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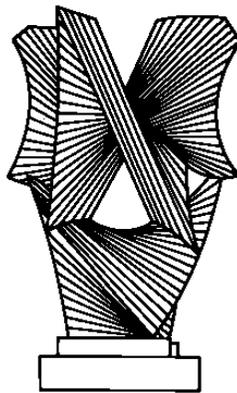
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## Steady the Course: Property Rights in Genetic Material

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## Steady the Course: Property Rights in Genetic Material

Richard A. Epstein\*

All-Or-Nothing-On-Property Rights Few issues today seem to generate more passion than the question of property rights in the human genome. The entire topic has become enmeshed in a multi-front war which takes place in successively narrower theaters.<sup>1</sup> The battle begins with broad questions about attitudes that one has to property rights, writ large, whether it be in human beings, body parts, tissues, cells, or molecules. Do we think that these elements, or some large portion of them, are, as if by nature, inappropriate candidates for reduction to private ownership?<sup>2</sup> For those, and there are many,<sup>3</sup> who think that it is immoral or worse to reduce living substances to private ownership, the debate is over. But for those who find these moral objections either insufficient or misplaced, negotiating this initial hurdle requires that others be surmounted as well. Within the traditional economic framework, is the case made out for creating private forms of property when "the commons" is useful for delivering at least some kinds of goods and services? That question in turn quickly leads to a discussion that is more focused on matters associated with intellectual property law more generally and

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<sup>1</sup>For a comprehensive account of all the arguments, pro and con, see Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for compulsory Licensing and A Fair-Use Exemption*, 76 N.Y. U. L. Rev. 1623 (2001), which collects virtually all the references to this debate. For yet another variation on this progression, see Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights In Genes and Gene Fragments: A Registration Solution for Expressed Gene Tags*, 85 Iowa L. Rev. 735 (2000).

<sup>2</sup>For this argument in another context, see Lawrence Lessig, *The Future of Ideas: The Fate of the Commons in a connected World* (2001).

<sup>3</sup>See, e.g., Jeremy Rifkin, *The Biotech Century* (1998); Jeremy Rifkin, *Genes Ought to Belong to Us All--Not Just to 'Bio- Prospectors,'* *Houston Chron.*, July 2, 2001, at 5C.

patent law in particular. The first inquiry asks, why it is appropriate for the law to adopt a system of patent protection instead of some other form of IP protection, such as copyright or trade secrets, or more generally why the use of private property systems at all, as opposed to state systems of bounties for the production and dissemination of this information. But once it is assumed that patent protection counts as the dominant alternative, we have to ask how the protection of the genome in its many phases comports with the broader objectives of the patent law on the one hand and the particular doctrinal requirements of current patent law on the other.

Let me state my conclusions quickly at the outset. I find little that is persuasive in the categorical objections to creating property rights in human or other living substances. But once that question is left behind, we do have to face hard questions about the structure of property relations. On that question I favor all-or-nothing solutions. There are some human and genetic substances that should be left in the public domain; and there are many that should be governed by the ordinary regime of patent protection, with some marginal adjustments for the distinctive problems of dealing with genetic substances and the biochemical agents used to treat them. I am suspicious of programs that seek to tweak the system with a variety of complex arrangements that rely on subsidies, tax breaks, rewards and honors, and, most notably, compulsory licensing, to outperform this simpler set of rules.<sup>4</sup> This position in fact leaves a number of important degrees of freedom. All-or-nothing solutions can be altered by varying the length of the patent term or the scope of the patent. They can hold that a patent applies with respect to some uses, e.g. commercialization, but not with respect to others, e.g. basic research conducted on a not for profit basis. The argument here is not meant to bias the shift between private and public domain property and strongly endorses the traditional practice of treating the inventions contained in expired patents to fall into the public domain.

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<sup>4</sup> F. Scott Kieff, Property Rights and Property Rules for Commercializing Inventions, 85 Minn. L. Rev. 697 (2001), for a detailed criticism of the shortfall of these alternative allocation rules.

So much for what the all-or-nothing approach does. But what it does not welcome are those clever schemes designed to split the difference, by weakening the normal rights of exclusion attendant on property rights, and subjecting them to either schemes of government condemnation on the one hand or compulsory licensing schemes on the other. It is tempting to think that the problems of monopoly inherent in any scheme of patent protection could be addressed by some system of forced exchanges, such as those which are involved under the law of eminent domain. But they will not work in this area. There is no coherent scheme to decide which patents should be condemned, or how the government should deal with them once condemnation has taken place. Nor do we have the enormous institutional capabilities to make all patent holders into public utilities who are obliged to do business with all comers under prices that are established and administered by the state. The current system is imperfect on any number of points. It is easy to find examples where current institutions lead to unhappy results. It is surely possible to envision intelligent forms of tinkering about the edges of established doctrine. There is a real question, for example, about the optimal scope of a patent. But the current legal structure, whatever its shortcomings, has fueled the enormous surge in biotechnology in the past generation. It is, in a word, best to leave well enough alone. The all-or-nothing solutions: either its private property or in the public domain, dominate any and all efforts to carve out some elegant but inoperable middle position.

The creation of a property rights system in genetic substances is part and parcel of this general debate. In order to place some order on the discussion, I shall proceed as follows. Section 1 addresses the moral arguments against property rights in human materials. Section 2 addresses the choices between common and private property. Section 3 addresses the various schemes for forced reassignment of property rights, first by condemnation and then by compulsory licensing. Section 4 then addresses the issue in connection with genetic material. It concludes first that all expressed sequence tags ESTs should be left in the public domain, and second that the usual rules of patent protection

work about as well as can be expected for most genomic products. We should not let the best become the enemy of the good.

Moral Arguments against Property Rights in the Genome and Elsewhere. One of the systematic objections to the creation of property rights in genetic material represents the vocalization of a powerful and deep sentiment that these technical activities are inconsistent with our considered judgments of what it is to be a human being. The point has been raised in many contexts, as for example, the cloning debate.<sup>5</sup> It surely has had an extensive influence on the way in which philosophers and bioethicists have attacked other problems in the health care system. The point usually starts with some invocation of the proposition that all things that matter in society should not be controlled by the market, which for these purposes can be defined as a system of voluntary exchange, protected and enforced by the state, off a known set of property rights in labor and external things. Those property rights are, the argument generally goes, more easily conferred to persons on things that are external to the self than they are on constituents of one's own being. Here the language of ownership (how does one own himself?) is always regarded as awkward if only because it is impossible to see how the agent (who does the owning) can be identical with the "thing" "or body" that is subject to ownership. Personhood is thus regarded in some sense as a unique category of experience, to which the usual rules on autonomy and voluntary exchange do not apply in any straightforward style.

The articulation of this general position has had payoff in the history of ethical and legal thought. Such notables of the English liberal tradition as Bracton, Locke and Blackstone believed both in the autonomy of the will and in the prohibition against suicide.<sup>6</sup> Their views helped influence the Supreme Court to rebuff any challenge to the

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<sup>5</sup> For a representative sample of views, see *Clones and Clones: Facts and Fantasies About Human Cloning* (ed. Martha C. Nussbaum & Cass R. Sunstein, 1998)

<sup>6</sup> See, e.g., 2 Bracton on Laws and Customs of England 423 (f. 150) (G. Woodbine ed., S. Thorne transl., 1968). "[J]ust as a man may commit felony by slaying another so may he do so by slaying himself." John Locke, *Second Treatise of Government* Chap. II, § 6: "But though this be a state of

prohibitions against assisted suicide.<sup>7</sup> Thus the prohibition against suicide, for example, rested on the belief that self-preservation was the norm for all individuals, so that no person could deprive himself of the agency to reverse his course of action in the future. The objections to voluntary slavery took much the same line: the sale of self\_ was not the same as the sale of any external object given this unity between the subject and the object of the legal rights. The great fear here was that the sale of self into slavery would result in the permanent loss of legal capacity, so that it would become impossible for that person to be able to reverse the transaction.

None of these concerns, of course, has anything to do with the instant issues on the patenting of various manifestations of genetic material. In these contexts, the concern with autonomy is, if anything, urged in precisely the opposite direction. The now classic case on the subject is *Moore v. Regents of California*.<sup>8</sup> At issue in *Moore* was whether the individual patient who had supplied an invaluable cell line was entitled to some ownership interest in the patent that proved to be of tremendous commercial value. The case itself revolved around two potential theories of liability. The first involved a claim for the conversion of the plaintiff's genetic material by the action of the defendant—a claim that necessarily presupposed that the defendant had a property interest in his genetic material in the first place—one that was not “abandoned” during the course of surgery. The second theory was based on an analogy to the law of informed consent in medical malpractice, and claimed that the defendants breached their fiduciary duty when they did not disclose the reasons why they continued to call the plaintiff back for more and more tests, all of which increased their available supplies of his critical cell lines, without disclosing to him their ulterior purpose.

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liberty, yet it is not a state of license: though man in that state have an uncontrollable liberty to dispose of his person or possessions, yet he has not liberty to destroy himself, or so much as any creature in his possession, but where some nobler use than its bare preservation calls for it.” The last phrase seems to be an oblique protection for animals against cruelty. 4 W. Blackstone, Commentaries \* 189. “The law has . . . ranked [suicide] among the highest crimes.”

<sup>7</sup> *Washington v. Glucksberg*, 521 U.S. 702 (1997) and *Vacco v. Quill*, 521 U.S. 793 (1997).  
<sup>8</sup> 249 Cal. Rptr. 494 (Cal. App. 1988), aff'd and rev'd in part in 793 P.2d 479 (Cal. 1990).

The mere fact that a plaintiff could bring the conversion claim at all shows how far this particular protest against the ownership of human beings is from matters of suicide or slavery. The California Supreme Court rejected that claim even as it accepted a version of the disclosure obligation. But on a forward-looking basis, the differences between the two positions disappear. In the simplest scenario under the disclosure obligation, a plaintiff who knows the value of his cell line can refuse the service and look elsewhere, perhaps under a contract with some other physician, to undertake the extraction of all needed materials by himself and then sell those materials to other individuals as part of an ordinary commercial transaction. Once they have been removed from the body, they become a form of tangible property subject to exclusive ownership like any other chattel. The sales or licenses of that material can then be used to give the owner a contractual right to share in the proceeds of any patent that the statutory inventor can claim under the system. It thus becomes a business judgment whether the genetic material is sold for a lump sum or variable payment, contingent on its therapeutic usefulness. On this view of the matter, Moore was stymied only because of his ignorance at the time of the initial surgery and the subsequent visits.

The real question in *Moore* relates to the long-term implications of that flow from the creation of self-ownership of tissues and organs. If the conversion theory had been accepted, as was the case in the Appellate Court, then the critical issue of fact is abandonment, which should not be presumed with respect to material to which both the original owner and, as it were, the subsequent finder attach extraordinary value. Requiring any form of disclosure thus will quickly eliminate any dispute over the abandonment question, because it eliminates the mistake of fact which gives the assertion of abandonment its tenuous plausibility. At that point, the property rights would have been robust.

California Supreme Court, however, refused to accept the conversion claim and thus never had to face the abandonment question at all. In deciding against the property

rights approach in this context, the California Court anticipated many of the concerns in this area, when it denied noted any claims of private ownership of genetic materials could dull the pace of medical innovation, in much the same way that interlocking patents, subject to different holders, could block research on the genome.<sup>9</sup> The point lies certainly at the core of any debate over the scope of patent protection in the genome, but it has little consequence in any forward looking world once the Court held that the treating physicians had a definitive obligation to disclose the fact that the cell line could come from the plaintiff's tissue. Once that disclosure takes place, astute individuals who are aware of the unique value of their cell lines will market them to the highest bidders, as noted above.

