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7 PATENT LAW'S PROBLEM CHILDREN: SOFTWARE AND BIOTECHNOLOGY IN TRANSATLANTIC CONTEXT

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Introduction

Modern patent law applies across a vast range of developed, developing, and as yet undeveloped technologies. Indeed, the international TRIPS Agreement requires that, with only a few exceptions, patent protection is to be available in signatory nations without respect to technological field.¹ At the same time, modern technologies display a highly varied and even disparate set of technical features, economic characteristics, and innovation profiles.² In order to accommodate this diverse array of technologies, patent statutes incorporate flexible provisions allowing their application to be modulated to the needs of different subject matter categories.³

And yet, even with such statutory flexibility, some technologies fit only very uncomfortably within the ambit of current patent statutes. In particular, recombinant DNA technology and computer software have long been the problem children of modern patent law.⁴ For at least the last thirty years, on both sides of the Atlantic, patent doctrine has been in a constant state of turmoil regarding these technologies,

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1. Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

2. DAN L. BURK & MARK. A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* (2009).

3. *Id.*

4. Dan L. Burk, *The Problem of Process in Biotechnology*, 43 *HOUS. L. REV.* 561, 588 (2006).

sometimes accepting them, sometimes rejecting them, and almost continually revising itself in unsuccessful attempts to accommodate them. This difficulty has been apparent across multiple patent doctrines, including disclosure, obviousness, and utility.

But perhaps the most pronounced difficulties have manifested in attempting to fit inventions from these high technology fields reliably, if at all, within the subject matter provisions of American and European patent law. Despite a lengthy period of consideration and reconsideration, patent authorities in these major jurisdictions have generally failed to settle on a solution to the subject matter problems concerning software and biotechnology inventions. The law on this question remains in constant flux, attempting new formulation every few years, leaving the industries founded on these technologies uncertain as to the criteria for patentability in their fields. No stable resolution to these issues is currently in sight.

However, it may be that the extended effort that has gone into considering the problem has not been entirely in vain, even if no firm criteria for determining software and biotechnology subject matter have yet emerged. Instead, what arguably has emerged from thirty years of judicial, legislative, and administrative struggle is the outline of the problem that bedevils these technologies. This outline is apparent in examining the common threads running not only between decisions regarding these two technologies, but among the law developed by adjudicators in different jurisdictions. A comparative study of such decisions shows that such institutions have consistently relied upon a similar pattern of doctrines, interpretive strategies, and jurisprudential constructs in their attempts to accommodate software and biotechnological developments within patentable subject matter.

In tracing the skein of such decisions we must of course be aware of certain differences in the contexts of the various decisions regarding patentable subject matter. Much of the development of this law in North America has been common law development, generated in the courts, either by judicial interpretation of statutes, or from entirely judicially created doctrine. The United States Patent Office in particular, has a relatively subordinate role in developing the meaning of the patent statute. In Europe, only Great Britain follows the common law approach; other national courts are largely creatures of civil law.

Perhaps more important, much of European patent law development emerges from the intersection of national laws and interpretation of international treaties. The European Patent Office is a treaty organization, with quasi-judicial functions in interpreting the language of the European Patent Convention. Separately and contiguously, the Court of Justice of the European Union, a different treaty organization, assumes responsibility for interpreting the language of European Union directives, as well as the compatibility of national laws with the functioning of a

common market under the relevant community treaties. The language of certain directives has a bearing on the development of patent laws, whereas the functioning of national patent laws has a bearing on the common market. The interpretive latitude of such bodies is markedly different than that of common law courts.

Additionally, it is important in such comparisons to recognize that these treatments of patent law do not develop in isolation. Judges and patent examiners on both sides of the Atlantic are well aware of the decisions of their counterparts elsewhere; they are in frequent communication and familiar with doctrinal developments in other jurisdictions.⁵ International treaties lend a measure of harmonization to the patent regime in different jurisdictions, or may impose constraints channeling local developments along similar courses. Consequently, to the extent that similar patterns of addressing patent issues constitute parallel development, it is often conscious parallelism rather than an independent convergence.

Nonetheless, even bearing such caveats in mind, tracing particular patterns across jurisdictions can help us triangulate on core issues that exist despite disparate institutional and jurisprudential contexts. In examining similar fact patterns from different jurisdictions, I will highlight common approaches to common problems, which I will argue reveal a fundamental deficiency to be corrected in modern patent law.

I. Categorizing Subject Matter

Perhaps the best place to begin tracing the commonalities of treatment in biotechnology and software patenting is in North America, with the landmark decision of the Canadian Supreme Court in *Harvard College v. Canada (Commissioner of Patents)*.⁶ The invention at issue in the decision was the so-called “Oncomouse,” a genetically modified rodent carrying genetic sequences, called oncogenes, that confer on the animal a greater susceptibility to cancer, making it a valuable laboratory model for biomedical research. The mouse was the subject of a lengthy patent battle in the European Patent Office; was celebrated in the United States as one of the first patents on a genetically modified animal; and was the subject of a patent rejection in the Canadian Patent Office, which contended that such living subject matter was not within the scope of the Canadian patent statute.

That decision was upheld by the Canadian Supreme Court. Over a vigorous dissent, the majority of the Court in *Harvard College* accepted the position of

5. See PETER DRAHOS, *THE GLOBAL GOVERNANCE OF KNOWLEDGE: PATENT OFFICES AND THEIR CLIENTS* (2010).

6. [2002] 4 S.C.R. 45 (Can.).

the patent office, holding that a living organism was not within the meaning of the subject matter provisions of the patent statute. The Canadian patent statute defines patentable subject matter as “any new and useful art, process, machine, manufacture, or composition of matter.”⁷ The Court concluded that a living, “higher” organism could not fit the definition for any of these categories. In particular, the majority held that the mouse could not be a “composition of matter” under the statute, reasoning that the ordinary meaning of this term included only inanimate material, not living organisms, or at least, not “higher” organisms such as a mouse. And, if the mouse could not be a composition of matter, then similarly it surely could not be an art, process, machine, or manufacture, placing it outside all the statutory categories.

One finds a surprising strain of vitalism in this opinion—in considering the proper definition of “composition of matter,” the Court dwells on the transcendence of “higher” life forms, arguing that the common understanding of “matter” does not capture this transcendent quality.⁸ The court all but argues that the mouse has a soul; at least it asserts that the common understanding of the term “matter” would be that it lacks whatever vital spark a mouse has. As a consequence, given that a “composition of matter” cannot be alive, the Court concluded that only a new act of the legislature—presumably, using a different terminology—could bring genetically modified higher organisms within the scope of the statute.

