

Open Source Human Evolution

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INTRODUCTION

Genetic engineering of humans holds the potential of transforming the human body and mind. In fact, it may become a dominant influence on the future evolutionary trajectory (or trajectories) of humanity. Genetic engineering already allows humans to alter genomes in a highly targeted manner and to yield genetically novel organisms with distinctively new traits in a single generation. Deliberate alteration of specific genes in a single generation can achieve genetic changes in organisms that formerly took many generations to achieve. The results have included such novelties as glow-in-the-dark tobacco plants, laboratory mice that develop cancer almost on command, and corn plants almost impervious to their usual pest insects. Genetically “enhanced” humans may not be far behind.¹

Beyond some restrictions on federal funding,² genetic engineering remains relatively free of legal encumbrances in the United States. Genetic engineering research and development tend to be relatively

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1. This Article uses the descriptors “enhance” and “enhancement” *sensu* Henry T. Greely. See, e.g., Henry T. Greely, *Regulating Human Biological Enhancements: Questionable Justifications and International Complications*, 4 SANTA CLARA J. INT’L L. 87 (2006).

2. Federal funds are unavailable to support research on human cloning, a technique that can involve somatic cell nuclear transfer, a process likely to facilitate human genetic enhancement. LEE SILVER, REMAKING EDEN—HOW GENETIC ENGINEERING AND CLONING WILL TRANSFORM THE AMERICAN FAMILY 152 (1998).

expensive, encouraging reliance on the patent system to protect the considerable investment required. Since 1980, when the United States Supreme Court confirmed the patentability of genetically engineered eubacteria,³ patent protection has been available for newly discovered or synthesized genes and related technologies. Patents can confer strong rights to exclude others from making, using, offering to sell, or selling patented genes and related technologies within the United States, or to exclude others from importing patented genes into the United States.⁴ Because chemical and pharmaceutical patents appear to generate net economic benefits to their owners,⁵ availability of patent protection for gene and gene-related inventions may promote innovation in those types of inventions. The prospect of patent protection may promote research and development of more new genes and gene-related technologies. Thus, the patent system may lead to the creation of more raw material for human genetic enhancement while simultaneously limiting access to its applications.

Genetic engineering may allow human parents to choose the traits of their biological children precisely and predictably, where, previously, such trait selection only could be accomplished by selecting a mate possessing a subset of desired traits, and then hoping that at least some of those traits were heritable. With genetic engineering, and the high-fidelity genetic trait selection it may allow, human evolution has the potential to become a fine-tuned, deliberate, and directed process. According to the title of a book addressing human genetic enhancement and public policy, human evolution may change course, "From Chance to Choice."⁶

The patent system may influence parents' choice of genetic traits for their children. In fact, gene and gene-related patents may enable private policing of genetic engineering technologies, with strong implications for the evolutionary future of humanity. Parents wishing to ensure that their children receive particular traits might have to secure permission from owners of patents claiming such traits, and

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

4. See 35 U.S.C. § 271(a) (2003).

5. See JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 16 (2008).

6. ALLEN BUCHANEN, DAN W. BROCK, NORMAN DANIELS & DANIEL WIKLER, FROM CHANCE TO CHOICE: GENETICS & JUSTICE (2001).

then pay for such permission. Although not all genes or gene-related inventions would be protected by patents, many genes would be. In fact, research and development into especially advantageous genes could spur ever more genetic innovations that might become available to parents in the genetic enhancement marketplace. Genetic enhancement of children, though controversial, looks set to proceed apace.

