</sup>

The genetic revolution prompted the revolution in biopatenting. The view of DNA as code was rewritten judicially with articulation of “DNA as chemical”<sup>74</sup> and has since gained hegemony. As chemicals, DNA is patentable because of its isolation and purification—criteria that mythologically rewrite DNA as “invention” rather than “discovery.” The 1995 case *Howard*<sup>75</sup> found that “[i]t is established patent practice to recognise novelty for a natural substance which has been isolated for the first time and which had no previously recognised existence.”<sup>76</sup> On appeal, the Technical Board of Appeal affirmed that, “[i]t is worth pointing out that DNA is not ‘life,’ but a chemical substance which carries genetic information and can be used as an intermediate in the production of proteins.”<sup>77</sup>

Myriad Genetic’s controversial BRCA1 and BRCA2 gene patents associated with a propensity to develop breast and ovarian cancer further tested this concept in *Ass’n for Molecular Pathology v United States Patent and Trademark Office*. On petition for certiorari, the USSC vacated the Federal Circuit’s

71 See Neil Gerlach et al, *Becoming Biosubjects: Bodies, Systems, Technologies* (Toronto: University of Toronto Press, 2011).

72 See Thacker, above note 67 at 64.

73 Rakoff, above note 14 at 1380.

74 In *Parke Davis and Co v HK Mulford and Co*, 189 F 95 (SDNY 1911), *aff’d* 196 F 496 (2d Cir 1912), Justice Learned Hand had to address the patentability of adrenaline as a purified form of a natural product that was extracted from the other gland tissue in which it was found; see also Dutfeld, above note 2 at 534 for analysis of the significance of this decision in enabling the patentability of natural products.

75 *Re Howard Florey Institute-Relaxin*, [1995] EPOR 541 (Opp Div). The product claims were characterized by their chemical structure and disclosed a use of the protein encoded by the DNA. All charges for invalidity were dismissed: “until a cDNA encoding human H2-relaxin and its precursors was isolated . . . the existence of this form of relaxin was unknown” at para 4.3.1; though pregnant bodies are natural producers of this hormone.

76 *Ibid* at para 4.3.1.

77 *Ibid* at para 6.3.4.

decision reversing the District Court finding<sup>78</sup> and remanded the matter to the Federal Circuit for reconsideration of the validity question in light of the USSC *Prometheus* decision. On 16 August 2012, a two to one panel of the US Federal Circuit Court of Appeal reaffirmed the view that both isolated DNA and cDNA are patent eligible and ruled in favour of Myriad's gene patents. The majority found that "[e]verything and everyone comes from nature, following its laws. But the compositions here are not natural products. They are the products of man, albeit following, as materials do, laws of nature."<sup>79</sup> The majority drew a distinction between unauthored "native" DNA and "invention":

[T]he challenged claims are drawn to patent-eligible subject matter because the claims cover molecules that are markedly different—have a distinctive chemical structure and identity—from those found in nature. It is undisputed that Myriad's claimed isolated DNAs exist in a distinctive chemical form—as distinctive chemical molecules—from DNAs in the human body, *i.e.*, native DNA. Natural DNA exists in the body as one of forty-six large, contiguous DNA molecules. Each of those DNA molecules is condensed and intertwined with various proteins, including histones, to form a complex tertiary structure known as chromatin that makes up a larger structural complex, a chromosome . . . . Isolated DNA, in contrast, is a free-standing portion of a larger, natural DNA molecule. Isolated DNA has been cleaved . . . or synthesized to consist of just a fraction of a naturally occurring DNA molecule.<sup>80</sup>

Simply cleaving covalent (chemical) bonds to isolate the BRCA1 and BRCA2 genes from the rest of the DNA was now sufficient to gain a patent. For the dissent, genes could not be patented simply because they were isolated from the body; this would be like recognizing snapping a leaf from a tree as worthy of a patent. Though chemically different in structure once severed and with potential new uses, the leaf is no less a leaf found in nature. Though the majority agreed that snapping a leaf would not make the leaf patentable, they rejected the analogy to the DNA context: "Snapping a leaf from a tree is a physical separation, easily done by anyone. Creating a

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78 *The Association for Molecular Pathology v United States Patent and Trademark Office*, 653 F 3d 1329 (2011).