In other words, the ultimate rationale behind this conclusion was that a particular technology, such as genetically modified living subject matter—or at least, multicellular genetically modified subject matter—must be within the contemplation of the legislature when enacting the statute, rather than within the ambit of the language chosen by the legislature. The import of such a holding for patent policy is striking. It effectively means that the patentable subject matter canon is closed, reasoning that if the legislature did not envision a particular technology when enacting a statute, it can only mean that unanticipated innovation is not patentable. According to the majority in *Harvard College*, only if Parliament indicated acceptance of a new category could an invention such as a genetically modified mouse become eligible for patenting.

As I have pointed out in previous work,⁹ this result is particularly striking because two decades earlier, the US Supreme Court considered essentially the same question, but reached a diametrically opposite result in *Diamond v. Chakrabarty*,¹⁰ the first American case to squarely address the patenting of living

7. Patent Act, R.S.C. 1985, c. P-4, s. 2.

8. Dan L. Burk, *Reflections in a Darkling Glass: A Comparative Contemplation of the Harvard College Decision*, 40 CAN. BUS. L.J. 219 (2003).

9. *Id.*

10. 447 U.S. 303 (1980).

organisms. The *Chakrabarty* decision concerned a patent application covering a genetically engineered microorganism capable of digesting petroleum. Most of the arguments on either side of the *Chakrabarty* decision paralleled those that either supported or opposed the patent in *Harvard College*. But most surprisingly, the courts in each case were interpreting the identical statutory language, because the subject matter provisions of the Canadian patent statute were lifted almost verbatim from the US statute.

As with the Canadian statute, the US patent statute also states as its subject matter new and useful processes, machines, articles of manufacture, and compositions of matter.¹¹ But unlike the Canadian statute, the US understanding of these terms extends to living organisms. According to the US Supreme Court, the bacterium at issue in *Chakrabarty*, being composed of matter, clearly qualified as a composition of matter under the statute. The Court adopted the very straightforward position that bacteria, whatever their properties as organisms, are composed of matter, and that term as used in the statute includes technologies not specifically foreseen by the legislature. This conclusion was informed by a policy conclusion somewhat contrary to that of the Canadian court: that the US Congress in choosing the language of the statute had intended patentable subject matter to encompass “anything under the sun made by man,” so consequently the language must be read expansively.¹² On the American view, the subject matter categories might be viewed as illustrative, or at least broadly inclusive.

In fact, unless one is possessed by the vitalism that seems to have gripped the Canadian Supreme Court in the *Harvard College* case, it is fairly difficult to identify items in the modern world that do *not* fit into one or more of the four categories of process, machine, composition of matter, or article of manufacture. For example, in addition to the *Chakrabarty* bacterium being a composition of matter, one could easily imagine drafting claims by which such a recombinant bacterium might also constitute an article of manufacture, given that it was the object of human processing, produced in a laboratory. Similarly, one might envision a creative set of claims under which the bacterium could be claimed as a machine—molecular biologists view various microbial structures as molecular machines, including nanoscale electrical motors, flywheels, and driveshafts that drive bacterial flagella.¹³ Indeed, much of current nanotechnology is based on the mechanics of molecular assemblies originating in microorganisms.

11. 35 U.S.C. § 101 (2011)

12. *Chakrabarty*, 447 U.S. at 309 (quoting S. REP. NO. 1979, at 5 (1952)).

13. See Jared Diamond, *Transport Mechanisms: The Biology of the Wheel*, 302 NATURE 572 (1983).

For that matter, claims to the *Chakrabarty* invention need not necessarily be confined to the “product” categories of machine, composition, or manufacture. One could imagine the bacterium being claimed in terms of its processes—although product patents and process patents are generally placed into separate categories, living organisms in fact constitute a discrete set of biological processes. On this view, Chakrabarty’s bacterium comprised a large bag of biochemical reactions, if you will, and could likely be distinguished in terms of such characteristics. It may be that as a practical matter such a characterization would be too onerous as a claims-drafting exercise. But the implication of such a thought exercise is that the Supreme Court’s reading of the statutory subject matter categories as illustrative and inclusive largely transforms the subject matter question into a descriptive problem.

There is of course a critical policy consideration animating the US Supreme Court’s reading of the statute, which is a prescription remarkably different from the Canadian approach in *Harvard College*. Each court read essentially identical language, and purported to defer to the legislative meaning of that language, to reach diametrically opposite defaults: in one case that the categories of subject matter were intended to be open to unforeseen innovation, in the other that the categories were intended to be closed. In other words, the US Supreme Court held that the door to new technologies was open unless Congress explicitly shuts it; the Canadian Supreme Court held that the door to new technologies is shut unless Parliament explicitly opens it.¹⁴ The implication for our analysis here is that the former position invites new readings of the subject matter categories, whereas the latter position precludes them.

A. Describing Biotechnology Inventions

But the *Harvard College* decision was short-lived, at least in its practical effect; within two years the Canadian Supreme Court negated its previous opinion, albeit without directly overruling it. In the subsequent *Monsanto Canada Inc. v. Schmeiser*¹⁵ opinion, the subject matter restrictions of *Harvard College* were undermined and perhaps entirely undone, even though the particular holding of the opinion was retained. The *Schmeiser* case again concerned the patentability of a living, multicellular organism, this time in the form of a genetically modified plant. The plant in question was a patented recombinant canola plant that was resistant to the herbicide glyphosphate; the herbicide was marketed by

14. Burk, *supra* note 8, at 229.

15. [2004] 1 S.C.R. 902 (Can.).

Monsanto under the brand name “Round-Up,” making the plants “Round-Up Ready.” Monsanto alleged that a farmer, Percy Schmeiser, had been growing such “Round-Up Ready” plants without a license from Monsanto, in violation of the Monsanto patent.

Schmeiser argued at trial that he was unaware of the presence of the patented plants in his fields, and did not know how they came to be growing there. It is fairly clear that neither the trial court nor subsequent appellate courts believed this assertion, finding contrary evidence that the plants were placed in Schmeiser’s fields intentionally. Schmeiser’s level of intent or knowledge may have made little difference to the infringement analysis, as intentional or not, making using or selling a patented invention constitutes violation of the patent statute as a matter of strict liability, and requires no scienter. So before the Canadian Supreme Court, Schmeiser argued that Monsanto’s patent could not be proper under the subject matter criteria articulated in the *Harvard College* case: the genetically modified plant was clearly a multicellular, “higher” organism with complexity equivalent to a genetically modified mouse. If the Canadian patent statute does not cover living organisms, so that it does not cover transgenic mice, surely it does not include transgenic plants either.