Open source biology offers the prospect of an alternative approach to the invention of new medicines and therapies, including those with a genetic basis. An open source approach has been suggested as being especially suited to under-researched diseases, such as those that predominate in the developing world.⁷ Although precisely defining what is meant by “open source” is difficult, one prominent definition has been proposed by the Open Source Initiative (“OSI”).⁸ The OSI definition mandates that, to qualify as open source, a particular set of software code must be made available to others under the terms of an agreement that includes at least ten specified criteria.⁹ These criteria include free redistribution, availability of the source code, and permission to develop derivative works.¹⁰ Open source biology offers an approach to biological research whose parameters are adapted from the open source software model. Although open source biological approaches have been criticized for lacking incentives to biological innovation as effective as those offered by patent systems,¹¹ a number of recent initiatives, such as the Tropical Diseases Initiative (“TDI”), have begun to test the advantages and disadvantages of open source biology.¹²

7. See, e.g., Stephen M. Maurer, Arti Rai & Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, 1 PLOS MED. 183 (2004), available at <http://medicine.plosjournals.org/perlserv/?request=get-document&doi+10.1371/journal.pmed.0010056>.

8. Open Source Initiative Homepage, <http://www.opensource.org> (last visited on Mar 17, 2009).

9. The Open Source Definition, <http://opensource.org/docs/osd> (last visited on Mar. 17, 2009).

10. *Id.*

11. See, e.g., David W. Opderbeck, *The Penguin's Genome, or Coase and Open Source Biotechnology*, 18 HARV. J.L. & TECH. 167 (2004).

12. The Tropical Disease Initiative, <http://www.tropicaldisease.org> (last visited on Mar. 17, 2009).

If open source biology were applied to genetics, the results for human genetic enhancement could be significant. The application of open source genetics could affect rates of genetic innovation and access to enhancing genes. Part I of this Article introduces the biology of evolutionary change. Part II discusses the current state of genetic engineering and its potential application to human genetic enhancement. Parts III and IV discuss the legal contours of proprietary patent and open source genetics models of innovation, respectively, and consider what differences the two alternative models might have on rates of genetic innovation and access to genetic innovations. Part V analyzes the effects that proprietary patent models and open source genetics models could have on the future trajectory of human genetic enhancement, and suggests that open source genetics would likely yield a relatively lower rate of genetic innovation coupled with democratized wider access to the resulting smaller number of genetic enhancements.

This Article explores legal, policy, and societal implications that the patent and open source biology systems may hold as alternative methods for regulating human genetic enhancement. It argues that public policy must grapple with these implications before current technological possibilities become societal realities. It further suggests that open source genetics offers a significant alternative to the prospect of the patent system as arbiter of parental decisions regarding genetic enhancement of their children. The choices society makes about how to regulate access to human genetic enhancement could have important implications even for future trajectory of human evolution.

I. EVOLUTION¹³

A. *Early Evolution*

Biologists estimate that life on earth first arose more than four billion years ago. In its earliest form, life was probably little more than a simple single cell composed of a phospholipid cell membrane

13. This section is adapted from Andrew W. Torrance, *Patenting Human Evolution*, 56 U. KAN. L. REV. 1075, 1077–84 (2008).

within which was housed a mixture of just enough simple nucleic acids, proteins, carbohydrates, and lipids to allow the cell to carry out basic survival functions, such as metabolism, and to make faithful copies of itself. Over time, in response to both the natural selection imposed by environmental conditions and random genetic drift, this single-celled organism and its offspring gave rise to every lineage of life on earth, from microscopic archaea and eubacteria, to gargantuan sequoias and whales, to humans.

Some lineages of life met their demise through extinction. Others gave rise to additional lineages that persist into the present day. Surviving lineages include organisms spanning the range of physical size from single cells to multiple cells to billions of cells. Evolutionary success can be measured by considering any number of criteria, such as evolutionary radiation (that is, the number of relatively closely related lineages), location within a trophic web (that is, who eats whom), longevity, physical size, speed, complexity of social behavior, or cognitive capacity. However, the ultimate measure of evolutionary success is survival and reproduction into the next generation. If a lineage has persisted into the present day, it is more successful than those lineages already extinguished by the mere fact of its continued existence and its unbroken ability to transmit its genes from past to future generations.