Now suppose the physician decides to deliberately breach that duty to disclose. Here, the rejection of the conversion claim means that any third person who takes the patient's genetic material will have clear title to its use, now that the conversion claim has been rejected. But, although the point is not nailed down in *Moore*, it appears that the physician (or his institutional employer) could be liable in damages for the same amount that could be recovered from the third party if the conversion claim had been allowed. Punitive damages could easily be added into the mix. The upshot is that nondisclosure becomes costly for the institutional defendant even if the tort of conversion is banished from the area. Going forward, the remedial differences between the conversion and the nondisclosure regime should not in most cases influence the pattern of control. The better view is conversion because it creates cleaner property rights in those cases where individuals do enter into various kinds of business transactions. But that point is not a

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<sup>9</sup>See Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 Science 698 (1998). The term anticommons adds little to the debate. It only refers to a system in which multiple vetoes stand between an idea and its realization. It is thus a restatement of how the holdout problem can reduce value. For a general proof of the proposition that multiple rights of exclusion have parallel (negative) consequences with multiple rights of access, see James Buchanan & Yong J. Yoon, Symmetric Tragedies: Commons and Anticommons, 43 J. Law & Econ. 1 (2000). For a systematic evaluation of this claim in the patent area, see *infra* at .

first-order consideration. Either way the person with the distinctive cell-lines gets to control them himself.

The above analysis presupposed that the initial choice between conversion and disclosure theories determined the ultimate distribution of rights in this cell-line version of the eternal triangle. But like all property and tort solutions, this one is subject in principle to contracting out. These contracts could be designed to achieve one of two objectives. The first is to exclude the individual patient from the fruits of the use of its genetic materials. That result may well make sense if genetic materials gathered from a large cohort of treated individuals is used to concoct some new genetic compound that depends on assembling the genetic material of hundreds of different individuals. At that point, either no compensation or nominal compensation seems appropriate. And the entire subject is largely moot because the compensation could easily come in a small credit on the bill for services, which may not be separately acknowledged at all.

The situation is much more complex where the cell line from a single individual packs the same punch as it did for Mr. Moore. Here the treating institution could insist on a generalized waiver of all genetic material before any treatment is undertaken. But that waiver could be declined, or itself be subject to attack on the ground of insufficient disclosure of the size of the stakes involved with the transaction. Hence in today's climate, this contractual waiver could be undermined by a disclosure obligation that imitates the underlying doctrine of informed consent. Waiver is very hard to come by, even when normally required in routinized transactions.<sup>10</sup> It would not work well here. Nor should it be tried. The better approach in these situations is to have a provision that allows the institution to use the extracted material in exchange for a value to be determined by some pre-set formula or by arbitration. That agreement could also set the ground rules for further cooperation between the parties, which is critical when other body tissue and fluids contain the key cell-line. They could provide for additional

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<sup>10</sup> See, e.g., *Obstetrics & Gynecologists Ltd. v. Pepper*, 693 P.2d 1259 (Nev. 1985).

insurance to the patient, and do a whole host of things that make joint sense. An agreement that has that larger objective is far less likely to be attacked as an illegitimate because of its intrinsic substantive balance. Nor should one fear that markets will result in these skewed alternatives. The usual view of 19th century employment relations in England was that workers just waived their rights of recovery against an employer for accidental injury on the job. But in many dangerous industries, such as mines and railroads, this is not what happened. Instead these contracts typically put in place a pioneer equivalent of the workers' compensation system that allowed for limited compensation for all accidents that arose out of and in the course of employment.<sup>11</sup> It may be that transactions costs block some transactions, but those that do survive will in general lead to improvements for both parties.

Viewed more broadly, the issue in *Moore* is in some sense orthogonal to that found in the genome cases, for it seeks to track down unique genetic material while the much genomic research finds value in the genetic material shared by all persons in common so that, as a first approximation, the value lies in the genomic material or the derivatives, such as complementary DNA (cDNA), that have medical and economic value. But *Moore* does serve the valuable function of showing that the strong objections against patenting human material cannot rest on any variation of the philosophical tradition of personal autonomy.

The Common versus Private Property. *A Mixed Equilibrium* The next line of argument against the patenting of genes or other genetic material looks less to theories of individual autonomy and more to theories of overall social welfare. The question is what form of property rights in genetic materials will best promote human resources. The potential variations on the theme of property ownership are not unique to intellectual property, but apply with all other sorts of resources. In dealing with this question in its

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<sup>11</sup> Richard A. Epstein, *The Historical Origins and Economic Structure of Workers' Compensation Law*, 16 Ga. L. Rev. 775 (1982).

most general form, the optimal system of property rights requires us to negotiate our way between Scylla and Charybdis. Any system of exclusive ownership in distinctive issues runs the risk of hold-ups. Any system of common (by which I mean open)<sup>12</sup> ownership runs the risk of governance and coordination. The more individuals who fall under the tent, the less likely it is that they will be able to find ways to rule themselves effectively. The divergence of views on what uses to make of what assets will place genuine strains on their alliance, which is why most commons tend to have single uses, such as grazing or traffic. Where heavier levels of investment are needed for particularized uses, the sensible social allocation calls for good neighbors separated by good fences. In other cases we want to knock down those fences and create some form of commons.

This tension has been with us from the earliest times. The creation of the commons carries with it the risk of tragedy, at least if Garrett Hardin is to be believed.<sup>13</sup> But it is in principle quite difficult to draw any inference about the relative strength of private and public property, without some real knowledge of the physical characteristics of the particular resource—land, chattels, water, oil and gas, spectrum, intellectual property—and the details of the legal regime, either common or private that governs its use. It is very difficult, for example, to find strong regimes of private property that govern flowing water. Thus the standard Roman treatment of property rights duly noted that air and water were held in common, given that no one had the right to exclude others from their use.<sup>14</sup> The “going concern” value of the resource depends not only on its chemical formula, but also on its ability to flow from site to site, to support multiple

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<sup>12</sup> An open commons is one in which all may enter. It differs from closed commonses in which a large number of identified people have rights of entry. For the various permutations, see Clifford G. Holderness, *The Assignment of Rights, Entry Effects, and the Allocation of Resources*, 18 *J. Legal Stud.* 181 (1989). On the commons generally, see Elinor Ostrom, *Governing the Commons* (1990); Carol Rose, *The Comedy of the Commons: Custom, Commerce, and Inherently Public Property*, 53 *U. Chi. L. Rev.* 711 (1986). The plasticity of human arrangements is quite large. For a discussion of the semicommons in which land is used privately for growing grain and collectively for grazing cattle, see Henry E. Smith, *Semicommon Property Rights and Scattering in the Open Fields*, 29 *J. Legal Stud.* 131 (2000).

<sup>13</sup> Garrett Hardin, *The Tragedy of the Commons*, 162 *Science* 1243 (1968).

<sup>14</sup> See Justinian’s *Institutes*, Book II, Title I.

human uses (bathing, recreation), as well as to support multiple forms of animal and plant life. The system therefore is one in which private and common uses uneasily *but necessarily* coexist,<sup>15</sup>

There are strong reasons for the creation of the limited commons in water. If each riparian owner could stop its flow, or at least the navigation along his portion of the river, could lead to the loss of this collective use altogether. The (limited) commons removes that blockade right. But all systems of property rights involve implicit economic trade-offs, such that open access creates the reciprocal risk of congestion, which also reduces the value of navigation. The task is to find identify the smaller risk in this setting. Placing intellectual property in a commons however, does not give rise to the same risk for the use of an idea or invention by another does not crowd out its use by a competitor. It is for this reason that placing certain forms of intellectual property within the public domain has always had an enormous attraction, and remains an indispensable part of any property rights regime.<sup>16</sup> The costs of running the system are virtually zero. No one need to purchase or license the property in question from anyone else, because it is always there for the taking. The difficulties in running a system of private contract and private property rights are thus neatly sidestepped, and the use and absorption of the information takes place at a rapid rate. When patents and copyrights are created for limited periods of time, the reversionary interest to the public is in the form of public domain (as opposed to government-owned) property, that has these same welcome characteristics. As will become clear, we best in the world of extremes, where we have either a system of strong private property rights on the one hand or public domain property on the other. What should be avoided at all costs are mixed regimes that feature forced exchanges, be it by state condemnation of patents or by compulsory licensing agreements.<sup>17</sup>

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<sup>15</sup> For discussion, see Richard A. Epstein, *On the Optimal Mix of Common and Private Property*, 11 *Soc. Phil. & Pol.* (No. 2) 17 (1994).

<sup>16</sup> For my views on the heterogeneity of intellectual property, see Richard A. Epstein, *Intellectual Property: Old Boundaries and New Frontiers* (Addison C. Harris Lecture) 76 *Ind. L. J.* 803 (2001).

<sup>17</sup> See *infra* at .

In order to understand how these property rights regimes apply to patent issues generally and to the genome in particular, it is useful to return to the water situation. Suppose that a river (or a bridge) is in need of some improvement in order to become navigable, which require some form of private investment. How ought this to be handled? One possibility allows a single regulated monopolist to charge some kind of toll sufficient to thin out the traffic but not so high as to lead to underutilization of the resource. That response in turn gives rise to the famous marginal cost controversy.<sup>18</sup> The a bridge costs money to build but nothing to maintain. Any positive charge on its operation involves the exclusion from the bridge at someone who attaches positive value to its use that is lower than the price charged. But reduce the cost of the bridge to zero, and then there is no reliable way to determine whether it should have been built in the first place.

Patents raise the same issue. The marginal cost of an additional dosage of a new drug, for example, may be virtually zero, so that any positive price precludes new users at the margin. But even if it is not, there is always a gap between the competitive and monopoly price, such that monopoly pricing always produces deadweight losses. The decision to price it at zero (or at marginal cost) requires some other institution to make the initial decision as to whether, and to what extent, investment should be made in the development of this drug and none other. We cannot avoid some real-world inefficiency; we can only trade in one problem for another.

*Multiple Monopolies* However difficult that last choice might be, it is easy to think of a worse situation: sequential monopolies. One grim possibility (though one, thankfully, never entertained at common law) is to allow each riparian owner to extract a toll of his own choosing, and the combination of obstacles could reduce the value of the river to virtually nothing. That could not happen within a single jurisdiction where property owners were subject to the rule of one sovereign. But it could well happen when

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<sup>18</sup> See Ronald Coase, *The Marginal Cost Controversy*, reprinted in Ronald Coase, (1988).

independent sovereigns could in fact run their portion of a longer waterway. The best way to think of this problem is as an illustration of the so-called double marginalization question, where, when the dust settles, to unrelated monopolists acting independently reduce the social gains from the utilization of their resources.<sup>19</sup> The basic intuition is that each of the monopolists will ignore the harms that his decision imposes on any other monopolist, so that acting separately the riparians do far worse than they would if they coordinate. This problem arises only, however, when the two monopolists stand in an upstream and downstream relationship to each other, a term that is descriptive, not metaphorical, in the water case. So understood the problem of uncoordinated exclusion is the mirror image to the problem of uncoordinated overuse of many rivers, or other rivalrous commons, where again the problem arises because each of the potential users of the common resource ignores the costs that his use impose on others.<sup>20</sup>

So understood, the double marginalization problem presents the opposite of the normal situation, where the (horizontal) monopoly is created when two competitors combine their operations. To continue the water metaphor on this case, it as though the river forked into two branches at the only point where tolls were allowed, such that the owners of each branch could each charge tolls. So long as they operated separately, they formed a Cournot duopoly whose price lies between the monopoly and competitive price.<sup>21</sup> In contrast to the upstream/downstream situation, their combination reduces social welfare by driving the price further from the competitive solution. The combination that is welcome in one context (upstream/downstream) becomes dangerous in another (sidestreams, to coin a phrase). The spatial relationship really matters, such

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<sup>19</sup> See, e.g., See\_Dennis Carlton and Jeffrey Perloff, *Modern Industrial Organization*, 398-410 (3rd ed, XXXX). See also material, *supra* note 8.