The Court rejected this argument, albeit in a somewhat circuitous fashion. In the interim between *Harvard College* and *Schmeiser*, the Court had undergone a shift in personnel; the *Schmeiser* opinion was decided by a new majority, written by a justice who had dissented in *Harvard College*, over the dissent of the justice who had written the majority opinion in *Harvard College*. The *Schmeiser* majority, while acknowledging that the court had previously held higher organisms to be unpatentable, observed that the claims in the Monsanto patent were directed to a particular recombinant DNA sequence that conferred herbicide resistance. The *Harvard College* opinion had said nothing about the exclusion of DNA molecules from patentable subject matter. Thus the court reasoned that the Monsanto patent was not precluded by the *Harvard College* decision.

By permitting the “Round Up Ready” plant to be patented as a practical matter by means of a claim to a constituent transgenic DNA sequence, the *Schmeiser* opinion avoided expressly overruling *Harvard College* but instead limited it to insignificance. True, the DNA claimed in the patent happened to be present in the plant, but it was not the plant itself that was claimed. This formalism propagates a version of the *Chakrabarty* description exercise above. After *Schmeiser*, clearly the path to patenting a plant, or a mouse, or any other “higher” organism in Canada is to draft the claims in terms of the genetic modification, not in terms of the host embodying the modification. The *Harvard College* prohibition thus becomes no more than a prohibition on terminology.

B. Expression and Function

Crossing now over the Atlantic, the conceptual thread that begins with *Harvard College* takes on yet an additional twist in the more recent opinion of the Court of Justice of the European Union in *Monsanto v. Cefetra*.¹⁶ This case concerned, once again, Monsanto's herbicide resistance "Round-Up Ready" technology. However, this time the genetically modified plants were soy, rather than canola, and were grown in Argentina, a country where Monsanto held no patent on the herbicide-resistant plant. Patents are national in effect, and no patent owner holds patents to an invention in every possible jurisdiction. As the transgenic soy beans at issue in the case had been grown in Argentina, no patent infringement occurred in the use of the plant there.

The beans were then ground into soymeal, which was imported into the European Union through Rotterdam. Monsanto did hold a Dutch "Round Up Ready" patent, but of course it was not the plant that was being imported: it was a processed product derived from the plant.

However, as in the *Schmeiser* case, the Monsanto patent claims were drafted in terms of the recombinant DNA sequence. Monsanto asserted that the DNA sequence was present in the ground soymeal, so that importation of the meal constituted importation of the sequence, violating its patent. In particular, Monsanto argued that the patent was drawn to protect the DNA sequences *as such*, not in meal or in a plant or any other particularized context.

The importers alleged that this claim was improper under the European Biotechnology Directive, an EU requirement to which the patent law of member states—including the Netherlands—must conform. Article 9 of the European Biotechnology Directive provides:

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.¹⁷

Recital 23 of the directive additionally provides that:

... a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention.¹⁸

16. Case C-428/08, *Monsanto Tech. LLC v. Cefetra BV*, 2010 E.C.R. I-6765.

17. Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13 (EC).

18. *Id.* pmbl. ¶ 23.

Interpreting the Biotechnology Directive, the Court of Justice of the European Union rejected the assertion of the patent against the DNA in the soymeal. The Court took the inverse proposition of Article 9 as limiting biotechnology patents: protection shall *not* extend to material in which the genetic information does *not* perform its function. The DNA sequence, although present in the soymeal, was clearly not performing its function, because the material in which it was situated was dead. Even if the patent were properly read under Dutch law to cover the DNA sequence as found in the meal, this reading would conflict with the language of the Directive.

The opinion distinguishes between DNA as “genetic information” and as constituting “technical information,” which is to say, as enabling biological function. It seems clear the language in the Directive serves to deter naked claims to DNA, by linking molecular claims to a biological function.¹⁹ In the United States such claims have been similarly limited, under the utility requirement for patentability, by requiring disclosure of the biological function of the gene to which the patent is directed.²⁰ Because the rate of discovery for DNA sequences far outpaces their characterization, absent such limitations, claims to isolated DNA molecules could be advanced long before their biological function is known, preempting later beneficial applications of the molecule.

However, the *Cefetra* opinion extends this restriction to create a functional limitation on DNA *product* claims. This not only assumes that the biological function of the process is known and disclosed, it ties DNA product claims to a particular process implementation.²¹ By limiting DNA claims to a functional milieu, nucleotides become patentable only as part of a larger biological apparatus. This mirrors the rationale of decisions concerning software in the context of digital processing apparatus,²² a parallel line of precedent to which we now turn.

II. Subject Matter Exclusions

As we have seen above, nearly everything “under the sun made by man,” if properly described, potentially fits into one or another of the American subject

19. Andreas Hübel, *General Issues of Biotech Patents*, in *BIOPATENT LAW PATENT STRATEGIES AND PATENT MANAGEMENT* 1, 10 (Ulrich Stols ed., 2012).

20. *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

21. See Sven J.R. Bostyn, *A Decade After the Birth of the Biotech Directive: Was It Worth the Trouble?*, in *BIOTECHNOLOGY AND SOFTWARE LAW: A COMPARATIVE REVIEW OF NEW DEVELOPMENTS* 221, 231 (Emanuela Arezzo & Gustavo Ghidini eds., 2011).

22. See Kambiz Fathi, *Scope of Protection of Gene Patents in Europe*, 48 (Dec. 9, 2011) (Master's Thesis, University of Stockholm), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1970209.

matter categories. This realization leaves one to wonder if there are items that, even if described so as to fit one or more of the statutory categories, are *not* “made by man” and so might be excluded from patentable subject matter. In fact patent law, both in Europe and America, deploys a series of doctrines intended to winnow out patent candidates that are not inventions by virtue of existing independent of, or perhaps prior to, human ingenuity. In the United States these doctrines have been primarily addressed in a series of cases dealing with the patentability of computer software.²³ This developmental path may seem odd, given that computer technology seems clearly a product of human engineering, and other technologies such as biotechnology may seem drawn from natural materials. However, as process-based inventions, digital processors implement general principles in a manner that tends to implicate the division between the natural and the artificial.

Additionally, such software decisions are tightly coupled to the biotechnology developments we have already explored. The relevant software cases begin with a trilogy of opinions from the US Supreme Court, beginning in the 1970s. These cases are contemporary with the *Chakrabarty* case, making their way through the US court system at approximately the same time that the *Chakrabarty* case was wending its way to the Supreme Court. *Chakrabarty* followed the first of the major software decisions, *Gottschalk v. Benson*,²⁴ and was initially remanded back to an intermediate court of appeal for reconsideration in light of the second decision in the software trilogy, *Parker v. Flook*.²⁵ The *Chakrabarty* opinion was in turn heavily relied upon in the subsequent decision on software in *Diamond v. Diehr*.²⁶ Notwithstanding the different subject matter, *Chakrabarty* was effectively part of the same contemporaneous discourse as the *Gottschalk*, *Flook*, and *Diehr* decisions.