79 *The Association for Molecular Pathology v United States Patent and Trademark Office*, 2010-1406 (Fed Cir 2012) at 51-52 [*Assn Molecular Pathology*].

80 *Ibid* at 44-45.

new chemical entity is the work of human transformation, requiring skill, knowledge, and effort.”<sup>81</sup> It is not clear why, in deciding patentability, the change in the structure of DNA should be decisive when the isolated DNA continues to function as information in the same manner as the native DNA.<sup>82</sup> James Watson’s brief opposed gene patenting and expressed concern over the misapprehension by the court of the unique nature of DNA:

It is a chemical entity, but DNA’s importance flows from its ability to encode and transmit the instructions for creating humans. Life’s instructions ought not be controlled by legal monopolies created at the whim of Congress or the courts.<sup>83</sup>

The panel’s decision was subject to a new petition for *certiorari*, granted by the USSC on 30 November 2012 and heard on 15 April 2013.<sup>84</sup> Twenty-four *amici* briefs were filed, indicating significant public interest in this issue. In the tradition of prior human biopatent cases, the Federal Circuit failed to consider the agency of the person in maintaining her body, her creative contribution was rendered public domain for private appropriations<sup>85</sup> and allowed the law to intextuate the body by inscribing new meanings and socializing stories for exerting inordinate control over the potential for private personhood.<sup>86</sup> Insofar as patents confer exclusive property rights, they create monopolies that limit access and use, and mediate human relations:

[A]s a legal term property denotes not material things but certain rights. In the world of nature apart from more or less organized society, there are things but clearly no property rights . . . [W]e must recognize that a prop-

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81 *Ibid* at 52.

82 Andrew Bowman, “Genes 101: Are Human Genes Patentable Subject Matter?” (2012) 18:4 *Rich JL & Tech* 15 at 21–23.

83 Interest of Amicus Curiae James D Watson in Support of Neither Party, United States Court of Appeals for the Federal Circuit — *Association of Molecular Pathology v USPTO*, No 2010-1406 (15 June 2012) at 2, online: DocStoc.com [www.docstoc.com/docs/123708444/2012\\_06\\_15\\_-\\_james\\_d\\_watson\\_brief\\_on\\_remand](http://www.docstoc.com/docs/123708444/2012_06_15_-_james_d_watson_brief_on_remand).

84 *Assn Molecular Pathology*, above note 79.

85 See *Moore v Regents of the University of California*, 271 Cal Rptr 146 (1990); Karla Holloway, *Private Bodies, Public Texts: Race, Gender, and a Cultural Bioethics* (Durham: Duke University Press, 2011), regarding the HeLa cell line developed from tissue taken from Henrietta Lacks’ cervical tumour.

86 See, for example, Holloway, *ibid*.

erty right is a relation not between an owner and a thing, but between the owner and other individuals in reference to things.<sup>87</sup>

Indeed, “dominion over things is also *imperium* over our fellow human beings.”<sup>88</sup>

On 13 June 2013, in a decision written by Thomas J for a unanimous Court,<sup>89</sup> the USSC held “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA [complementary DNA] is patent eligible because it is not naturally occurring.”<sup>90</sup> The Court’s analysis was informed by policy considerations; namely, the need to ensure balance in the patent regime so as not to impede the flow of information necessary to spur important inventions.<sup>91</sup> Isolated DNA fragments are not patentable because unlike cDNA, it was found, they are naturally occurring and severance of chemical bonds is insufficient human agency to render them otherwise. Isolating DNA from the human genome does not create “a nonnaturally occurring molecule”<sup>92</sup> and is insufficient to warrant a patent. Moreover, Myriad’s claims “are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA.”<sup>93</sup>

The Myriad litigation emphasizes how contentious—and variable—determinations of patentability are, and how contingent on conceptions of nature and degree of “inventive faculty”:

The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA . . . . Myriad did not create anything. To be sure, it found an important and useful gene, but *separating that gene from its surrounding genetic material is not an act of invention.*<sup>94</sup>

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87 Morris R Cohen, “Property and Sovereignty” (1927-28) 13:1 Cornell LQ 8 at 11-12, online: University of Texas at Austin <https://webspace.utexas.edu/ob242/www/cohen.pdf>.

88 *Ibid* at 13 [emphasis in original].