B. Human Evolution

Modern humans are genetically very different from their ancient human ancestors. Over the past five to ten million years, an evolutionary lineage arose in Africa and acquired, among many other distinctive characteristics, bipedal gait, a brain very large relative to body size, and highly complex social behavior. This lineage is the humans, and includes modern *Homo sapiens*, the single extant species of the family *Hominidae*. Over the course of human evolution, ancestors of modern humans underwent radical changes in morphology (for example, body, head, foot, hand, and pelvis shape and size), physiology (for example, hidden estrus), and behavioral ecology (for example, grammatical and symbolic language and tool use).

A widespread assumption exists that modern humans have ceased evolving. Some derive this conclusion from religion, many varieties of which view humans as the apogee, or even the perfected final product, of biological evolution.¹⁴ Others posit that human technological mastery of the natural world has allowed humanity to sidestep nature, red in tooth and claw, avoiding the effects of natural selection entirely, and has “stopped human evolution cold.”¹⁵ Still others suggest that cultural evolution,¹⁶ which can act much more quickly than biological evolution,¹⁷ has displaced biological evolution as the dominant force molding humanity, and that, while human ideas may evolve, human genes no longer do.

Even some biologists have sounded the demise of human evolution. Julian Huxley, for example, suggested that “the more elaborate social life is, the more it tends to shield individuals from the action of natural selection.”¹⁸ Stephen Palumbi has outlined the hypothesis of human evolutionary stasis as follows:

When we provide medical treatment to the injured, give food to the hungry, replace brute muscle with John Deere tractors—the argument goes—we prevent selection from weeding out a myriad of weak or physically imperfect individuals. Because we can clothe ourselves in winter, feed ourselves from storehouses during droughts, predict tsunamis and the paths of hurricanes—the argument continues—we break the link between physical variation among different humans and differences in reproductive success.¹⁹

However, actual biological evidence suggests that evolution by natural selection still strongly affects humans.²⁰ Technological

14. Of course, some religions include beliefs that are inconsistent or incompatible with the very existence of biological evolution.

15. STEVEN R. PALUMBI, *THE EVOLUTION EXPLOSION: HOW HUMANS CAUSE RAPID EVOLUTIONARY CHANGE* 211 (2001).

16. Also known as “exo-somatic evolution” and “technological evolution.”

17. RICHARD DAWKINS, *THE ANCESTOR’S TALE: A PILGRIMAGE TO THE DAWN OF TIME* 26 (2004).

18. PALUMBI, *supra* note 15, at 209.

19. *Id.*

20. *Id.* at 211–30.

development has “failed to halt human physical evolution.”²¹ Although some of the natural selective forces acting to change human genotypes and phenotypes may have changed (for example, predation by other large organisms certainly plays a much lesser role than once it did), humans continue to evolve today.

C. Evolution and Genes

Darwin’s theory of evolution by natural selection depends upon three observations about the natural world: first, “[a]ll organisms tend to produce more offspring than can possibly survive”²² in a world of limited resources; second, offspring tend not to be identical, but vary among themselves; and third, at least some of this variation is inherited by future generations.²³ As an inference from these three observations “on average . . . survivors will tend to be those individuals with variations that are fortuitously best suited to changing local environments. Since heredity exists, the offspring of survivors will tend to resemble their successful parents. The accumulation of these favorable variants through time will produce evolutionary change.”²⁴

All organisms are subject to natural selection, including humans. Despite apparent mastery of many aspects of their environment, humans continue to evolve with every new generation.

Evolution in its most general sense simply means change over time. Biological (or organic) evolution (hereinafter simply “evolution”) refers to “[g]enetic changes in lineages of organisms over time. Through this process, a lineage may split and diversify into new species.”²⁵ Evolution is universal. It occurs in every lineage. While there may be an implicit assumption, especially outside of the scientific communities, that evolution is something that happens only to organisms other than humans, it would be remarkable, and

21. *Id.* at 211.