The earliest of these Supreme Court decisions, the *Gottschalk* case, involved a method or “algorithm” for converting one type of numerical notation into a different type of numerical notation. The algorithm involved application of a particular mathematical procedure to convert the numerical notation; the court characterized patenting the algorithm as tantamount to patenting a mathematical procedure. As previous commentators have noted, *Gottschalk* lay at the confluence of several concatenated patent doctrines dealing with subject matter: the laws of nature doctrine, the abstract ideas doctrine, the mental steps doctrine, and the printed matter doctrine.²⁷

23. Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371, 406 (2005).

24. 409 U.S. 63 (1972).

25. 437 U.S. 584 (1978).

26. 450 U.S. 175 (1981).

27. See Pamela Samuelson, *Benson Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions*, 39 EMORY L.J. 1025 (1992).

Each of these closely related, judicially created doctrines serves to restrict the subject matter categories articulated in the statute.

The first of these, figuring prominently in the opinion, is the prohibition against patenting laws or principles of nature. Among the possible exceptions to the very broad categories encompassed by the language of the American and Canadian patent statutes are items that exist independent of, or perhaps prior to human invention. If the Court in *Chakrabarty* held that anything under the sun made by man falls within patentable subject matter, this implies the inverse that items under the sun *not* made by man do *not* fall within patentable subject matter. Although there is no statutory language to this effect, the Court has at times held that laws and principles of nature, such as the theory of relativity, as well as naturally occurring items such as “a mineral discovered in the earth or a new plant found in the wild”²⁸ constitute unpatentable products of nature.

But this prohibition rests on the somewhat philosophically dubious proposition that what we label “natural law” originates, not from human invention or ingenuity, but as a feature of the material world, preceding human perception. The *Gottschalk* opinion equates mathematical procedures with laws of nature, extending the prohibition on patenting the latter to a prohibition on the former. One might of course question whether mathematics is in some sense constitutive of natural law, somehow embedded in the fabric of the universe, rather than constituting a human construct that is useful to describe the universe.²⁹ And regardless of one's view on the natural state of mathematics, one might question separately whether what we call natural law is not a product of human formulation. Nonetheless, US patent law since *Gottschalk* assumes that mathematics, as well as natural law, is somehow embedded in the fabric of the universe, waiting to be discovered, not invented.

Acknowledging the laws of nature issue leads quickly to the second and related doctrine at issue in the case: the prohibition on patenting abstract ideas. Black-letter patent law has long prohibited the patenting of ideas that have not been reduced to some specific instantiation.³⁰ The relationship to the principles of nature doctrine is almost immediately apparent: all patentable inventions are at some level based upon the operation of natural law or principles. A description of the invention at this abstract level frequently constitutes the idea or concept of the invention. Thus, claims that are not wedded to a fairly specific embodiment may be sufficiently imprecise to encompass the principle of the invention rather than its implementation, and so encompass laws of nature.

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

29. See PHILLIP J. DAVIS & REUBEN HERSH, *THE MATHEMATICAL EXPERIENCE* 410 (1981).

30. Dan L. Burk, *Patenting Speech*, 79 TEXAS L. REV. 99, 137 (2000).

The abstract idea prohibition in turn raises a third problem. Although perhaps not stated as explicitly as the other doctrines, the *Gottschalk* opinion indicated a concern with the mental steps doctrine.³¹ Patent law has long resisted claims encompassing steps that could be carried out in the human mind. To some extent, such claims simply raise practical problems of enforcement: if mental activity were covered by exclusive legal rights, it would be difficult to detect, police, assess, or prove infringement when someone is thinking patented thoughts. The very concept of exclusive rights in mental processes raises in turn related concerns regarding encroachment on freedom of speech and thought. Such concerns might not seem implicated by processes carried out in a digital computer. But to the extent that computers were in the 1970s and early 1980s viewed as “electronic brains,” some correspondence was seen between operations in carbon memory and operations in silicon memory. And, human cognitive processes might be implicated by broad undifferentiated claims including steps that could be carried out in either silicon or carbon memory, which is to say in a constructed data processor or in the human brain.

Fourth, following from the mental steps doctrine is an inevitable concern regarding the “printed matter doctrine.”³² Patent law has tended to reject as unpatentable any claims where the novelty of the invention lies in the arrangement of symbolic indicia. As a practical matter, this prohibition helps to police the boundary between patent and copyright, preventing patents on novel arrangements of symbols that constitute literary or artistic works. But symbolic indicia are of course largely constitutive of software: human-readable indicia at the level of source code, machine-readable indicia at the level of object code. Software is inscribed in magnetic and optical media, and encoded in electronic circuits. The power of computing technology is that it is quite literally inscribed with writing, so that anything that can be described can be modeled in a data processor.³³ Thus, patent claims involving software or recorded data tend to blur the line between function and expression; claims encompassing encoded functional operations could just as well read on recorded texts or music.³⁴

31. See Samuelson, *supra* note 27, at 1056–57.

32. See Burk, *supra* note 30, at 141.

33. Philip E. Agre, *Internet Research: For and Against*, in INTERNET RESEARCH ANNUAL: SELECTED PAPERS FROM THE ASSOCIATION OF INTERNET RESEARCHERS CONFERENCES, 2000–2002, at 25, 27 (Mia Consalvo et al. eds., 2004).

34. See Burk, *supra* note 30, at 144–45.

A. *Tangible Inventions*

In a follow-on case, *Parker v. Flook*, the US Supreme Court held that software that was used to calculate the parameters for an industrial process was not patentable; a numerical “alarm limit” calculation, used to monitor the state of an industrial process, was held too abstract to meet the tests for subject matter.³⁵ But the outcome was decidedly different in the third case the Court took during its twentieth-century run of software decisions, *Diamond v. Diehr*.³⁶ This opinion, citing repeatedly to *Chakrabarty*, held that an industrial process for curing rubber *was* sufficiently concrete to garner a patent, even though the process involved the use of a chemical equation in a digital processor to perform calculations that determined the timing of the process. The difference between *Diehr* and *Flook* appeared to rest largely on the palpability of the end product of the claimed process. In *Flook* it was a number, but in *Diehr* the output was a concrete, tangible, and useful result—that is, cured rubber.