<sup>20</sup> See Lessig, *supra*, at 19-23.

<sup>21</sup> For a general exposition, see Gibbons, *etc* (1992); for its application to patents, see Carl Shapiro, *Navigating the patent Thicket: Cross Licenses, Patent Pools, and Standard Setting* (2000)(mss. with author)

that the terms vertical and horizontal are not just blackboard conventions, but are defined by the elemental forces as gravity.

One great difficulty in connection with patent law generally, and with the genome in particular, is that we cannot draw easy spatial diagrams to indicate the relationship that one invention has to any other within the sphere. The first and most obvious feature of all intellectual property is that it does not face the problem found with water usage, where congestion effects do matter. In principle a thousand individuals could use (or, for that matter prove) the Pythagorean theorem before dinner and it remains as available to everyone else as it did before. That characteristic is not characteristic simply of those ideas or laws of nature that have long been held to fall outside the scope of patent protection. They are equally true of any invention (or writing under copyright law) as well. The point is almost beyond dispute because one of the tests of patentability is the requirement that the inventor describe his invention with specific particularity so that others with ordinary skill in the art could make it from his plans.<sup>22</sup> It is here that we face the rub. In the case of water, that is a resource that is (at least in the simplest scenarios) given by nature, so that the key questions are those of its effective utilization. But nature does not gush forth ideas or inventions, and the question then arises as to what system of human relations will best direct both their creation and utilization.

In the case of a single stand-alone patent—which is most emphatically not the case with the genome—the issue of legal protection tends to gravitate to the well-known “bargain.” The inventor gets the exclusive right to use his invention for a limited number of years, so long as he makes public information on how it is created, so that at the expiration of the term it falls into the public domain. The monopoly is created in order to accelerate the invention. Here it should never be forgotten that the *social* benefits from

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<sup>22</sup> See, 35 U.S.C. § 112. “The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor in carrying out his invention.”

the new invention come *during* as well as *after* the patent period. First, it is better that people purchase a good at a monopoly price than they have no good to purchase at all. Thereafter the deal gets even sweeter because the resource comes at zero marginal cost to all those who will use it. As everyone can use the resource, its subsequent exploitation takes place within a competitive framework. Second, even during the period of monopoly ownership, the patent disclosures could easily provide information that could encourage others to develop complementary or supplemental goods.

It is, however, one thing to identify the existence of the trade-off between monopoly today and public domain tomorrow. It is quite another to figure out whether this deal is good or bad from the point of view of the inventor and society. The position of a single present inventor, at least when considered in isolation, does not give rise to any pause. Without the monopoly, the inventor might have chosen some other line of work; so he is better off with limited monopoly protection than with none at all. Alternatively, the inventor could have gone ahead and relied only on the other forms of protection available to him; and again he is unambiguously worse off than he would have been with the additional choice of the patent monopoly. So at first blush the deal looks good from his side as against the feasible set of alternatives.

The situation, however, becomes more clouded in a dynamic sense in light of the multiple roles occupied by inventors as a class. No inventor works in a void; all build off a set of ideas and techniques that were always in the public domain or have lodged their after the expiration of other patents. It may therefore be that this inventor could never have reached the point of invention if the intellectual commons stripped bare. No inventor behind the veil of ignorance wants a system that gives patent protection that is too broad or too long, for that would strangle his own opportunities for innovation in two ways. It would reduce the amount of public domain information on which he could rely; and it would reduce the field of action into which he could move. The case for open use of inventions is even more insistent for society as a whole. It does not consist solely of

inventors, but of large number of individuals who use inventions in all sorts of direct and indirect ways, but do little if anything to create them (even if they own shares in companies with extensive patent portfolios). Yet even noninventors are aware that they cannot utilize today inventions that were not made yesterday.

How then do we make the appropriate balance between protection and access? Debates over this subject are legion. Here the first question that has to be asked is what is the location of any new patent relative to all others in the patent universe. Speaking at the most general level, patents do not self-identify as upstream, downstream or sidestream. Everything depends on the network of existing patents into which they are thrust. It is not even clear that the directional element implicit in these descriptions apply across the board, so that the term "thicket" has been used in order to capture the potentially unruly and nondirectional formations that patents can describe any larger field.<sup>23</sup> Yet in particular situations patents might well line up as either strict complements or substitutes, at which point the analysis follows the argument made above about water rights. The integration of complements avoids the double marginalization problem. The integration of substitutes facilitates cartels. We need to be aware of that difference.<sup>24</sup>

The angular distribution of patents in hot subject matter areas is not lost on patent prosecutors who take enormous care in structuring patent claims for their inventors: make your patent as large as you can to secure an effective scope for future use.<sup>25</sup> But make it too large and you might run into difficulties with infringement or prior art. Finding that balance requires a detailed knowledge of the particular landscape for the inventor and poses genuine problems of analysis for the rest of us. Thus in some cases the new patent could be quite benign in its application. It may introduce a new treatment for, say, intestinal disorders that at first has as its only competitor surgery. But shortly thereafter

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<sup>23</sup> See Shapiro, *supra* at note XX

<sup>24</sup> On which more, see *infra* at .

<sup>25</sup> See generally, Robert P. Merges & Richard R. Nelson, On the Complex Economics of Patent Scope, 90 Colum. L. Rev. 839, 866 n.118 (1990)

someone else comes up with a rival drug over which it has a monopoly that is usable for roughly the same end. Here the legal patent monopoly is demoted to an economic duopoly in relatively short order, and it in turn is subject to erosion by the invention of further substitutes for the proposed treatment, even from remote technologies such as lasers. In this case the creation of side-by-side legal monopolies hastens the emergence of a quasi-competitive situation long before the expiration of the patent period. It is as though there were two or more forks in the river, with no prospect of any form of unified control. The patent system thus appears to foster a great social deal insofar as the second patent competes away many of the gains of the first patent long before expiration. The rash of new entrants undercuts the idea of any systematic patent blockade. Some patents undermine blockades that other patents seek to create.

Within this confused array, however, any two patents could operate in upstream/downstream configuration. That possibility has already been suggested in connection with HGS's recently patented CCR5 receptor gene, where drug companies could be required to get releases from multiple patent holders if it turns out that other inventors obtain patents adjacent to HGS's patent.<sup>26</sup> But this is not the only possible outcome for that one gene. The presence of so many other patents in this imaginary space may also create rather different configurations. Thus at each patent gate we could have two alternatives to the problem is to figure out the interaction of two duopolies instead of two monopolies, where the social outcome is likely to be somewhat better than they are with the dual marginalization problem raised by successive monopolies. Of course the patterns could be more complex, more like a neural network and less like a river. For some uses of Patent A, it is necessary to take advantage of Patent B, but for other uses of Patent A, Patent B is quite irrelevant, but the choice between Patents C and D is critical.

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<sup>26</sup> Gitter, at 1669 citing, Paul Smaglik, Could AIDS Treatments Slip Through Patents Loophole?, 404 Nature 322, 322 (2000)

More generally, it is easy to think of thousands of different patent pathways through which some new conception may travel in order to crystallize into a commercial application. These patents are not always thickets,<sup>27</sup> in that they frequently have a clear directional bias that thickets lack. But usually there is no unique path so the holdout value at any key pressure point is difficult to determine. The hard problem is to make some universal judgment about the applicable patent regime at so general a level when we do not know which configuration of patents dominates the landscape. It is interesting to note that the professionals in the field are in general optimistic about their ability to transact in this business. At the original conference at Washington University, it was said publicly and more than once, that experienced operators in the field did not know of a single worth-while product that had been kept from the market because of blockade difficulties.

That conclusion has been fortified by a recent survey published in *Science*,<sup>28</sup> whose three authors found that the strong patent protection that surrounded the use of research tools had done little to thwart the rate of innovation. The techniques that were involved included “licensing, inventing around patents, going offshore, the development and use of public databases and research tools, court challenges, and simply using the technology without a license (i.e. infringement).”<sup>29</sup> This list should be not dispositive on the question, but it is suggestive. The strategies of licensing, inventing around patents, and using public databases and research tools are wholly unexceptionable because they only take advantage of the opportunities that the patent system intends to create. The use of off-shore research devices is trickier to evaluate because that option would be removed if the patent system offered world-wide protection of the sort that is contemplated under

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<sup>27</sup> For the use of the term, see Carl Shapiro, Navigating the patent Thicket: Cross Licenses, Patent Pools, and Standard Setting, mss (2000)(with author)

<sup>28</sup> John P. Walsh, Ashish Arora, Wesley M. Cohen, Work Through the Patent Problem, 299 *Science* 1021 (2003).

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

the TRIPS agreement. In any event, that device is not available to use the product in domestic markets.

More puzzling, if not troublesome, is any decision to work without getting a license. To be sure, such uses do amount to infringement, but the social arrangements are more complex, for many patent holders may choose to turn a blind eye to certain infringements. Their actions need not constitute disinterested generosity, but could rest on the self-interested calculation that the use of these tools, especially in universities for research purposes, could produce results that could find new commercial applications for their patented goods.<sup>30</sup> Thus even without the benefit of an explicit research exception to patent protection, practices along those lines appear to be well-ingrained in the United States, at least until the universities start to act like commercial concerns, at which point the amnesty is off, and the litigation begins.<sup>31</sup>

The full range evidence is, as it always seems to be, incomplete, but the burden seems now to be on those who claim that the patent system builds blockades against innovation, as through the creation of an anticommons, as Heller and Eisenberg have suggested.<sup>32</sup> The vast and sustainable increase in the rate of genomic patent filings is not consistent with the view that new patents strangle innovation, but points to the opposite conclusion. The lawyers and businesspeople who work in this area are built evidently for speed not for stubbornness, and the gnawing sense that inaction leads to slow starvation and death keeps the rate of transactions humming. One could of course dispute this characterization of the field, but I should be reluctant to belittle or disregard this information. Transactions are what define this field. Patent positions are what make these

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<sup>30</sup> The European Community recognizes a formal research exemption from the patent protection, see Commission of the European Communities, Proposal for a council Regulation on the Community Patent, art. 9 (August 1, 2000) 43 *Off. J. Eur. Communities* 278 (2000); available at [europa.eu.int/eur-lex/pri/en/oj/dat/2000/ce337/ce3370001128en02780290.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/ce337/ce3370001128en02780290.pdf)

<sup>31</sup> *Madey v. Duke University*, 307 F.3d 1351 (4<sup>th</sup> Cir., 2002), on which see Rebecca Eisenberg, *Patents, Swords and Shields*, 299 *Science* 1018 (2003).

<sup>32</sup> Heller & Eisenberg, *supra* note 9.

possible. The burden is on those who want to explain why the property rights regime should be displaced in particular contexts.

Forced Transfers of Patent Rights The situation, moreover, is not unique to intellectual property. It can of course arise, albeit in less dramatic fashion with respect to land where separately assets stand in fixed relation with each other. Any individual who owns Blackacre has of course the exclusive right to that territory, and so too does his neighbor over Whiteacre. But like patents, we cannot tell simply from their location how these two plots of land interact with each other. It could easily happen that each will be used for a single family residence in which case the side by side legal monopolies are preconditions to a competitive market. But if both of those plots are needed to complete a key road, then their sequential use in an unregulated market creates the double marginalization problem.<sup>33</sup> The legal responses are predictable insofar as no one thinks that use of the condemnation power is inappropriate to assemble land for a highway, but this problem is easy in comparison with the patents, because our objectives are far more modest and the two-dimensional physical layout of the land gives us a relatively clear guide as to which parcels have to be included once the (political) task of route selection is accomplished. The question now arises what social responses could be introduced to deal with the admitted efficiencies that some patents may create on some occasions in this section I deal with, and generally reject, two such responses: condemnation and compulsory licensing arrangements.