22. STEPHEN J. GOULD, FULL HOUSE: THE SPREAD OF EXCELLENCE FROM PLATO TO DARWIN 138 (1996).

23. *Id.*

24. *Id.*

25. Tree of Life Glossary, <http://tolweb.org/tree/home.pages/glossary.html#evolution> (last visited Feb. 27, 2009).

extremely improbable, if human evolution were to cease. Evolution is continuous. Though rates of evolution certainly fluctuate, whether due to natural selective challenges or to mere stochasticity, genetic changes in lineages of organisms march ever onward. Even humanity experiences continuous genetic changes over time.

Evolution can occur rapidly. Though some evolutionary changes take long periods of time, rates of evolutionary change need not be slow. Numerous examples exist of rapid evolution within populations of microbes. Perhaps the most prominent example of rapid microbial evolution is the emergence of antibiotic-resistance among some infectious eubacteria, such as *Staphylococcus aureus*, *Streptococcus pneumoniae*, and *Salmonella* species.²⁶ Rapid evolution has also been observed in much larger multicellular organisms, such as insects.²⁷ However, even vertebrates appear capable of rapid evolution. A series of studies of *Anolis* lizards on Caribbean islands by Jonathan Losos's research group have challenged assumptions that vertebrate evolution requires many generations and long periods of time.²⁸ Based on an empirical study tracking evolutionary change in *Anolis sagrei* lizards found on six small Bahamian islands, Losos's group observed that

[b]ecause of its potentially epochal scope, evolutionary biology is often caricatured as a strictly descriptive science, but recent years have shown that evolution can be studied on short time scales and that evolutionary biology can be both experimental and predictive. . . . [W]e showed that selection dramatically changed direction over a very short time, within a single generation, favoring first longer and then shorter hindlimbs. The behavioral shift from the ground to higher perches of smaller diameter apparently caused this remarkable reversal;

26. See generally ROBERT VERNE MILLER & MARTIN J. DAY, MICROBIAL EVOLUTION (2004).

27. See, e.g., Raymond B. Huey, George W. Gilchrist, Margen L. Carlson, David Berrigan & Luis Serra, *Rapid Evolution of a Geographic Cline in Size in an Introduced Fly*, 287 SCIENCE 308, 308 (2000).

28. See, e.g., Jonathan B. Losos, Thomas W. Schoener, R. Brian Langerhans & David A. Spiller, *Rapid Temporal Reversal in Predator-Driven Natural Selection*, 314 SCIENCE 1111, 1111 (2006).

behavioral flexibility, indeed, may often be the key in driving extremely rapid reversals in evolution.²⁹

Evidence also exists for rapid evolution of humans.³⁰ “Evolution is the result of accumulated changes in the composition of the gene pool.”³¹ Biological evolution is genetic change in a lineage of organisms over generations.³² A genotype is the “genetic constitution, latent or expressed [or] the sum total of all the genes present in an individual.”³³ “Genetic information is encoded in the sequence of nucleotides in molecules of DNA, and these, in turn, determine the sequence of amino acids in molecules of protein.”³⁴ A phenotype is the “physical appearance of an organism.”³⁵ The phenotype of an organism “results from the interaction between the genetic constitution (genotype) of the organism and its environment.”³⁶

An organism’s genes encode information used in the synthesis of molecules that construct the organism, maintain its various functions, and form the physical embodiment of the organism. Biological evolution occurs when different gene variants (“alleles”) change their relative frequencies in population of organism over time:

In natural populations, some alleles increase in frequency from generation to generation, and others decrease. (The frequency of an allele is simply the proportion of that allele in a population in relation to all the alleles of the same gene.) If an individual has a favorable combination of alleles in its

29. *Id.*

30. GREGORY CLARK, *A FAREWELL TO ALMS: A BRIEF ECONOMIC HISTORY OF THE WORLD* (2007). This controversial book includes a hypothesis that the population of Britain underwent rapid genetic change during and after (and possibly in response to) the Industrial Revolution.