The approval of software claims grounded in “concrete” and “tangible” embodiments ushered in an era of what Professors Lemley and Cohen have called the “doctrine of the magic words.”³⁷ For the next two decades, the Patent Office and lower courts in the United States struggled with the problem of when a claim constituted a claim to software, and when it constituted a *Diehr*-type claim to software implementation. Patent applicants and their attorneys drafted what were effectively software claims in terms of apparatus, engaging in much the same subject matter exercise illustrated above with regard to the *Chakrabarty* bacterium: How many statutory subject matter categories could claims for a software invention be drafted to fit?

The most obvious characterization of software is of course the statutory category of process, as computer code implements a series of electromechanical transformations with a specified output. However, given that “algorithm” is very nearly synonymous with “process,” and *Gottschalk* largely disparaged the patenting of algorithms, the logical category for software became suspect. *Diehr* permitted claims to a type of algorithm, but seemingly only as embodied in mechanism, not pure process claims. But this of course points to a second statutory categorization; as the language of *Diehr* ostensibly valorized software in the context of apparatus claims, many software claims oriented toward characterization as a machine.

35. *Parker v. Flook*, 437 U.S. 584.

36. *Diamond v. Diehr*, 450 U.S. 175 (1981).

37. Mark A. Lemley & Julie E. Cohen, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 9 (2001).

Thus a potential alternative was to claim software as a machine. As some commentators struggling with software in the copyright context have noted, software constitutes a machine built of text.³⁸ But this is of course precisely the characteristic that runs afoul of the printed matter doctrine. Hence, machine-based claims were drafted in terms of the state of the hardware, as configured by software. In a similar vein, yet another alternative was to attempt to describe software as an article of manufacture: for example to claim semiconductor chips inscribed with novel code, or in the now-infamous patent application in *In re Beauregard*, to claim a floppy disc incorporating novel magnetic flux.³⁹ After some resistance, the Patent Office grudgingly agreed to accept such claims, although it is worth noting that recent decisions have limited the use of these claims by examining the patentability of the underlying encoded process.⁴⁰

The overall consequence of the *Gottschalk* decision was that securing allowance of software claims became fundamentally a claims-drafting problem. Claims were couched in terminology either to obscure the presence of software entirely, or to describe it in a way palatable to the examiner's degree of adherence to the cases interpreting the subject matter provisions. This trend reached its apex with the now-infamous Federal Circuit decision in *State Street Bank*, holding that any invention that produced a "concrete, tangible, useful result" fell within patentable subject matter⁴¹—but "concrete" and "tangible" appear to have been metaphors, as the Federal Circuit approved as concrete and tangible results such things as numerical output, which was expressly disapproved by the Supreme Court in *Gottschalk* and *Flook*.

And it is critical to note, with regard to composition of software patents, that several of the limiting doctrines identified in *Gottschalk* might themselves be viewed as inchoate products of indefinite claims drafting and inadequate disclosure. For example, one view of the prohibition against claiming laws of nature is that such claims violate the requirements of enablement, commensurability, and written description. The patentee cannot claim multiple instantiations of an invention unless she has enabled and described those instantiations, but claiming abstractions or principles of nature inevitably encompasses embodiments that are not enabled or described. Conversely, claims that are insufficiently precise might encompass the principle of an invention rather than its implementation,

38. Pamela Samuelson et al., *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308, 2320 (1994).

39. *In re Beauregard*, 53 F.3d 1583 (Fed. Cir. 1995).

40. *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1374 (Fed. Cir. 2011); *Digital Vending Servs. Int'l LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270 (Fed. Cir. 2012).

41. *State Street Bank & Trust Co. v. Signature Fin. Grp.*, 149 F.3d 1368 (Fed. Cir. 1998).

and so encompass laws of nature. Likewise, mental steps are almost by definition difficult to describe and enable.

This view of descriptive inadequacy certainly was the position taken by the Federal Circuit in *State Street*, dealing with business methods.⁴² American patent jurisprudence has displayed a fairly strong historical bias against business method patents, many of which have traditionally involved mental steps or printed matter. Business methods became a recurring issue in software cases; once patent software begins to be patented, it is inevitable that some software will be directed to accounting or investment or inventory or other business methods. But the Federal Circuit opined that there was in fact no prohibition or animus against business methods; rather, that the cases disfavoring business methods had simply invalidated specific patents that failed enablement and claim definiteness—which happened to involve business methods.

B. In Search of the Technical

Such issues were of course not confined to the United States; software patents are sought in other jurisdictions as well. On the other side of the Atlantic, the European patent systems were confronting much the same set of problems.⁴³ There has not been and is not at the time of this writing a pan-European patent; consequently a significant portion of this jurisprudence evolved in the context of diverse national court decisions.⁴⁴ Those from Germany and the United Kingdom are particularly notable in their distinctive approaches to software as patentable subject matter.⁴⁵

Because a complete review of such decisions would exceed the limits imposed by this volume's editors (and perhaps the patience of the audience, as well), I will focus here on decisions rendered by the appellate boards of the European Patent Office. The EPO is charged with examining applications under the provisions of the multilateral European Patent Convention (EPC). The EPC contains explicit treaty prohibitions addressing most of the judicially created doctrines at issue in *Gottschalk*. Article 52(2) of the EPC excludes from patentable subject matter:

- (a) discoveries, scientific theories and mathematical methods;
- (b) aesthetic creations;

42. *Id.*

43. See Justine Pila, *Dispute Over the Meaning of the Word "Invention" in Article 52(2) EPC—The Patentability of Computer-Implemented Inventions in Europe*, 36 I.I.C. 173 (2005).

44. See Rosa Maria Ballardini, *Software Patents in Europe: The Technical Requirement Dilemma*, 9 J. INT'L PROP. L. & PRAC. 563, 567–68 (2008).

45. Convention on the Grant of European Patents, *opened for signature* Oct. 5, 1973, 13 I.L.M. 268 (entered into force Oct. 7 1977).

- (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- (d) presentations of information.⁴⁶

On its face the provision might seem to end the question of patents for computer programs, as the treaty is explicit about excluding them from patentable subject matter. However, Article 52(3) adds a troubling caveat: that the enumerated categories are only excluded from patentable subject matter “as such.”⁴⁷ This leaves the troubling question as to what could be meant by a computer program “as such”—that is, a computer program as a computer program and not as something else.