*Condemnation* One way to deal with the patent-monopoly is to adopt the condemnation option used to assemble land in highway cases. As with the state subsidy of the bridge, the purpose of condemnation is to eliminate the dead weight loss that is associated with monopoly pricing, but to preserve the pecuniary incentive for invention that the current patent law provides. The theory is that the government acquires the patent

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<sup>33</sup> See, for further discussion, Richard A. Epstein, *Bargaining with the State* 36-37 (1993), where I used the electrical parallel to circuits that are organized in series and parallel.

for a price that compensates the inventor for his labors . It then turns around and licenses the invention, or sells products produced with it, at their marginal cost, or places it the public domain. The lump sum payment does not distort future use, so that we get optimal innovation and optimal utilization as part of one package. The position in question is one that reflects the new-found fondness for the use of liability rules (which allow buyouts at collective valuations) over strong property rules by which entitlements (patents included) are only transferred with the consent of their owner.<sup>34</sup>

A moment's reflection should show why this general approach to the patent problem should be dismissed as a hopeless pipe dream. The best way to make the point is that condemnation does not work all that well in those settings for which it is most suitable: the condemnation of land for public works. In the land context, the target of condemnation is frequently raw land for use as a highway. That land normally has an easily determined market value. Subjective values, moreover, are far more likely to inhere in the family home than in the back forty acres, which may be already leased anyhow. But the simplicity is deceptive, even in the easiest cases. The first question is *which* land should be targeted for condemnation. In some cases, local citizens vie to have the road built near them; in other cases to keep it far away. These costs are worth bearing because roads (at least most roads) have to be built, so that the costs of route selection are part of the cost of doing business, even if not linked to the acquisition of any parcel one the program is in place.

The problems do not cease, however, with the identification of the targeted land. Valuation is a constant headache. Often only fractional interests are taken for roads, raising problems with severance and spillover values. The residual land retained by one party may be enhanced in value owing to the condemnation and this could give rise to an

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<sup>34</sup> For one notable exception to the general trend, see generally Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 Cal. L. Rev. 1293 (1996), noting that in the copyright area, the firms themselves were able to design a distinctive licensing system that was superior to any that the state could impose of its own will. For discussion, see *infra* at .

offset against liability. Alternatively, the residual land could be rendered functionally barren because of the loss of some key component (the land is no longer large enough to be zoned commercial, for example) so that some severance damages should be added to the mix so as to leave the owner indifferent to the government imposition. Yet that compensatory ideal is systematically frustrated because the landowner does not get moving expenses, appraisal fees, loss of good will and the like.<sup>35</sup> Neighbors whose value diminish in consequence of the taking are also ignored under the mix. Good will is ignored; subjective value is ignored; costs of appraisal and legal defense are ignored. Every bias in land acquisition cases favors the state. These biases are, moreover, only accentuated when the condemnation is directed at homes and business, where the valuation issues become still more complex.

The use of condemnation (or prizes) is a far more complex issue for patents. The rich network that surrounds any individual patent raises at the very least all of the contextual questions found with land. The initial question is which patents should be subject to the buyout and which ones not. Here one alternative is to condemn all patents once their validity is determined, at which point the system will be overwhelmed with hundreds if not thousands of complex condemnation proceedings. All of these could drag on for years, often for inventions that will never be able to turn a profit. In the interim exploitation of the patent will lag, out of uncertainty over whether the additional investments will received compensation, or at least adequate compensation, from the government.

Alternatively, the government could engage in selective condemnation, choosing only certain key inventions for this process. But that approach will unleash immense political pressures over the exercise of the power. Will some people angle to have their inventions condemned because they think that they will not hold value in the long run?

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<sup>35</sup> For an examination of these biases, see Richard A. Epstein, *Takings: Private Property and the Power of Eminent Domain* 182-194 (1985).

Will they resist the condemnation of a competitive drug for fear that the government will then underprice their own product? Will they encourage the condemnation of the products of competitors in order to enmesh them in controversy?

Once the process were set in motion, it would raise in acute form all the valuation questions that dog to land condemnations, only worse. If some patents within a cluster are taken over, while others are not, then an accurate system of condemnation has to taken into account the influence on retained interests, positive or negative, to be true to the original ideal of full compensation for the economic losses brought on by the condemnation. But as the identification of "neighboring patents" is far from self-evident, these calculations will be far from routine events. If 13 other patents have their values altered by the condemnation of the one patent from the suite, how are those collateral losses assessed? What duties of mitigation are incumbent on the private owner?

Even self-sufficient patents will produce their share of knotty condemnation difficulties. The net value of any patent depends on a complex set of judgments about its exploitation, sale and pricing, all of which are constantly revised in response to new market conditions and technical innovation. It is relatively easy (but still very hard) to telescope future cash flows to assign a value to land. That is done all the time in voluntary transactions. But there are few naked cash sales of patents precisely because it is so hard to discount their future worth to present value. Within the condemnation framework, their valuation depends at the very least on complex calculations as to the allocation of joint costs and the possibilities of entry of novel competitors. The fiscal pressures to lowball compensation will lead to systematic expropriation of patent values in any individual case. The condemnation process cannot work as an answer to the monopoly problem.

*Compulsory Licensing* **Basic Proposal** One variation of the eminent domain position is to abandon the notion of state takeover of patents, which are then placed into the public domain, but to preserve the idea that state coercion can overcome the blockade

effects of patenting through a system of compulsory licensing.<sup>36</sup> In part the argument for government intervention rests on the sense that individual biotech firms will be reluctant as a general matter to forfeit the exclusive control over their patents by entering into various cross-licensing and patent pool arrangements. There is, indeed, some limited precedent for federal intervention to mandate cross licensing in specific contexts relating to the preservation of health, the development of nuclear energy, and the preservation of clean air.<sup>37</sup> There is no doubt that just as the takings power is a useful, if limited, antidote to the holdout problem, so too mandatory cross licensing could achieve that same result on some select occasions. But it is a far cry to assume that this device should be imposed (as opposed to used) as a general practice in patent law, or even that fraction of the patent law that is confined to biotechnology.

My uneasiness here does not rest solely on the predictable opposition from within the biotech industry,<sup>38</sup> although that should serve as a warning bell to the aggressive implementation of these schemes, which will founder unless they can rely on the cooperation of the relevant parties. But the opposition to this proposal runs deeper. In this context, as in others, the strong presumption should be in favor of a regime of strong property rights (defensible only with owner's consent) unless and until there is some clear showing of necessity that justifies the switch to a regime that requires forced purchases.<sup>39</sup> The simple complications of negotiating deals under uncertainty does not meet that threshold; indeed it describes a condition that is applicable to just about every dynamic industry under the sun. To be sure, it may to identify isolated circumstances for a compulsory licensing program. That was proposed, for example, for Cipro during the

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<sup>36</sup> See, e.g., Gitter, at 1679-1691.

<sup>37</sup> Id. at 1682.

<sup>38</sup> See W.R. Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* 291 (3d ed. 1996). Philippe G. Ducor, *Patenting the Recombinant Products of Biotechnology and Other Molecules* 157 (1998). Gitter at 1681-1682.

<sup>39</sup> I have said my piece on this issue on other occasions, see Richard A. Epstein, *Principles for a Free Society: Reconciling Individual Liberty with the Common Good* (1998); *A Clear View of The Cathedral: The Dominance of Property Rules*, 106 *Yale L.J.* 2091 (1997).

anthrax scares in the aftermath of 9/11. But even then circumstances moved so quickly that this problem fell to the back burner as soon as a voluntary deal was completed. We should take warning given the extensive negotiations over a single drug for a single use, when it is known to go off patent in eighteen months. There are good reasons for the admitted “rarity” of the practice.<sup>40</sup> It takes a vast leap of faith to posit the social and technical infrastructure that could make it worthwhile to implement on a mass basis.

All this is not to say that the current system is perfect. The monopoly problem still remains in some form, such that the ostensible allure of the proposal comes from the vision that intransigent holdouts would become happy royalty holders. Professor Donna Gitter offers one description of the proposal as follows;

Congress should enact a compulsory-licensing system, which would require an owner of patent rights in a DNA sequence to license that sequence to any and all scientists pursuing commercial research related to that sequence in return for a reasonable licensing fee. The licensing fee would not be established by the individual licensor, but would instead depend on the commercial value of the product developed as a result of the research. Thus, potential licensees would not be dissuaded from making an initial investment to pursue research, because the amount of the royalty payment would be tied to the success of the product they develop. This system is also fair to the licensor, who would receive adequate compensation from licensees who achieve financial success through their use of the patented sequence.<sup>41</sup>

Her proposal does not stand alone, but in fact builds on a similar proposal for the compulsory licensing of “research tools,” advanced earlier by Janice Mueller.<sup>42</sup> Mueller’s compulsory licensing scheme would embrace in addition to ESTs’, “cell lines,

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<sup>40</sup>Dawson Chem. Co. v. Rohn & Haas Co., 448 U.S. 176, 215 & n. 21 (1980)(noting the Congressional proposal in the Patent Act).

<sup>41</sup> Gitter, at 1679

<sup>42</sup> Janice M. Mueller, No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for biomedical Research tools, 76 Wash. L Rev. 1, 58-66 (2001).

monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry, libraries, drugs and drug targets, clones and cloning tools (such as PCR [polymerase chain reaction]) methods, laboratory equipment and machines, databases and computer software.”<sup>43</sup> Thereafter the proposal calls for a “reach-through” royalty structure that targets the products sent to market by means of the research tools, even if sold after the expiration of the underlying patent.<sup>44</sup> Unlike the usual voluntary license, Mueller believes that the compulsory licensee need make no disclosure of the nature or the details of the use, so long as he makes a declaration of “an intention to use” that puts the patentee on notice “so that it can police any subsequent introduction of new products into the marketplace by the tool user.”<sup>45</sup> The stated royalty structure “is computed at twenty-five percent of the licensee’s pre-tax profit rate on his sales,” subject to “fine-tuning in individual cases.”<sup>46</sup>

In one sense, these proposals might be defended for being more modest than they seem. Far from being command and control mechanisms that force parties to do business on terms that they do not like, they simply invite them to renegotiate the their arrangements in ways that better serve their joint interests. But compulsory licenses have more teeth than this optimistic account suggests, because they change the threat positions of the parties to any negotiation. The patent owner who cannot get the terms he wants is no longer allowed to walk away from the deal, but must continue to do business with someone who will not budge from the compulsory license unless he gets terms that he finds better than the ones guaranteed under the law. At the very least therefore these proposals deny a patent holder the right to choose the parties with whom he will do

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<sup>43</sup> Report of the National Institutes of Health (NIH) Working Group on Research Tools 3, at <http://www.nih.gov/news/researchtools/index.htm> (June 4, 1998) [hereinafter NIH Research Tools Report], referred to in Mueller, *Dilettante Affair*, at 11.

<sup>44</sup> This is a perfectly sensible way of doing business in voluntary or statutory markets. Clearly the use for which the royalty is paid took place during the period of patent protection. Only the compensation is deferred, which could take place with fixed as well as variable sums. What will not happen is a royalty, absolute or contingent, for work done after the time of patent expiration.

<sup>45</sup> Mueller, *No Dilettante Affair*, at 59..

<sup>46</sup> *Id.* at 64.

business in the first place. Necessarily, they make exclusive licenses a dead letter, even though these are often consummated in practice. In order for this use of compulsion to be a sensible social procedure, one has to have some confidence in the licensing rules themselves. Yet too much optimism lurks behind these compulsory licensing proposals, which underestimate at every turn the contractual density and sophistication of licensing transactions.