31. PETER H. RAVEN ET AL., *BIOLOGY OF PLANTS* 258 (6th ed. 1999).

32. A number of scholars have posited the importance of cultural evolution as a complement, or sometimes an alternative, to biological evolution. Consider, for example, Dawkins’s theory of the meme. *See generally* DAWKINS, *supra* note 17. However, such cultural evolution was most likely made possible by underlying biological evolutionary changes, such as increases in brain size and complexity.

33. RAVEN ET AL., *supra* note 31, at 231.

34. *Id.*

35. *Id.* at 905.

36. MARYANN WHITMAN, *WILD ONES PHILOSOPHY* (2005), <http://www.for-wild.org/download/wophilos/wophilos.html> (last visited Apr. 8, 2009).

genotype, it is more likely to survive and reproduce. As a consequence, its alleles are likely to be present in an increased proportion in the next generation. Conversely, if the combination of alleles is not favorable, the individual is less likely to survive and reproduce. Representation of its alleles in the next generation will be reduced or perhaps eliminated. Evolution is the result of such accumulated changes in the gene pool over time.³⁷

Genotypic change over time produces phenotypic change over time.

Evolution does not progress towards any particular goal, destination, or end-point (except, in some cases, extinction). Evolutionary change proceeds by the “accumulation of . . . favorable variants through time.”³⁸ Natural selection favors the survival and reproduction of those organisms that happen to be better adapted to their local environments. However, local environments tend to change. This leads to constant adaptation for survival, rather than progress:

If a sequence of local environments could elicit progressive advance through time, then some expectation of progress might be drawn from natural selection. But no such argument seems possible. The sequence of local environments in any one place should be effectively random through geological time—the seas come in and the seas go out, the weather gets colder, then hotter, etc. If organisms are tracking local environments by natural selection, then their evolutionary history should be effectively random as well.

These arguments led Darwin to his denial of progress as a consequence of the “bare bones mechanics” of natural selection—for this process yields only local adaptation, often exquisite to be sure, but not universally advancing.³⁹

37. RAVEN ET AL., *supra* note 31, at 239.

38. GOULD, *supra* note 22, at 138.

39. *Id.* at 139–40.

D. Deliberate Evolution

Evolution by natural selection is not the only form of evolution that Charles Darwin observed. In fact, he transposed principles of animal and plant breeding, which is known as “artificial selection,” to understand how natural selection might function to drive biological evolution. Darwin was struck by the rapidity and magnitude of the biological change allowed by means of artificial selection:

We cannot suppose that all the breeds were suddenly produced as perfect and as useful as we now see them; indeed, in several cases, we know that this has not been their history. The key is man’s power of accumulative selection: nature gives successive variations; man adds them up in certain directions useful to him. In this sense he may be said to make for himself useful breeds.

The great power of this principle of selection is not hypothetical. It is certain that several of our eminent breeders have, even within a single lifetime, modified to . . . a large extent some breeds of cattle and sheep.⁴⁰

Darwin concluded that, to alter genotypes and phenotypes, “the accumulative action of selection . . . is by far the predominant power.”⁴¹

The Tibetan Yak provides a vivid illustration of the fundamental changes to an organism’s biology that artificial selection can make, in this case “artificial selection over the centuries that Tibetans have depended on them.”⁴² Tibetan yaks have become superbly suited to existence in the mountains of Tibet:

Over the generations, Tibetan yaks have become so adapted to high altitudes they suffer poor health under 10,000. Their coarse hair, hanging in ragged insulating cascades, combines with other features of their physiology to protect them from the

40. *Charles Darwin, On the Origin of Species, in THE WORKS OF CHARLES DARWIN* 1, 11 (Paul H. Barrett & R. B. Freeman eds., New York University Press 1988) (1859).

41. *Id.* at 32.