Answering that question has produced, much as in the United States, two to three decades’ worth of uncertainty and turmoil over software patenting. The EPO has focused on whether an invention as claimed has some type of “technical” nature, which the Article 52 categories such as business methods and computer programs “as such” have been said to lack. Various tests have evolved to assay the technical character of suspicious claims. Initially the EPO looked for inventions to make a “technical contribution” to the art, that is, to have some inventive aspect outside the software.⁴⁸ Later this was amended to look for inventions having a “technical effect,” that is, some concrete output.⁴⁹ More recently even this approach was abandoned to allow any claim involving hardware to come within patentable subject matter.⁵⁰

The parallels between these approaches and those in the contemporary *Gottschalk/Flook/Diehr* trilogy are apparent, as are the attendant pitfalls. As the suspect Article 52 categories frequently are implemented in computing apparatus, it becomes extremely difficult to determine when a computer program, business method, or even a game has a technical character. The result has been the EPO’s version of the “doctrine of the magic words,” by which software patents passed the scrutiny of the examining corps so long as certain suspect terminology was avoided. The attempt to distinguish technical character has produced largely rhetorical stratagems: decades of patent applications concerning software, whose claims were drafted in terms of hardware or apparatus so that the claims would not be drawn to a computer program as a computer program.

46. *Id.* art. 52(2).

47. *Id.* art. 52(3).

48. See Ballardini, *supra* note 44, at 565.

49. *Id.* at 566.

50. *Id.*

The issue is well bracketed by two decisions of the Technical Board of Appeal of the European Patent Office that concern business methods implemented in computer technologies. The first of these is the *Pension Benefits* decision, which considered an automated system of investment—that is to say, a business method.⁵¹ The claims of the patent were drawn to both the method of investment and an apparatus implementing the method. Reviewing the application, the Board opined that a technical character is inherent in the EPC concept of invention, and that merely reciting computing means within a method claim does not confer a technical character on a claimed process invention. At the same time, an apparatus claim to a suitably programmed data processing device would constitute patentable subject matter, rendering the claimed invention patentable subject matter. However the method claims in the patent were rejected as lacking a technical nature.

A later decision, *Hitachi*,⁵² in some respects supports and in others contradicts the *Pension Benefit* outcome. The patent application in *Hitachi* claimed an automated system of auctioning; again, from a categorical perspective, the invention constituted both a computer program and a business method, and was described in an application encompassing both apparatus and process claims. Following the *Pension Benefits* reasoning, the Board's decision again held that the implementation of the invention in hardware, by virtue of incorporating the apparatus, clearly presented a claim with a technical nature. However, unlike the *Pension Benefits* decision, the Board held the *method* claims as executed by means of a physical apparatus also entail a technical nature.

Each of these decisions takes the position that by reciting an apparatus claim implementing the method, the method characterized as hardware comes within patentable subject matter, and no longer constitutes a program “as such.” This is essentially a version of the drafting techniques already discussed for the United States following *Diamond v. Diehr*. The opinions part ways with regard to the permissibility of method claims as method claims. But both cases then deny the applicant a patent for failure of an inventive step, holding that given the invention, implementation in a general purpose data processor is obvious.

This approach is logically somewhat suspect due to what American courts would term “hindsight reconstruction”; that is, taking the invention as given when assessing its own inventiveness. Such an approach comes very close to the discredited analysis of *Parker v. Flook*, which considered an abstract method as its

51. Case T 0931/195, *Controlling Pension Benefit System PBS Partnership*, [2001] OJEP 441.

52. Case T 0258/03, *Auction Method/Hitachi*, [2004] OJEP 575.

implementation's own prior art.⁵³ But notwithstanding the questionable logic of the inventive step analysis, the overall outcome of the cases may chart the most pragmatic and productive route for questions involving problematic technologies. Rather than struggle with intractable subject matter questions, the decisions concede that interminable, unwinnable fight; grant the method patentable subject matter status; and instead hold firm on the patentability questions of utility, novelty, and obviousness. This approach was unfortunately rejected by the US Supreme Court when recently urged by the Obama administration as a sensible resolution to subject matter confusion.⁵⁴ But the EPO decisions may chart a path to a more sensible subject matter jurisprudence.

Or perhaps they will not. It is worth noting that the president of the EPO, perhaps in response to the invitation of a British court attempting to fathom the EPO case decisions,⁵⁵ convened an enlarged Board to reconcile the disparity between the approach typified by *Hitachi* and that typified by *Pension Benefits*.⁵⁶ After spending considerable time with the problem, the Board declined to do so, issuing an opinion that some variation was inevitable in developing technologies. Given that the technology, and the problems associated with claiming, have been developing for a good thirty years, it is difficult to understand how much more development is needed before a coherent approach could be articulated.

III. Process and Apparatus

The subject matter themes found in biotechnology and software cases converge in a series of recent disputes over patents for diagnostic tests. These cases combine the recurring questions we have seen regarding principles of nature, mental steps, abstract ideas, and subject matter categories. Although these process inventions frequently involve some biological molecule, sometimes including DNA or another nucleic acid, and may be automated, employing some type of digital processor, the doctrinal convergence is due to more than a technological convergence. The method claims at issue in such cases involve biological rather than electronic processes, but implicate the same set of doctrines and policies.

53. See *Diamond v. Diehr*, 450 U.S. 175, 189 n.12 (rejecting the prior art approach of *Parker v. Flook*, 437 U.S. 584 (1978)).

54. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1304 (2012).

55. *Aerotel Ltd. v. Telco Holdings Ltd.* [2006] EWCA (Civ) 1371 (Eng.).

56. See Justine Pila, *Software Patents, Separation of Powers, and Failed Syllogisms: A Cornucopia from the Enlarged Board of Appeal of the European Patent Office*, 70 CAMBRIDGE L.J. 203 (2011).

The commonality is largely a product of the form of the claims at issue more than of the particular technology involved. The most troublesome diagnostic claims have been directed to minimalist versions of test procedures, seemingly relatively low-tech processes centered on drawing a biological sample and performing simple chemical analysis, possibly by hand. Rather than reciting a specific apparatus they claim the steps of testing and diagnosis simpliciter. Consequently, as in the software controversy over mental steps, these claims do not distinguish whether the procedure is to be performed in silicon or carbon data processors, and they are concomitantly broad enough to encompass the idea or principle on which the test is based.

Claims of this type were at issue in *Labcorp v. Metabolite*,⁵⁷ where the diagnostic process claims at issue involved a “correlation” step—that is, testing for the presence of a certain substance in the blood of a patient, and deciding on the basis of the concentration of that substance whether the patient was ill. This case was originally accepted for review by the US Supreme Court, then dismissed as having been improvidently granted review.⁵⁸ Justice Breyer, dissenting from the dismissal order, indicated in a lengthy opinion his discomfort with such patents as possibly encompassing laws of nature—that is, the relationship between a certain metabolite and disease—and possibly encompassing a “mental step” in the doctor’s recognition of disease from a test result.⁵⁹ Breyer urged review of the case or a similar case in order to reign in subject matter overreaching. Breyer’s commentary signaled to lower courts the likelihood of Supreme Court action on the topic, and is widely credited with moving the inferior Court of Appeals for the Federal Circuit away from its permissive “useful concrete tangible result” test for patentability.