89 *Association for Molecular Pathology v Myriad Genetics Inc*, 569 US \_\_ (2013) at 11, [Assn Molecular Pathology USSC]; Justice Scalia wrote a separate opinion, concurring in the judgment.

90 *Ibid* at 1.

91 *Ibid*.

92 *Ibid* at 14.

93 *Ibid*.

94 *Ibid* at 12 [emphasis added].

The judicial adoption of the view of DNA as chemical enabled the patentability of life as a fragmented, disarticulated, and disembodied part of the self. Yet, it ignored that DNA is also information, something that may well make it analogous to other exclusions such as abstract theorems and scientific principles. While DNA fragments and genes remain patentable in Canada, in the US, ambiguity persists: What is “naturally occurring” and the degree of human intervention necessary to constitute “invention”? Isolation is insufficient but removing introns to create exons-only strands is enough to characterize the resulting cDNA as not naturally occurring but “synthesized,” and therefore patent eligible even if the sequence is “dictated by nature.” Will law remain beholden to lawyers’ particular abilities to evidence “nature”?<sup>95</sup>

DNA is not simply unidirectional code—a linear simplification of genes as encoding for proteins and prescribing protein function and phenotypes. Nor is DNA *merely* chemical (though chemicals themselves can demonstrate a “life cycle”).<sup>96</sup> DNA is, rather, a communication medium in a complex biological and biochemical systems network with other actants. There are reading, coding, translating, and all sorts of other familiar communicative processes engaged in by DNA, RNA, mRNA, etc.<sup>97</sup> The conceptual shift alone to the communicative and discursive view of DNA as biomedica would be a major milestone towards more diversified analyses of the legal issues in biopatenting. Normative understandings operating in the law have broader consequences for us all. Biotechnological intervention is characterized by human conceit; the intervention is irreversible, notes Habermas, in a self-regulated process, and will lead to consequences

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95 See, for example, Brief for Amicus Curiae Eric S Lander in Support of Neither Party, No. 12–398, noting that the Federal Circuit assumed, without citing evidence, that isolated fragments of the human genome do not occur in nature but that in fact these are present in the human body and thus are products of nature.

96 Dutfield, above note 2. “In the article announcing their breakthrough, the polio-makers commented as follows: ‘if the ability to replicate is an attribute of life, then poliovirus is a chemical . . . with a life cycle’” at 535 [footnote omitted]; see also Pier Luigi Luisi, *The Emergence of Life: From Chemical Origins to Synthetic Biology* (Cambridge: Cambridge University Press, 2006) at 25.

97 Bray, above note 5. The author contends that “the distinction between chemistry and mechanics is a human invention and not one that concerns a cell. At the atomic level, all movements entail a chemical change and all chemical changes create movements. The difference is one of degree rather than kind” at 93.

we cannot control.<sup>98</sup> In short, “patent law needs to evolve to recognize that biotechnology is different from all other technologies.”<sup>99</sup>

Marshall McLuhan famously stated that the “medium is the message.”<sup>100</sup> He, amongst other media theorists such as Walter Benjamin and Martin Heidegger, discussed “the ways in which the human subject and the human body are transformed in the interactions with different technologies.”<sup>101</sup> For McLuhan, the “message” is “the change of scale or pace or pattern” that a new invention — new media — “introduces into human affairs.”<sup>102</sup> Indeed, do-it-yourself biology proliferating as biohacking becomes the new play for a young generation of biopunks<sup>103</sup> no longer willing to trust in the “pretense of professionalism and the cult of the expert.”<sup>104</sup> Such interventions may prove problematic but no more so than when conducted in research labs without necessary regulatory oversight.<sup>105</sup> Yet, as a democratic movement to open access to biology and therefore technology, these actors see themselves more as co-actors than inventors and so are willing to co-labour wittingly in everyday grassroot performances<sup>106</sup> that test the capacity for property to enclose biology. Insofar as patent law is a spur or drag on bio-media’s broader social and structural meanings — the unintended or anticipated impact on how society relates — it would help to remain mindful that “patent law is there for human beings in general. They may not read it as

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98 See Hans Jonas, “Lasst uns einen Menschen klonieren” in Hans Jonas et al, *Zur Praxis des Prinzips Verantwortung* (Frankfurt am Main: Suhrkamp, 1985) as discussed in Jürgen Habermas, *The Future of Human Nature* (Cambridge, UK: Polity Press, 2003).