To start from the beginning, all compulsory licensing schemes show a decided preference for some kind of “liability” as opposed to “property” rule whereby the holder of any given entitlement is subject to its purchase at some for some fair valuation determined by some independent party.<sup>47</sup> When introduced by Calabresi and Melamed in 1972, protection by liability rules only helped explain why injunctions need not necessarily be awarded in all nuisance cases. In some situations, the defendant could continue to pollute, presumably at some defined levels, so long as some provision was made for the payment of permanent or temporary damages.<sup>48</sup> In practice, the law of nuisance has not been as receptive the damages-only approach as their characterization suggests, preferred in most cases to award the injunction as of right unless there was some manifest imbalance between the trivial advantages to the plaintiff and the massive dislocations to the defendant.<sup>49</sup> In some other cases, it has been suggested that liability rules are better ways to decide which of two people will be able to make better use of a divided asset (e.g. land in which a determinable fee is subject to a possibility of reverter) by inducing the parties to reveal the intensity of their preferences for the unitary asset.<sup>50</sup>

This thumbnail sketch shows that at their inception liability rules were meant at most to serve the modest role of adjudicating boundary disputes; somewhat later it was

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<sup>47</sup> For the initial distinction, see for one defense of the superiority of liability rules, see Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules and Inalienability: One View of the Cathedral*, 85 *Harv. L. Rev.* 1089 (1972). Ian Ayres & Eric Talley, *Solomonic Bargaining: Dividing a Legal Entitlement To Facilitate Coasean Trade*, 104 *Yale L.J.* 1027, 1036-37 (1995).

<sup>48</sup> See Calabresi & Melamed at .

<sup>49</sup> For discussion, see Richard A. Epstein, *Torts*, § 14.7 (1999).

<sup>50</sup> See Ayres & Talley, *supra*. 1030-1035.

proposed that they take a transitional role in moving assets between persons. Assuming, for the sake of argument only, the soundness of these conclusions, the traditional accounts did not contain any hint that liability rules should sanction the deliberate expropriation or use of the property of another in complex and cooperative business transactions. One sense of the limits of these forced commercial exchanges comes from the law of contract. The all-too fashionable theory of “efficient breach” posits that a promisor can break his promise, pay expectation damages, and pocket the surplus.<sup>51</sup> The appeal here is for the substitution of a liability rule for the stronger property rule protection from, say, a remedy of specific performance. The argument is that the promisee is not worse off (because of the expectation damages) while the promise is better off, such that the unilateral breach with compensation amounts to a Pareto improvement. But the entire scheme flounders because the computation of expectation damages is next to impossible whenever the breach by promisor creates ripple effects that are hard to quantify. The usual reaction to efficient breach among businesspeople is to gasp in genuine horror about its universal application. Most trades work on the assumption that the expectation measure of damage is permissible only for want of a better, that is, in those cases where the defendant is not in a position to perform a contract. The usual response is expulsion from trade association where the defendant engages in a deliberate breach of contract in order to sell the goods to some third party above the contract price.<sup>52</sup> As with the other case, the liability rule tends to be rejected even when the breach disrupted all relations between the parties. This commercial response should offer a warning about any widespread substitution of liability for property rules in contexts that call for future interactions. Even if liability rules have some niche uses in necessity cases, they represent an impossible way to organize

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<sup>51</sup> On the question of efficient breach, see Daniel Friedmann, *The Efficient Breach Fallacy*, 18 *J. Legal Stud.* 1 (1989); Richard Craswell, *Contract Remedies, Renegotiation, and the Theory of Efficient Breach*, 61 *So. Cal. L. Rev.* 629 (1988).

<sup>52</sup> See, Lisa Bernstein, *Merchant Law in a Merchant Court: Rethinking the Code’s Search for Immanent Business Norms*, 144 *U Pa. L. Rev.* 1765 (1996),

complex social interactions if what they are construed any individual is entitled deliberately to take the property of another individual so long as there is some assurance that he will be required to pay the appropriate social price. The level of instability is enormous, for no remedy can calculate the full consequential damages that follow from loss of entitlements.

In this context it bears stressing that the object of a license agreement is not simply to place the patent in the hands of one party or another. It is to institute at a conscious level some system of divided control over the use of information in the ordinary course of business. These shared arrangements require continued trust and cooperation, which is hardly to be expected when one person is able to foist himself on another. It is instructive to see just how difficult it is to organize a system of compulsory licenses when divided, not unitary, control is the end of the process.

**Mechanics of Compulsory Licenses** Recall that the Gitter proposal applies only to DNA sequences, while the Mueller proposal extends to a wide array of other products, including such things as computer software. But the danger of creeping compulsion cannot be overlooked in assessing this proposal in either its broad or narrow manifestations. The first question is the simple one of who initiates the license. In the ordinary voluntary transactions, the licensor as owner of the patent can control the stable of licensees and pick those whom he believes have the greatest chance of producing some invention or product that will yield a high return from the relationship. Resources of monitoring and supervision can thus be effectively conserved. That form of control is wholly lost once the patent holder is converted into a de jure common carrier, so that these licenses must be made available as of right to all who wish to work with some research tool or DNA sequence. Unlike other situations, this sequence information is in the public domain and it provides information that allows the new licensee to begin work on the project without notification to the patent holder. In order to curtail that risk, it will become necessary to mandate that licensees post on some neutral site a notice of its

“intention to use” the covered materials of another company, and to subject that party to heavy damages in the event that they proceed without supplying the requisite notice.<sup>53</sup>

Unfortunately, an enormous gap remains between a notice provision on the one hand and a completed contract on the other. So the first task that the licensor must face is how to respond once it learns of the notice. Must the patent holder now enter into some detailed investigation of the financial position and technical abilities of the putative licensee to determine whether it is worth while to incur the expenses necessary to police the activities of the licensee in order to preserve some future royalty stream? Voluntary licenses of course contain provisions whereby the activities of the licensee are policed, often through the use of elaborate “milestone” provisions, in which future work under the license is tied to previous progress. The cost of overseeing these operations, however, are generally taken into account in setting out the overall deal. Otherwise, the licensor would have a negative expected value for the transaction, which would not then ordinarily go forward. But with these compulsory licensees, no front-end payment is contemplated, and security arrangements and guarantees are virtually impossible to devise, especially if the licensee is permitted to conduct its work under a shroud of secrecy, so that the firm has to go out of pocket on monitoring, knowing of the serious risk that the licensee could be subject to reorganization, takeover or bankruptcy, leaving its ultimate collection rights very much in danger. The point here is no small one for a firm that has multiple patents, each of which could become the subject of hundreds of mandatory licenses. It makes matters only worse that the licensing firm may use multiple patents to get its own product to market. This effort to solve the holdout problem could create in short order massive administrative burdens over which licensed patent contributed what to the final outcome.

Matters do not look any better when one considers the possible terms and conditions of the licenses so imposed. As a benchmark for this analysis, it is useful to consult the voluntary licensing agreements right now in place for various forms of

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<sup>53</sup> On which see Mueller, No “Dilettante Affair” at 58-59.

technology. These agreements are of course complex affairs that must track the wide range of permutations that frequently arise in any ongoing relationship. The terms of particular licenses are confidential, but even a quick look at a specimen template of an exclusive license shows the complexity inherent in deals of this sort. The exclusive license agreement used by Harvard University<sup>54</sup> is only a few pages—before the particulars are filled in. It contains detailed provisions that govern not only the conduct of licensee but also of its affiliates<sup>55</sup> lest there be confusion as to what activities are covered. It contains detail description of the materials supplied<sup>56</sup> and covered the products and processes.<sup>57</sup> It contains a four part definition of what counts as “net sales” on licensed product.<sup>58</sup> It deals with such matters as patent rights<sup>59</sup> and sublicensee income.<sup>60</sup> It contains various reservations so that its exclusive license does not stop non-commercial research work by Harvard or other licensees. It contains, as it must, as best efforts clause, so that the exclusive license does not remain fallow.<sup>61</sup> Further, it has complex provisions to determine the royalties owed under the license.<sup>62</sup> And it includes provisions that deal with reporting<sup>63</sup> and record keeping,<sup>64</sup> to backstop the agreement.

It is easy to see how this list can be expanded: Are there specific procedures for modification of terms? What are the rights for termination or cancellation? Assignment and sublicensees? Payment provisions: lump sum, periodic, contingent? Security for payment provisions? Cooperation provisions? Sharing of information between the parties or with third parties? Compliance with regulatory norms? Remedies for breach of

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<sup>54</sup>Harvard Exclusive License Agreement as of June 1, 2001 WILL ATTACH ON LINE COPY. Have no site address.

<sup>55</sup>Id at 1.1

<sup>56</sup>Id. at 1.2

<sup>57</sup>Id. at 1.5 & 1.6.

<sup>58</sup>Id. at 1.8.

<sup>59</sup>Id. at 1.10

<sup>60</sup>Id. at 1.11

<sup>61</sup>Id. at 3.2 (d) & (e).

<sup>62</sup>Id. at 4.1-4.4.

<sup>63</sup>I. at Art. V.

<sup>64</sup> Id. at Art. VI.

contract before during and after the formation of the agreement? Coverage of payments after the expiration of the patent? For its international use? It seems highly unlikely that any compulsory license could cover enough of these issues to be sustainable in the long run.

The payment issue alone shows the magnitude of the problem. The only system that is practicable in compulsory is a percentage of revenues, along the lines of most voluntary agreements. But there is this subtle difference. It is not enough to say that consequential losses don't matter under compulsory licenses because ordinary licensing agreements don't call for them.<sup>65</sup> True enough, but that is because the patent holder will *not* enter into any voluntary licensing arrangement if any consequential losses from the new entrant exceed the expected royalty stream. A selection effect thus weeds out some transactions that will now take place under the compulsory licensing stream. These additional transactions are loss transactions to the patent holder, so that over the full range of deals, its economic position will be eroded by compulsory licensing. That downward bias in returns will still be greater if the return is posited at some "competitive" level, i.e. lower than the voluntary market would yield for this particular transaction.

Other problems with transactional mechanics will undermine this scheme. Professor Mueller's proposes a standard of a "reach-through" 25 percent of pre-tax profits. But there is little reason to think that any single number will capture the wide variation in voluntary deals. One key element in the royalty rate involves the amount of downstream work that is left to be done once licensing is complete. If that amount of work is extensive, then the license royalty is likely to be lower. If the work required is slight than the rate would increase. Picking a presumptive standard that is too high would render the entire licensing system inoperative because no potential licensee will seek to

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<sup>65</sup> Nor should they. See Richard A. Epstein, *Beyond Foreseeability: Consequential Damages in the Law of Contract*, 18 J. Legal Stud. 105 (1989).

exercise its rights under the compulsory scheme. In the limit, one way to repeal the compulsory license scheme is to mandate that the licensee pay one hundred percent of its revenues to the licensor. But alternatively the figure set could be below the market royalty rate, at which point the licensor may not be able to recoup its expenditures with a reasonable rate of return. Here the product, if made at all, will be gobbled up by a large number of nonexclusive licenses which might yield too little in revenue to encourage systematic investment over time. There is in short no single number which makes sense as a presumptive target for licenses, and no set of ad hoc exceptions to the rule that any public body can administer. It neither makes sense to allow the use to be made today subject to a royalty to be determined later, or to hold off the license until the question of particular rates receives some public validation.

But even if we could set optimal royalty levels that work for the full range of covered products, this system will fail as an administrative matter if the licensor is not allowed to monitor the books to determine these profits, and will likely fail even if that monitoring is allowed. Most percentage leases in real estate work off gross revenues not net profits, precisely because the latter figure is so elusive in contested settings. Even if some voluntary transactions calculated royalties off net profits, it is doubtful whether that practice would make sense when the number of transactions increases, the dollar stakes of the transactions (in at least some cases go down), and in which the level of access and trust is far lower. It simply does not do to transplant isolated terms of business arrangements to new contexts. What is needed is a keen appreciation of how each individual term fits into the large mosaic.