Nonetheless, similar patents continued to issue, and the Supreme Court took up this series of questions in the *Mayo v. Prometheus*⁶⁰ decision, another diagnostic method case. The method claims in the patent held by Prometheus were drawn to the process of measuring the levels of certain metabolites in a patient’s blood after administering thiopurine drugs, and then adjusting the dosage to avoid either an ineffectively low or harmfully high dosage. As in *Metabolite*, the patent was challenged on the ground that its claims were essentially drawn to laws of nature, that is, to the relationship between the level of metabolites in the patient’s blood and the efficacy of the drug dosage. Additionally, also as in

57. *Lab. Corp. of Am. Holdings (LabCorp) v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006) (per curiam).

58. *Id.*

59. *Id.* at 126–28 (Breyer, J., dissenting).

60. 132 S. Ct. 1289 (2012).

Metabolite, the claims included a “determining” step that could have been characterized as an impermissible mental step.

The court focused on the “principle of nature” argument, relying on the reasoning from the *Diehr* and *Flook* software decisions to emphasize that processes consisting largely or entirely of physical correlations, without some significant physical apparatus or application, lie outside patentable subject matter. The Federal Circuit had opined that the claims met this standard because they involved a “transformation” of matter in vivo, which is to say that the drug administered to the patient metabolized in the body to the substances measured. But the Supreme Court viewed metabolic transformation itself as merely the product of natural biological processes, and inconsequential in limiting claims to the process of gathering data from which physicians could draw an inference about the patient’s treatment. The Court particularly emphasized that broad method claims of this type could preclude use of the underlying principle, potentially inhibiting future research or advancement based on the principle.

The commonalities between the software cases and the diagnostic cases are not limited to the appearance of the laws of nature or mental steps doctrines. The printed matter doctrine has reared its head in the diagnostic cases as well, as for example in the *King Pharmaceuticals v. Eon Labs*⁶¹ decision from the Federal Circuit. The claims in the contested *King* patent concerned a method of administering a pharmaceutical orally with food, which was shown to increase the efficacy of the drug. There was nothing new about the drug or its use in treatment, or oral administration. For that matter, people had long taken the drug with food, but had done so to avoid an upset stomach, rather than to increase the efficacy of the drug. The only new aspect of the method was informing or encouraging the patient to take the drug with food for enhanced efficacy. Thus, the claims of the method of treatment patent at issue were drawn to either verbally informing the patient of the positive effects of administering the drug with food, or communicating this information to the patient by means of a printed label on the drug container.

The most recent chapter in this ongoing story is found in the American court decisions involving the so-called Myriad gene patents, *Ass’n for Molecular Pathology v. United States Patent and Trademark Office*,⁶² a case that was recently decided by the US Supreme Court.⁶³ The lawsuit is contemporary with the *Bilski*, *Prometheus*, and *King* lawsuits, moving through the court system in

61. 616 F.3d 1267 (Fed. Cir. 2010).

62. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012), *aff’d in part, rev’d in part*, 133 S. Ct. 2107 (2013).

63. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

parallel with those decisions. The *AMP* lawsuit concerned claims to genetic sequences and to diagnostic procedures employing the gene sequences, for BRCA-1 and BRCA-2, which confer on carriers of the genes a heightened risk of breast cancer.⁶⁴ Both the product patent claims directed to the nucleotides and the process patent claims directed to using the sequences were challenged as encompassing unpatentable laws or products of nature.⁶⁵

The Myriad product claims included different types of molecules with different relationships to naturally occurring DNA. The patent claimed both “isolated and purified” genomic (gDNA) sequences, as well as complementary (cDNA) sequences, that are reverse transcribed from messenger RNA (mRNA) transcripts drawn from human cells. The genomic sequences were a particular target of the “products of nature” argument, as their nucleotide sequences were drawn from those found in the human body. However, relying on several decades of precedential practice from the USPTO, Myriad argued that the limitation in the claim to “isolated and purified” sequences set them apart from naturally occurring DNA. The DNA sequences as found in human somatic cells are surrounded by and bound to an array of other macromolecules, making the isolated sequence a product of human intervention that is not naturally occurring.

Myriad further argued that, even if the claims to isolated genomic DNA read on products of nature, the patent claims to cDNA did not. cDNA does not normally exist in human cells, being the product of a laboratory reverse transcription procedure using mRNA transcripts as a template, read by a special type of viral enzyme that will assemble a DNA strand complementary to the RNA.⁶⁶ As a result, cDNAs typically have structural and coding differences from genomic human DNA; in particular, they are missing long “intervening sequences” or “introns” that are not transcribed into mRNA, and so are not present in the reverse transcribed cDNA.⁶⁷ Transcription from RNA to DNA does not normally occur in human cells, so that the claimed cDNAs were fairly clearly the product of human intervention.

However, the trial court held both types of DNA molecules, cDNA and gDNA, unpatentable, reasoning that they contained the same “information” as a native DNA strand, which is to say that they contained essentially the same coding sequence.⁶⁸ As the “physical embodiment of genetic information,” the

64. *Ass'n for Molecular Pathology*, 689 F.3d at 1309.

65. *Id.* at 1317.

66. JAMES WATSON ET AL., *MOLECULAR BIOLOGY OF THE GENE* 745 (6th ed. 2008).

67. *Id.* at 415.

68. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 230 (S.D.N.Y. 2010).

trial judge found them to constitute products of nature rather than products of human invention. The court additionally held Myriad's process claims, drawn to the use of the genes in diagnosis, to be unpatentable on much the same grounds as the Supreme Court later articulated for invalidating the *Prometheus* diagnostic claims. The process claims recited a method for assessing the relationship of particular nucleotide sequences to the risk of breast cancer, without specifying any particular apparatus or embodiment. This, the court reasoned was tantamount to patenting a natural principle: the correlation between the presence of certain DNA variants in the body, and the risk of developing breast cancer.⁶⁹

On appeal to the Federal Circuit, and again subsequently on remand to the Federal Circuit from a brief sojourn at the Supreme Court, a three-judge panel unanimously upheld the trial judge's holdings with regard to the Myriad diagnostic claims, unanimously reversed the trial judge's holding regarding cDNA, and reversed by a majority the holding regarding gDNA.⁷⁰ The panel all agreed that the process claims encompassed abstract laws of nature, and all agreed that cDNAs are the patentable product of human intervention, but split regarding the "product of nature" claims for gDNA.