99 Stuart Laidlaw, “Monsanto Decision Hurts Equity, Innovation Expert Ruling Sows Seeds of Conflict; Court Treats Genes like any Old Widget Richard Gold Thinks that’s a Big Mistake” *Toronto Star* (21 June 2004) DO1 at 1, quoting Richard Gold; see generally, Amani, above note 4.

100 Marshall McLuhan, *Understanding Media: The Extensions of Man* (New York: McGraw Hill, 1964) at 9, online: <http://beforebefore.net/8Of/s11/media/mcluhan.pdf>.

101 Thacker, above note 67 at 7.

102 McLuhan, above note 100 at 8.

103 Marcus Wohlsen, *Biopunk: Kitchen-Counter Scientists Hack the Software of Life* (Toronto: Penguin Books, 2011).

104 *Ibid* at 6.

105 See, for example, Martin Enserink, “Scientists Brace for Media Storm Around Controversial Flu Studies” *Science Insider* (23 November 2011), online: Science Insider <http://news.sciencemag.org/scienceinsider/2011/11/scientists-brace-for-media-storm.html>; see also Carlson, above note 42 at 19.

106 Kac, *Signs of Life*, above note 34. Kac notes that “[i]n art, to work with biomedicine is to manipulate life, and . . . is part of the global network known as evolution” at 3.

avidly as they read literature, but they are nevertheless touched by the law at least as — if not more — significantly, whether they know it or not.”<sup>107</sup>

## E. ON COLON-IZATION AND INDIGINEITY: TRANSGENICS AND YOU, A MODERN DAY MASH-UP

This paper began with the space adventure of *Prometheus* and travelled to inner space with the 2012 *Prometheus* decision; “[t]he two new investment frontiers, outer space and inner space, vie for the futures market.”<sup>108</sup> The final frontier may be the colon-ization via fecal transplants currently contemplated as a means to restore the destroyed flora, the “natural ecosystem,” of the gut. The transplants would reintroduce what were indigenous bacteria. These natives did not survive our over-consumption of prescription antibiotics.<sup>109</sup> The aliens within are not simple imaginings of science fiction authors contending “we are all *aliens* until we get to know one another.”<sup>110</sup> Rather, scientific advancements evidence our hybrid selves as transgenic.<sup>111</sup> Our survival and destruction is contingent on the agency of these non-human actors. Some of these boundary penetrating aliens are friendly, others hostile. Their presence renders us the material of modern day mash-ups, generated discursively with the “other” content-providing, sometimes process-abiding, user-generated actants.

Jennifer Ackerman reports that bacterial cells in the body outnumber human cells by a factor of ten to one. She also reports that the number of genes distributed among the friendly bacteria that live in people’s bodies (3.3 million in gut microbiome) outnumber the genes inherited from our

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107 David Vaver, “The Problems of Biotechnologies for Intellectual Property Law” (2004) *Hors Série Les Cahiers de Propriété Intellectuelle: Mélanges Victor Nabhan* 375 at 392.

108 Donna Haraway, “The Promise of Monsters: A Regenerative Politics for Inappropriate/d Others” in Lawrence Grossberg, Cary Nelson, & Paula Treichler, eds, *Cultural Studies* (New York: Routledge, 1992) 295 at 319, citing the work of Sarah Franklin [Haraway, “Promise of Monsters”].

109 Jennifer Ackerman, “The Ultimate Social Network” (2012) 306:6 *Scientific American* 36.

110 Expressed by Commander John Koenig (Martin Landau) in *Metamorph*, the first episode in the second season of the 1999 television series *Space*.