In sum, the negotiations over any particular agreement present an uneasy mix between standard provisions on the one hand and dickered clauses on the other. Someone has to engage in fine-tuning, but legislatures cannot do it for contracts any more than they can do it for violins. More precisely, owing to the wide range of licensed and derivative products and processes there is little hope that all will be able to gravitate to the same

standardized agreement, or whether certain kinds of clauses will be relevant for certain classes of arrangements. All products are not created equal; more narrowly, even all cDNA sequences may not be created equal either. All that is known from the outside is that every business agreement involves trade-offs between the ideal incentives on the one hand and the administrative costs of enforcement on the other. We rely on voluntary agreements not because we (collectively) know the right answers but because we know that transacting parties in sophisticated transactions have both the incentives and the knowledge to get it right.

Yet what can be said when the terms of the compulsory license are stacked up against those which are part and parcel of every voluntary agreement? Initially, we can be confident that the terms of these agreements should if anything be more exhaustive than their voluntary counterparts. When contracting parties select each other they can rely on a full set of informal, reputational or relational sanctions to help keep each other in line. As the level of trust diminishes, the need for explicit monitoring between the parties may well increase, at a time when the sheer numerosity of these agreements strains all the resources available for monitoring. Where net licenses are used, moreover, some procedures must be developed to allow the patent holder to determine whether the licensee has padded expenses in order to reduce the net profits owed under the agreement, or reallocated the income to some other product to the same customers, perhaps as part of a complex package. The inquiries require the parties to delve into the intricacies normally associated with rate-of-return regulation used for regulated public utilities, such as the phone company, where suits drag on for eons, and the term “reasonable” does not begin to unpack the host of interpretive and factual difficulties. The entire history of rate regulation for network industries should lead one to doubt that anyone could so price these licensee fees in such a manner that leaves the licensing companies in tact. This is one road down which no one should travel.

Contracting Strategies. In light of the difficulties with any set of state mandated forced licenses or exchanges, the sound collective approximation is to stick with the patent system, and then to rely on other devices to make needed adjustments at the edges. Virtually all these techniques rely on some form of contracting that avoids the holdout problems that arise when distinct interlocking arrangements are held by unrelated parties. One common device is the humdrum system of assignments. Only inventors are entitled to file for patents, and corporations do not invent. To avoid the excessive Balkanization of the process, a corporate employer typically requires its employees by contract to assign all patents that he receives to his employer. The full arrangements will in most cases contain some return compensation for the inventor above and beyond the usual salary, as a spur to invention.<sup>66</sup> The automatic assignment provisions allow the institution to organize a suite of coherent inventions, often from multiple workers within the same discipline. The alternative scenario allows each inventor to keep his initial invention, which in turn could create difficulties where related inventions have different combinations of inventors drawn from a pool of related workers. These arrangements have been attacked from time to time under contract law on grounds of exploitation, unconscionability and the like. But their overall efficiency enhancing characteristics should immunize them from such challenges. Nor should the antitrust law apply to the division of labor within the firm, but only to connections made across firms.

The next consolidation device is more tricky precisely because it does involve cooperation between firms. Cross-licensing agreements give each firm access to the technology of the other, but carry with them the risk of coordinated pricing-arrangements that could violate the antitrust prohibition against horizontal arrangements. Patent pools involve a procedure whereby two or more firms create a package of patents that they then license en masse to third parties. In both situations, the critical distinction is between

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<sup>66</sup> The University of Chicago, for example, has such a policy with regard to inventions that rise out, which stipulate percentages of the payment that go to the inventor, to his division and his department. The University undertakes all the expenses of bringing the invention to market.

economic *substitutes* and economic *complements*, for pooling arrangements are far more attractive in the latter situation than in the former.<sup>67</sup> With complements, the effect of the pool, is to allow coordinated licensing which would eliminate some of the inefficiencies of the Cournot duopoly. Often these are royalty-free, much like the restrictive covenants and restrictions imposed on the residents of planned-unit developments. Nonetheless, if the commercial value of the respective patents suites are unequal, some overall transfer payment might be added to insure that the transaction is win/win. But the key point here is that the licensing takes place in bulk, so as to avoid the tedium of measuring value for individual patents.<sup>68</sup> But with substitutes the effect of the pooling arrangement could be the formation of a cartel in restraint of trade, as the Department of Justice has in fact ruled.<sup>69</sup> But whatever those difficulties are, the one solution that seems doubtful is a per se ban on all patent pools when the alternative to create the holdout questions that otherwise loom so pervasive in the area.

What then is the correct response to this array of interlocking, overlapping and independent monopolies in the patent world? In light of all that has been said, the effective choice boils down to either a general commons or the current regime. Writing on a blank slate Congress could create a new commons by refusing to exercise its patent power at all. The hope might be that the lower rate of invention would be more than offset by the higher rate of utilization of the fewer inventions that are developed in the first place. But that said, the crude empirical judgment of just about everyone is that the gains from increased incentives to create at some stage outweighs than the losses from

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<sup>67</sup> See Shapiro, Navigating the Patent Thicket, at 5-6.

<sup>68</sup> Id. at 12

<sup>69</sup> See [http://www.usdoj.gov/atr/public/press\\_releases/1997/1173.htm](http://www.usdoj.gov/atr/public/press_releases/1997/1173.htm).

Press release of 6/26/97, which approved a "one-stop" patent pool involving nine firms and one university for "essential patents," and created a mechanism whereby and "independent patent expert" would pass on whether patents should be added or removed from the pool. Id at 3. An "essential" patent refers to those which are complements. See also the press release of 12/17/98, [http://www.usdoj.gov/atr/public/press\\_releases/1998/2120.htm](http://www.usdoj.gov/atr/public/press_releases/1998/2120.htm).

restricted dissemination, so that the patent system should be preserved.<sup>70</sup> One way to reach this conclusion is that monopoly profits are never that great to begin with (say in the order 20 percent), and that owing to the imperfect correlation between legal and economic monopolies, many of those losses are competed away. All this dislocation is better than the total wipeout if innovation grinds to a halt. Contestable empirical judgments are required on all dimensions, but judgments that we make nonetheless. The patent system should stand more or less in its current configuration.

On to the Genome The next portion of this paper deals with the question of how these general conclusions should operate with respect to the genome. In order see how this works out, I shall proceed at two levels. The first asks how the patent bargain plays out without reference to the particular terms of the statute, that is, under some idealized version of the patent law that keeps to the property system and asks only one question: is this set of transactions one for which it is worth while to create a private monopoly. The second then examines the issues related to the patentability of genetic materials under the current law. The question then arises, how do these theories play out when applied in a more systematic fashion to the genome. Here the problem is in a sense simpler than that for the patent law general. The range of genetic patents is narrower than those for all inventions, so that it becomes possible to hazard more confident generalizations about the operation of the patent system in this proper subset of its overall domain, even before we examine the specific conditions of patentability under the current law.

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<sup>70</sup>For a listing, see Michael Abramowicz, *Perfecting Patent Prizes*, mss, at note 4. Included on his list are, Fritz Machlup, *An Economic Review of the Patent System* in Subcomm. on Patents Trademark and copy right of the Senate Comm. On the Judiciary 85th Cong. 44-45 (Comm. Print 1958) (exhaustive review of patent system); Brian Peckham, *Should the U.S. Patent Laws Be Abolished?*, 11 *J. Contemp. Prob.* 389, 421 (1985) (declining to advocate immediate abolition of the patent system); JAMES BESSEN & ERIC MASKIN, *SEQUENTIAL INNOVATION, PATENTS, AND IMITATION* (Massachusetts Inst. of Technology Working Paper No. 11/99, 1999). For an interesting compendium of quotations denouncing the patent system, see Gordon Irlam, *Coalition for Networked Information Forum*, <http://www.cni.org/Hforums/cni-copyright/1994-04/0648.html>.

*The Patent Law* In order to set the stage for the discussion that follows, it is useful to run through the normal requirements needed to assure patentability. The inquiry is important because nothing in the language of the patent act itself makes explicit reference to the overall patent bargain between the inventor and the state. But the individual elements required for patentability do, for the most part at least, seek to identify the terms and conditions under which the grant of a patent is likely to produce the desired results.

This process is in general divided into two stages. The first of these, which addresses the question of patent eligibility simply asks the question of whether the subject matter of the proposed invention is a machine, process, manufacture or composition of matter.<sup>71</sup> If it is not one of the above, then it just does not qualify for any form of patent protection. The implicit economic logic of this approach is that candidates for patent protection that fall outside these various elements do not deserve case-by-case examination to see if the patent bargain makes sense from the public's point of view. Mathematical ideas and compounds of nature are always in a sense there for the taking, so that no one should be allowed to claim an idea or an element just because he got it first. Madame Curie has no claim for the exclusive use of radium even though she isolated and purified first. She might be able to get a process patent, and she could certainly keep the radium that she purified. But beyond that she is not able to go if others find different ways (e.g. chemical reactions) to isolate radium.

In some cases, it is an open question of whether a particular claim falls on one side of the line or another. Justice Douglas is generally regarded as wrong in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*<sup>72</sup> to the extent that he rejected as a product of nature a mixture of six strains of bacteria that worked together as an effective inoculant for leguminous plants. It took a fair bit of ingenuity to sort out which combinations of bacteria could coexist with each other, and it was that array, rather than any of the natural

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<sup>71</sup>35 U.S.C. §101.

<sup>72</sup>333 U.S. 127 (1948).

strains of bacteria that constituted the composition of matter (or manufacture) which would be eligible for patent protection if all the other hurdles could be overcome. Even though each of the separate strains were found in nature, their juxtaposition was not. The 1980 watershed case of *Diamond v. Chakrabarty*,<sup>73</sup> which allowed the patentability for man-made microorganism, could be distinguished from *Funk* on the ground that it involved a new composition of matter rather than the simple admixture of existing items. But the usual view, which I share, is that *Chakrabarty* has moved the boundary line between natural products and human creations so that the latter occupies a larger scope than before.

Even when all this is done, however, the patent law contains an implicit prohibition that no person can obtain a legal monopoly over ideas on the one hand and natural substances on the other. The history of that proposition has been exhaustively documented in a recent article by Linda Demaine and Aaron Fellmeth.<sup>74</sup> The clear impulse for this general position is that no system of rewards should be created for people who just find something that others could find at some later point in time for themselves. The underlying deal is bad from a social point of view because the exclusive grant could cover matters of great value to which the patentee has added nothing. One prominent variation on this basic theme holds that the same prohibition against patenting ought to apply to natural substances that have been isolated and purified by human invention. In this case, the easiest and most sensible response is to allow someone to patent the *process* under which the purification and isolation has taken place, so long as the other requisites of the patent law have been met, but not to patent the *substance* to which that process has been applied. Just this solution was articulated as early as 1874 by Justice Strong in *American Wood-Paper Co. v. Fibre Disintegrating Co.*,<sup>75</sup> in which the

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<sup>73</sup>447 U.S. 303 (1980).