In fact, even the majority of the panel was in many senses a plurality, reflecting a three-way division of opinion as to how to think about the genomic DNA claims. Judge Bryson, in dissent, fully embraced the trial court's characterization of the genomic sequence DNA as an unpatentable natural product.⁷¹ Judge Lourie, writing for the majority, reached his conclusions by focusing primarily on the structure of the gDNA molecules, noting that the nucleotide chains, having been separated from their native environment of the chromosome, have a different chemical structure than the same sequences as found in human cells.⁷² Judge Moore, in concurrence, reached the same conclusions, but did so by focusing primarily on the function of the gDNA, noting that the DNAs claimed in the patent could be used for a variety of purposes that a native molecule could not.⁷³

The interplay between the district and appellate courts in *AMP* echoes and reprises certain themes recognizable from the computer software cases. Aside from the familiar "principle of nature" treatment of the diagnostic method claims, much of the discussion hinges on the proper categorical treatment of information-based inventions. Indeed, the discourse among the appellate judges,

69. *Id.* at 233–34.

70. *Ass'n for Molecular Pathology*, 689 F.3d at 1303.

71. *Id.* at 1327–28.

72. *Id.* at 1350.

73. *Id.* at 1341–43.

and between the appellate and trial judges, can be seen as a disagreement over “technical character” in a different context. At the Supreme Court, a unanimous court held gDNA to be unpatentable, but preserved the patentability of cDNA. The Supreme Court majority opinion appeared to adopt the informational view of gDNA, rather than focusing on the structure and function of the gDNA molecule. The Court also explicitly declined to pass judgment on the application of gene sequences and on other manipulations of the genetic code.

Conclusion

It is impossible to trace the trajectory of these cases without being struck by the multiple intricate cross-connections. The issues raised by biotechnology and software patenting cross both technological and jurisdictional boundaries. It may come as something of a surprise that *Gottschalk* and *Diehr* can only be properly read in the context of *Chakrabarty*, or that *Hitachi* and *Pension Benefits* are best understood in tandem with *Monsanto v. Cefetra*. But what may be more surprising is that full comprehension of the ramifications of the *Cefetra* decision requires the context provided by *AMP* and *Schmeiser*, or that the reasoning of *Hitachi* and *Pension Benefits* tracks both *Gottschalk* and *AMP*.

Reading such cases together demonstrates the recurrent doctrinal pattern in both biotechnology and software subject matter decisions. First, in comparing the cases reviewed here, it should be apparent that the doctrines invoked in such cases—laws of nature, abstract ideas, mental steps, printed matter—not only substantially overlap with one another but are frequently indistinguishable from one another, blurring across a doctrinal gradient: patent claims that are too abstract run the risk of capturing within their ambit a law of nature; claims that encompass mental steps are too abstract; claims that encompass symbolic indicia may read on mental steps. Hence these doctrines travel in a pack, appearing en masse in the patent decisions addressing biotechnology and software.

The effect of these doctrines, as shown above, is to transform the subject matter problem in biotechnology and software patents into a drafting problem. Language that seems sufficiently concrete, avoiding abstractions or conceptual claiming, will tend to skirt the around the limiting doctrines. Conversely, the prohibitions against software or biotechnology in certain forms shunt claims drafting toward descriptions that encompass familiar and permissible statutory categories (machines, articles of manufacture, compositions of matter), and away from process-based claims.

These acceptable categories are all product categories, and so necessarily tied to a particular physical substrate. And of course process claims, being largely conceptual, are most acceptable when described in terms of some physical apparatus.

The appearance of these doctrinal patterns in contexts that cross technological and jurisdictional boundaries allows us to observe not merely doctrinal similarities, but to excavate the underpinnings of such similarities. A key insight is the presence of informational claims, as acknowledged in cases such as *AMP* and *Cefetra*.⁷⁴ At some level all technology involves the embodiment of information; to a greater or lesser extent all artifacts carry information encoded in technical structures.⁷⁵ This is sometimes easily apparent, as in the case of a mechanical lock and key, and sometimes less apparent. Even artifacts whose informational encoding is not immediately recognizable entail informational content, as thermodynamically defined.⁷⁶

But where classic mechanical, electrical, or chemical inventions were concerned, this aspect of their character could largely be ignored or overlooked. Indeed, because description and specification of informational content is relatively recent and often imprecise, patent law proceeding out of the nineteenth century developed an antipathy toward informational characterizations, leaning instead toward definition of inventive artifacts in terms of more readily observable physical attributes.⁷⁷ We have seen in the reviewed cases above this tropism, across subject matter categories, toward definition by means of physical characteristics.

However, the informational character of process-based inventions is less amenable to being ignored than that of product inventions. Processes, whether chemical, mechanical, or electrical, necessarily implicate the transfer of information, as entropic changes between physical vectors.⁷⁸ Little wonder, then, that processes become suspect subject matter for patents unless limited to the objects or subjects of such transfer. And this antipathy extends to information-based technologies generally. As I have pointed out in previous work, informational encoding is eminent in both macromolecules and computer devices, where informational content is only lightly embodied, and the descriptive line between product and process is blurred.⁷⁹

74. Cf. Justine Pila, *Patents for Genes and Methods of Analysis and Comparison*, 126 L.Q. REV. 534, 538 (2010) (comparing the approaches to definition of invention in the *AMP* and *Cefetra* cases).

75. Burk, *supra* note 4, at 588–90.

76. *Id.*

77. See Dan L. Burk, *Method and Madness in Copyright Law*, 2007 UTAH L. REV. 587, 609–10.

78. Cf. John Collier, *Causation Is the Transfer of Information*, in CAUSATION AND LAWS OF NATURE 215, 221–23 (Howard Sankey ed., 1999).

79. See Burk, *supra* note 4, at 587.

In sum, all the doctrines common to trans-Atlantic software and biotechnology cases concern the disposition of information within patentable subject matter. Broad abstract claims constitute claims to information or information transfer; mental steps implicate the organic recording of information, just as printed matter necessarily implicates the codification of information. Patent doctrine attempts to confine software claims to a particular apparatus for data processing, or limit a DNA claim to the context of a particular function, in an effort to avoid the hard question of how to situate these information technologies within a nineteenth-century legal framework. The cases deploying these doctrines, in any jurisdiction, are difficult to parse, but the deficiency lies not in the “problem” technologies they address. Rather the problem is in the capacity of patent law to function in the information age. Until patent law develops some way to accommodate information-based technologies, courts on both sides of the Atlantic will continue to struggle to apply subject matter limitations.