111 Kac, “Life Transformation,” above note 43. “The Human Genome Project (HGP) has made it clear that all humans have in their genome sequences that came from viruses, acquired through a long evolutionary history. This means that we have in our bodies DNA from organisms other than human. Thus we too are transgenic. Before deciding that all transgenics are ‘monstrous,’ humans must look inside and come to terms with their own ‘monstrosity’” at 180.

parents (20,000–25,000). Some of these bacterial genes encode for compounds that the body cannot make while others “train the body not to overreact to outside threats.”<sup>112</sup> Advances in computing and gene sequencing have enabled the development of detailed catalogues of bacterial genes that make up the “microbiome.”<sup>113</sup>

Biotechnology will also force us to redefine the “self” and what constitutes our humanness. In *Harvard*, the majority found that

a judicially crafted exception from patentability for human beings does not adequately address issues such as what defines a human being and whether parts of the human body as opposed to the entire person would be patentable.<sup>114</sup>

We are all bio-objects, with alterable genetic identities, but also biosubjects; our biosubjectivity

alter[s] the field of social relations . . . and troubles traditional modernist dualisms between natural and artificial, human and animal, private and public, and present and future. The subject is both alienated from and dependent upon a fragmented body. It is a subject outside of humanist ethics and firmly within capitalist relations.<sup>115</sup>

Using contemporary immune system discourse, Haraway examines what counts as a self and an actor in a context where images of war and defense against invasions are dominant metaphors. The immune system has “a vast array of circulating acellular products . . . . These molecules mediate communication among components of the immune system, but also between the immune system and the nervous and endocrine systems, thus linking the body’s multiple control and coordination sites and functions.”<sup>116</sup> Immunity is discursive; the body is not passive audience but essential to the performance of the microbe. Moreover,

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112 Ackerman, above note 109 at 38.

113 The law will be forced to mediate these issues as we move into the realm of biobots (biological robots with active biological elements in its body). See, for example, Kac “Life Transformation,” above note 43, for a discussion of Eduardo Kac’s *The Eight Day* art exhibit, featuring transgenic bioluminescent plants, amoeba, fish, and mice that seek to expand biodiversity within “a self-contained artificial ecology” at 176.

114 *Harvard*, above note 4 at para 206.

115 Gerlach, above note 71 at 6.

116 Haraway, “Promise of Monsters,” above note 108 at 323.



[t]he genetics of the immune system cells, with their high rates of somatic mutation and gene product splicings and rearrangings to make finished surface receptors and antibodies, makes a mockery of the notion of a constant genome even within “one” body. The hierarchal body of old has given way to a network-body of amazing complexity and specificity.<sup>117</sup>

To conclude, the body produces not only networks of value but also networks of meaning. Yet, “invention” in biotechnology remains, according to the law, a singular deliberative act unless confronted with a law of nature, as iterated and conceived by the laws of man. Title as an explicit ground for invalidity is not assessed. Still, our composition and capacity for agency is due to the “active ‘de-composition’ of many invisible agents”<sup>118</sup> performing with(in) “us.” Can the mythological Prometheus claim credit for his own healing, his resistance against decay that perpetuated his suffering, any more than Prometheus Laboratories can claim credit for a metabolite process within the body or Harvard for the reproduction of a whole mouse? The failure of the law to address the broader social dynamics in the construction of institutional facts generates the risk of patent law being labelled a fetishized fantasy of active myth makers. The lack of interdisciplinarity in law may well reflect a paucity of interdisciplinarity in legal scholarship and legal education. Where it exists in biopatenting law and industrial policy discourse, the focus has been on a law and economics approach, rather than critical readings of text and language use in law.<sup>119</sup> ANT teaches us that

[n]ature is not a thing, a domain, a realm, an ontological territory. It is (or rather, it was during the short modern parenthesis) a way of organizing the division . . . between appearances and reality, subjectivity and objectivity, history and immutability . . . a fully *political* way of distributing power.<sup>120</sup>

Since “ecology seals the end of nature,”<sup>121</sup> it may serve society well to recognize the coercive power of authority; if we be Gods, so too we are monsters.

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117 *Ibid*; see also Robert Esposito, *Immunitas: The Protection and Negation of Life* (Cambridge: Polity Press, 2011). “[I]f, finally, the immune system is now the cutting edge in this performative dynamic, then a decisive game is played in defining it, not only on the ground of biology but also specifically on the ground of politics” at 153–54.

118 Latour, above note 36 at 474 [citation omitted].

119 Peter M Tiersma, “What Is Language and Law? And Does Anyone Care?” in Frances Olsen, Alexander Lorz, & Dieter Stein, eds, *Law and Language: Theory and Society* (Düsseldorf: Düsseldorf University Press, 2008).

120 Latour, above note 36 at 476 [emphasis in original] [footnotes omitted].

121 *Ibid*.