<sup>74</sup>See, Linda J. Demaine & Aaron Xavier Fallmeth, Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent, 55 Stan. L. Rev. 303 (2002)

<sup>75</sup>90 U.S. 566 (1874).

patent claim covered refined cellulose that had been extracted from wood, straw and other fibrous materials. The plaintiff sought to use the materials in the preparation of various forms of paper, but his patent application was rebuked in the following words:

There are many things well known and valuable in medicine or in the arts which may be extracted from divers substances. But the extract is the same, no matter from what it has been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture.<sup>76</sup>

Strong then illustrated the point by noting that a new process for the creation of Prussic acid could be patented even if the prussic acid itself could not be.<sup>77</sup> The decision here clearly rested on the notion that the extracted material was not patent eligible. The case did not concern any of the individuated elements relating to the nonobviousness or utility of this particular claim. In principle this same approach can be carried over to the new wave of biotechnology, including of course genetic substances. In addressing this issue, John J. Doll, the PTO's Director of Biotechnology, has urged that these "isolated and purified" sequences must be protected in order to supply an reward structure for work in this area.<sup>78</sup> But in this statement he did not respond, as Demaine and Fellmeth have noted,<sup>79</sup> to the obvious objection that the standard rule that denied patent protection to isolated and purified substances carries over without missing a beat to recombinant DNA technology, as the traditional case law required.

The question then arises whether the Doll pronouncement just misses the boat or whether the common position that supports genomic patents can escape this charge. In order to see how this works out it is necessary set out briefly some of the basics of recombinant DNA. Human DNA is an elaborate code that instructs each cell on how to

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<sup>76</sup>Id. at 693

<sup>77</sup>Id

<sup>78</sup>John J. Doll, *The Patenting of DNA*, 280 Science 689 (1998).

<sup>79</sup>Demaine & Fellmeth, 55 Stan. L. Rev. at 305.

combine different amino acids into proteins. Those instructions are contained in codons, which are triplets of three of the nucleotides, or bases. These are adenine (A), guanine (G), cytosine (C), and thymine (T). These four different nucleotides generate 64 ( $= 4^3$ ) combinations. But they code for only the 20 amino acids that the body synthesizes. The code therefore is degenerate or redundant, in the sense that there is no bijective (or one-to-one) correspondence between a given triplet and the associated amino acids. Each codon codes for one and one nucleotide, but many different triplets code for a single amino acid. The coding, however, does not take place directly. The DNA works through another molecule called messenger or mRNA. The ability to manufacture these proteins depends on the manipulation of this RNA, which serves as a template to generate complementary or cDNA from the mRNA molecule. The cDNA so produced will code for the same protein, but it is an *artificial* molecule that need not have the same configuration as the DNA found in nature. At this point, the patent process involves more than the isolation and purification of prussic acid, or indeed any other natural element or substance.

This point is important because it suggests that that genomic patents should be regarded not merely as process patents, but as subject matter patents that meet the test for a new composition of matter set out in the patent law. Nonetheless in their recent broadside against genomic patents, Demaine and Fellmeth downplay this structural difference in order to claim that genomic patents should not issue at all. They write:

That this position has swayed circuit courts and the PTO is surprising in light of the strong theoretical and scientific counterarguments against it. The argument both misstates the meaning of "purification" as defined by the Supreme Court and misrepresents the difference between natural DNA transcription and scientific recombinant DNA cloning. In the first place, the contention that recombinant DNA is not equivalent to purified, natural DNA is scientifically unsound. The notion of removing introns, regions of a DNA

sequence that do not code for proteins, is not a human invention. In fact, during the process of natural DNA transcription, an mRNA molecule is created as a copy of a gene in preparation for protein synthesis. During the creation of the mRNA, only the exons are reproduced. Thus, by merely matching the complementary nucleotides to those in a naturally occurring mRNA molecule, an "isolated and purified" sequence of nucleotides is created. Recombinant DNA technology produces, in effect, a kind of imitation of a naturally transcribed gene. Under well-established patent principles, a product that is an imitation of a preexisting product (naturally occurring or not) is not patentable per se. The practical implementation of recombinant DNA technology (a process) may be new outside of a living body, but it is hardly a new concept. The identity of naturally transcribed DNA to recombinant DNA provides an independent basis to find a lack of invention.<sup>80</sup>

There are several difficulties with this position. In the first place, it renders largely beside the point their long and tortuous defense of the rule that natural substances cannot be patented so long as they only purify and isolate what is found in nature. In this case, the cDNA is a product synthesized by human intelligence. To call it an recombinant DNA technology a "kind of imitation" is to give a backhand admission that the molecule in question is not an exact duplicate of what nature itself provides, so that the traditional prohibition against patenting natural substances no longer applies. There may well be individuated questions whether this or that genetic substance meets the second tier individuated questions on patentability, but the roundhouse blow to the entire system of patent protection, now in place for well over a decade, does not seem well advised.

Nor is there any reason to be alarmed at this result. To see why, suppose that in *American Wood-Paper* there was but one and only one method for the isolation and purification of prussic acid. At that point the process patent would give its holder the

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<sup>80</sup>Id at 408-409.

same economic advantage as a patent over the substance itself. Frequently exclusive holders of secret processes prefer to hold them as trade secrets, for if the product is one of standard manufacture, the mere appearance of that product on the marketplace offers no indication that the rival seller has turned the secret to his own advantage. He could have used some alternative process to reach the same result. But once the process is shown to be exclusive, then it can be patented, for if any one else produces the purified and isolated product, then it is no more difficult to do so for infringement of the process patent than a substance patent. It is only when an alternative process is developed that the prior process patent loses its exclusive force and the questions of enforcement (whose patent was used and why?) come to the surface.

The situation here is no different. There is no reason to think that any naturally occurring genetic substance can, for now and ever more be made only by constructing a cDNA molecule through recombinant techniques. This substance patent can be undermined in exactly the same way as the exclusive process patent. All it takes is human ingenuity to find an alternative pathway to the naturally occurring substance. The situation has of course analogies with common and private property in land. Suppose that X owns the only ski lift to a ski run at the top of a mountain that is open to the public. The charge for the use of the lift is identical to that he could charge if he owned by the lift and the ski run. There is no double marginalization problem because no one can be excluded from the slope. Yet we do not treat this situation as any different from one in which a single person owned both the ski lift and the ski run (which operates in competition with other ski lifts and run in the region). But the moment a second operator builds a ski lift to the top, the monopoly hold is broken, which would not be the case if the first owner had owned the slope as well. In most cases, it is a process patent that holds the key to public domain property. In this case, it is a substance patent that produces that result.

Nor is it difficult to see why Demaine and Fellmeth take so restrictive a view on the subject. Elsewhere in their paper they give their express approval of the restrictive interpretation of patent eligibility adopted in *Funk* and their disapproval of the more expansive definition of that term found in *Chakrabarty*, in large because that decision countenanced the patenting of various human life forms.<sup>81</sup> But it is one thing to attack the use of genomic patents on the restrictive views that dominated before the more expansive readings of *Chakrabarty* but a good deal more difficult to reach that result once it is recognized that that decision counts a good law, which helped spur the huge biotech boom.

This analysis of the problem helps explain and justify the outcome in the extensive dispute over the patenting of a gene that codes for Erythropoietin (EPO) for the treatment of human diseases. The key case for this short demonstration is *Amgen v. Chugai Pharmaceuticals*.<sup>82</sup> The most salient points about this dispute was that no one claimed the right to patent EPO as found in nature, but only the purified and isolated cDNA that allowed for its production on the one hand, and the “procaryotic or eucaryotic host cell’ that was so transformed to allow expression of this gene. These two limitations are critical because it means that anyone who developed a different recombinant DNA sequence could have a fair shot at patenting that gene.<sup>83</sup> Certainly anyone who produced EPO by the older and inefficient technique of “concentration and purification of urine” would be free to do so as well.

Nor was this exercise in recombinant technology a romp in the park. Dr. Fritsch, who headed the project for Genetics Institute, Inc. (GI), had labored over the program in a consistent fashion for three years, from 1981 to 1984, until he was able to reduce it to

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<sup>81</sup>Id. at 315-19,

<sup>82</sup>27 F.2d 1200 (Fed. Cir. 1991).

<sup>83</sup>Here the ambiguity arises out of the potential application of the doctrine of equivalents, which would in my judgment block the patenting of a new gene that simply represented the substitution of one or more codons in the isolated genes that coded for the same protein as the codons that it displaced. But what do I know?

practice. He had no idea when he began whether he would succeed in the end. His claim lost out to Dr. Lin's early reduction to practice because the Court held (rightly) that Fritsch's initial strategy to use "two sets of fully degenerate cDNA probes" was not tantamount to having a clear visualization of the molecule that he wished to create. The case at no point raised the possibility that the cDNA that coded for EPO belonged in the public domain. Indeed for any of the three participants to the dispute to adopt that decision hands a victory on a platter to any outsider who then commences to produce the EPO without having incurred the costs needed to develop the techniques for its generation. It is also deeply ironic that all of the arguments about the patentability advanced by the parties were directed to the processes by which EPO was purified and isolated, and none was directed toward the molecule which was (as a "composition of matter") the subject of the patent in the first place. As John Doll has stated: "In order for DNA sequences to be distinguished from their naturally occurred counterparts, which cannot be patented, the patent application must state that the invention has been purified or isolated or is part of a recombinant molecule or is now part of a vector."<sup>84</sup> The first phrase on purification and isolation may well be question, but the stricter requirements in the last two elements were satisfied in *Amgen* where the key claim "was the novel *purified and isolated* sequence which codes for EP) and neither Fritsch [the rival claimant] nor Lin [Amgen's scientist] knew the structure of the physical characteristics of it and had a viable method of obtaining that subject matter until it was actually obtained and characterized."<sup>85</sup>

What was so admirable about the *Amgen* opinion is that it ran through the full set of obstacles that any application must run in order to become a patent and demonstrated quite clear that this application satisfied them all without any special kind of tugging and hauling. It hardly works to deny the utility of EPO given the readily identifiable uses for

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<sup>84</sup>John J. Doll, *The Patenting of DNA*, 280 Science 689, 689 (1998).

<sup>85</sup>*Amgen*, at 1206.

it from the date of its synthesis. It could hardly be said that the synthesis was obvious given that three teams of crack scientists worked so hard to get to this solution. Nor could the “best mode” objections to this particular patent (which were rightly dismissed as groundless) ever be a serious issue on the larger structural question of whether to allow genetic patenting at all. The requirement only requires that the applicant give the clearest account within his knowledge as of the time of patenting, and in principle that requirement can always be satisfied with some fuller reckoning of the process of invention and production.

So in the end, what is so striking about the cases of genomic patents is that they suggest that the traditional analysis of patentability offers us a reasonably proxy thought the patent thicket. It is not that individual problems will not arise. Clearly borderline cases are part and parcel of the patent business whether we deal with pharmaceuticals, computers or biotech. But the point is that marginal problems require marginal responses, not social revolutions. Here it looks as though the law has got it about right. Once we remember that the best is always the enemy of the good, we should strive to leave well enough alone. It is not credible to assert that efforts of this time, cost and magnitude could take place without the shelter of the patent system.

*Express Sequence Tags* We are now in a position to contrast the treatment in *Amgen* with the well publicized controversy over express sequence tags, or ESTs where the analysis is quite different. These are a kind of gene fragment that works as a useful identifier or probe for a particular gene.<sup>86</sup> The EST is a subset of cDNA that represents only one, randomly selected, segment of the gene from which it was derived. As Holman and Munzer explain “an EST is generally about 400 to 500 nucleotides in length and encodes about 130 amino acids, whereas full-length genes are generally between 2000 and 25,000 nucleotides;...”<sup>87</sup> In most cases, it is not possible to infer the full structure of

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<sup>86</sup>For a fuller description, see Holman and Munzer at 741-750.

<sup>87</sup>Holman & Munzer at 749.

the gene from the EST involved, nor to speculate about its function. As Holman & Munzer observe:

ESTs can be useful as tools in isolating full-length genes, locating coding regions on genomic DNA, in identifying patterns of express in tissues other than the tissue of origin of the ESTs, or in the same tissue under different condition, and in other applications where unknown DNA fragments can be used. But, with a few exceptions, these uses are primarily intermediate. They do not themselves result in a “product,” but rather allow one to continue down the path to a useful end result.<sup>88</sup>

The main controversy arose over the patentability of these ESTs, which was pursued and then dropped by the National Institutes of Health under the leadership of Dr. Craig Venter. The application was eventually withdrawn,<sup>89</sup> but thereafter Incyte Pharmaceuticals had filed on a mass production basis what appears to be 400,000 patent applications for EST tags.<sup>90</sup>

I first encountered the issue of EST some years at a Symposium on intellectual property held at the University of Chicago. Professor Rebecca Eisenberg had written a general evaluation of the patent position of these ESTs<sup>91</sup> to which I added a short response,<sup>92</sup> which in my usual guarded style opined that “I could hardly conceive of a weaker case for patent protection than this one.” That bald conclusion was based solely on my own sense as to the desirability of the patent bargain from the point of view of the public. The basic intuition for the position runs as follows: once the techniques had been developed for the isolation of these ESTs, it was (and is, even more so) an easy task to

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<sup>88</sup>Id.

<sup>89</sup>Id. at 750-754. See also Christopher Anderson, NIH Drops Bid for Gene Patents, 263 Science 909 (1994).

<sup>90</sup>Holman & Munzer, Id at 750-754; Elliot Marshall, Patent Office Faces 90-Year Backlog, 272 Science 643 (1996).

<sup>91</sup>Rebecca S. Eisenberg, Intellectual Property at the Public Private Divide: The Case of Large-Scale Gene Sequencing, 3 U. Chi. L. Sch. Roundtable 557 (1996).

<sup>92</sup>Richard A. Epstein, Property Rights in cDNA Sequences: A New Resident for the Public Domain, 3 U. Chi. L. Sch. Roundtable 575 (1996).

identify them in buckets, as the deluge of Incyte patent applications demonstrates. In virtue of the fact that the ESTs are almost always “intermediaries,” once identified and so owned, their use lies largely in limiting the access that other investigators could have to the genes for which these tags supplied, as it were, a port of entry. No one thought, or thinks, that the ESTs were, or are, in and of themselves were a valuable pharmaceutical product. They form simply one link in the chain of processes that must be traversed in order to create useful pharmaceuticals out of the balky materials that nature had given us.

More to the point, perhaps, there did not seem to be any reason to pay the social price of giving patent protection to these large libraries of gene tags because private companies, most notably Merck, were prepared to fund efforts at Washington University in St. Louis to isolate and publish these ESTs in ways that brought them immediately into the public domain.<sup>93</sup> In these circumstances, it would be mistaken to assume that this decision was made out of a disinterested sense of the public good. Rather the motivation for the decision was that Merck as a firm was better off if the ESTs were unilaterally placed in the public domain than it would have been as a firm if these were kept as private property. It made that decision in the knowledge that other firms would be able to free ride on its decision to engage in unilateral publication of the information. The only reason for making this judgment is that the blocking value of the ESTs (at least at the time these decisions were made) was far greater than their use value. It was worth in a word privately creating some form of a public good. The quiescence with the EST cases suggests that other firms share this vision. No individual firm could simply pull its application with the knowledge that other firms might prevail on their own. So the applications remain in place, even when submitted by firms who think that the first best solution in cases of this sort is for all ESTs to fall within the public domain. So long as no one succeeds, everyone is better off. But if one firm succeeds then the usual logic of the

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<sup>93</sup>Holman & Munzer, at 755.

prisoner's dilemma game exerts its corrosive effect: all will want to obtain blockade positions if one does.

Nor need this effort be confined to ESTs, for the same logic could extend to any information about the genome that facilitates the creation of new commercial products without itself being a commercial product. Systematic efforts are now underway to insure that basic information about the genome is placed into what may be termed quasi public domain data bases available for general use. Creation of these bases are, for example, the object of the International Genomic Consortium<sup>94</sup> to assemble data bases that can be protected by patents, which in turn can be subject to open licenses for all. That system differs from a pure public domain system in that the IGC could use its patent position by licensing its materials to groups that make all or part of their own information available under similar licenses. It is a most difficult question to decide whether these tying sorts of arrangements are better than pure public domain, which other firms may incorporate without restriction into their own patentable inventions.

On a separate front, *Nature* also has worked hard to make sure that all the gene sequences referred to in its publications are made part of the public domain.<sup>95</sup> Other scientists have sent out the same call or alarm. Once ESTs or other information are placed in the public domain, any private firm may provide annotated libraries of the raw data, which it could market under contract as trade secrets. Presumably, the same could be done with information that is obtained under some general public license. That revenue stream would depreciate over time, but it could never be cut short by the patenting of the information that they had assembled. Looked at simply as a structural

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<sup>94</sup><http://www.intgen.org>

<sup>95</sup>Editorial, Human genomes, public and private, 409 *Nature* 745 15 February 2001): "As indicated in our "Guide to Authors", we require the results of genome sequence analyses, as with protein structure coordinates, to be immediately available from an appropriate data-base without restriction. This supports an unwritten contract with our readers that what they see described is what they can use, without obstacles, whether they work in the commercial or academic sector (an increasingly blurred distinction)."

bargain, the patenting of these ESTs did not, and does not, seem to be a good bargain from the point of view of the public at large.

That conclusion is as a matter of theory only strengthened by the considerations addressed in this paper. Whatever the abstract difficulties in working out the interaction among different patent monopoly in the general case, that problem does not exist in this situation. The function of ESTs is largely invariant, as is their mode of operation. Each EST is a gateway to some gene on which some useful work could be done. No EST has any end use. Structurally, patent protection for ESTs seems like a bad idea because it adds on downstream link in the chain of production. Sometimes this difficulty could be moderated, for two or more ESTs serve to identify a gene, so that the nice question comes up whether the second EST can be patented over the first if the two contain some but not all common elements. But even if there are two or more ESTs that give entry into a given gene, access will be more restricted under the duopoly than it would under any open access system—a system that can be effortlessly created by leaving all ESTs in the public domain. We know that there are ample incentives to create these gene tags wholly without patent protection. Why then should any protection be offered if it provides at best only small marginal stimulus for more rapid isolation and identification of these tags, but some real danger of entry blockade? If this analysis is correct, then the ESTs should be denied patent protection even if they represented some new chemical entity obtained by the intelligence of human beings. The simple fact that others put them into the public domain suggests that the public comes out the loser if they are made the subject to the patent bargain.

What is instructive about the current battle over the genome is that patent eligibility is not an effective stop against, for example, the patenting of ESTs (a point that eluded me in my 1996 denunciation of the practice). These are not like radium in the sense that they are creations through the rote manipulations of DNA and mRNA. Doctrinally, their exclusion from protection has to come for some other reason. Those

reasons are contained in the usual litany of other tests that are applied on a case-by-case basis to see, ultimately, whether it is a good bargain from the point of view of the public to extend patent protection to this cases. It is on these second-tier grounds that one has, within the confines of the patent statute to seek (in a resulted oriented sense, perhaps) ways to knock out patent protection for the ESTs, where the basic analysis so clearly points in one direction. One possibility for this result is to read the “utility” requirement of the law more strictly than is done with ordinary machines and processes, where the ability to commercialize a given invention is thought to go to the value but not the patentability of products.<sup>96</sup> But it is all too easy to imagine broad classes of chemical compounds that can be identified, and perhaps even synthesized, without any real sense of their worth. The patent law on its face looks as though all four classes of patent-eligible inventions should be treated as a piece, but this requirement has been tighten for chemicals<sup>97</sup> relative to what it has been in other areas. One of the attacks on the ESTs has been a proposal to read the utility requirement tightly so as to require the patent applicant to demonstrate specific, substantial and credible utility in ways that are explicitly meant to make it more difficult to patent ESTs.<sup>98</sup> The impulse is surely welcome, but the conclusion should be done in a categorical fashion, which is the only way to deal with the millions of applications of this sort that are before the PTO. Perhaps if utility does not work, then the sheer volume of the ESTs indicates that all of them (except perhaps the first batch) were so “obvious” that they should likewise be denied protection under the patent law which only allows patents to issue for nonobvious inventions.<sup>99</sup>

ESTs have generated a somewhat different response in a long and thoughtful article prepared by Molly Holman and Stephen Munzer. They rightly chide me for my

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<sup>96</sup>35 U.S.C. § 101.

<sup>97</sup>See *Brenner v. Manson*, 383 U.S. 519 (1966).

<sup>98</sup>See Patent and Trademark Office Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001). John J. Doll, the head of the biotechnology office of the PTO is on record as noting this consequence. Martin Enserink, Patent Office May Raise the Bar on Gene Claims, 287 Science 1196, 1197 (2000).

<sup>99</sup>35 U.S.C. § 103.

hyperbolic denunciation of the patent claims for ESTs and insist that these tags have enough useful applications so as to meet the “utility” prong needed to secure patentability, unless of course that requirement is made more stringent in this context.<sup>100</sup> Nonetheless they shy away from giving these tags full patent protection and urge as a conscious legislative reform a proposal of patent registration that offers lesser protection for ESTs, but at the same time eases the path toward their receipt of legal protection. The proposal for registration requires the state to register the patent on a showing that it is “novel,” that is has not been identified before, without a showing of any of the other requisites normally required for patentability: nonobviousness, best mode of production etc. The consequence of registration is to give the owner exclusive use for a five year period, to give the owner royalties under some compulsory licensing system for the next five years, before the EST finally falls into the public domain.

The first question is whether this proposal addresses a problem that is in need of solution. In my view, it does not. So long as we have a private party that is determined to place these ESTs in the gene tag, there is no functional justification for affording even this limited form of registration protection. In addition, it is not clear in the aggregate whether this protection is more or less valuable than ordinary patent protection. To be sure, the payoff from the registration is more limited than it is from patent protection. But by the same token the ease of registration means that individuals would spread their net wider with respect to under this system than would be the case if they were outside the patent system altogether. Five years of restriction is a long time in terms of modern research, and the second five year period raises all the troublesome question of how to price ESTs under compulsory licensing. There seems to be no reason to disturb the current situation which in essence leaves these ESTs within the public domain.

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<sup>100</sup>Such has been suggested by John Doll, the head of the Office of Biotechnology of the Patent and Trademark Office.

Conclusion: One of the most fundamental questions that arises in intellectual property law is the extent to which novel technology circumstances requires a displacement of traditional norms of property. This issue has been with us from earliest times. The rise of strong property interests in land, for example, only arose as a social response when agricultural became a viable mode of production in what had once been an exclusively hunter-gatherer society. The rise of cheap modes of printing gave birth to the law of copyright, and the institutionalization of scientific research clearly formed a powerful spur for the creation of a viable law of patents. But just as one should not assume that legal rules can remain static through all forms of social change, so it is wise to remember that legal rules need not change, and often should not change, in response to each movement in technology and trade. On a number of previous occasions, I have argued that many of the fixtures of the earlier law serve us well in modern settings.<sup>101</sup> Much depends on how the law was structured in the first instance. With patent law, it seems clear that the full range of tests of the classical were designed to figure out when it was best to give someone the exclusive rights to a given invention even at the cost of limiting its usefulness once its production has been secured. That task is inherently messy, and requires seat-of-the-pants judgments on issues for which everyone would prefer to have authoritative empirical evidence. But for these purposes, the critical point is that the fundamental tradeoffs made in the traditional patent law calculations are exactly those that have to be made in connection with the genome. Once we are secure in the obvious fact that the fundamental conditions of patent law are unchanged, then the best way to meet some test of social utility is to stick with the traditional patent law until it is shown to be misguided in some basic judgment. Although many have clamored for a basic change, that case for revamping the system not yet been made out. The innovation

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<sup>101</sup>See, Richard A. Epstein, *The Static Conception of the Common Law*, 9 J. Legal Studies 253 (1980).

we need is today is under the patent law, not of the patent law itself. Steady the course makes up in soundness what it lacks in novelty.

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