42. PALUMBI, *supra* note 15, at 178.

rigors of the Himalayas. They have immense lungs—three times larger than similar-sized cows—to pull oxygen from the miserly air. They have less hemoglobin in their red blood cells, and indeed fewer red blood cells, than their lowland relatives. This thin blood allows for a higher ability to withstand temporary dehydration in the dry air and prevents blood cells from being forced out of ruptured capillaries by the high blood pressure required in high-altitude environments. Even the microstructure of their lungs differs. Yaks have thin-walled arterioles in their lungs, allowing better transport of oxygen into their bloodstream.⁴³

Many of these adaptations are extreme, allowing Tibetan yaks to exist in habitats and achieve results their ancestral yaks could not. In fact, so extreme are some of their adaptations that Tibetan yaks can no longer thrive below high altitudes.

Humans too have evolved adaptations to their peculiar ecological niche. Like the Tibetan yak, many of these adaptations have a genetic basis.

II. HUMAN GENETIC ENHANCEMENT⁴⁴

A. Genetic Engineering

Genetic engineering allows the goals of artificial selection to be achieved more efficiently than traditional selective breeding programs. By inserting genes into the genome of an organism, such as a human, traits of that organism could be altered precisely and immediately within a single generation.

Genetic engineering, or recombinant DNA technology, encompasses a set of chemical methods by which means the “genetic endowment of organisms can now be precisely changed in designed ways.”⁴⁵ Genetic engineering “allows selected individual genes to be transferred from one organism into another, including genes from

43. *Id.*

44. This section is adapted from Torrance, *supra* note 13, at 1081–91.

45. JEREMY M. BERG ET AL., *BIOCHEMISTRY* 134 (6th ed. 2008).

unrelated species.”⁴⁶ Genetic engineering includes transgenics (transferring genes from organism to organism), genetic alteration (altering genes within the existing genome of an organism), and cloning (creating a genetic duplicate of an existing organism, and then, optionally, altering the genome of that organism). Although genetic engineering has heretofore relied largely upon existing genes, advances in the techniques of synthetic biology offer the imminent prospect of synthetic genes, and entire genomes, designed and synthesized *de novo*.⁴⁷

As long as there has been agriculture, humans have deliberately modified the genetic material of their crops and livestock through selectively breeding for desired genetic traits. Genetic engineering “can be used to promote a desirable . . . character or to suppress an undesirable trait,”⁴⁸ and has allowed genetic modification to be achieved more precisely, efficiently, and rapidly than previously possible. Genetic engineering allows the creation of high-fidelity genetic modifications within a single generation, in contrast to the slow rates of progress and low success rates of traditional selective breeding techniques. Genetic engineering has already created crops with enhanced yields and reduced requirements for agricultural inputs, such as nutrients, water, fertilizer, herbicides, and pesticides. Similar results have been achieved with genetically enhanced livestock.

46. NUFFIELD COUNCIL ON BIOETHICS, THE USE OF GENETICALLY MODIFIED CROPS IN DEVELOPING COUNTRIES: A FOLLOW-UP DISCUSSION PAPER 5 (2004), available at http://www.nuffieldbioethics.org/fileLibrary/pdf/GM_Crops_Discussion_Paper_2004.pdf.

47. See, e.g., Daniel G. Gibson et al., *Complete Chemical Synthesis, Assembly, and Cloning of a Mycoplasma genitalium Genome*, 319 SCIENCE 1215, 1215–20 (2008).

In fact, this work has already formed the basis for U.S. Patent Application No. 11/635,355, entitled “Synthetic Genomes,” which claims multiple variations on “[a] method for constructing a synthetic genome,” “[a] synthetic genome,” “[a] method for making a synthetic cell,” “[a] synthetic cell,” and, most comprehensively, “A method comprising: designing a synthetic genome; constructing the synthetic genome; introducing the synthetic genome into a biological system; and expressing the synthetic genome.”

Torrance, *supra* note 13, at 1084–85 n.39, citing U.S. Patent Application 20070264688, available at <http://patft.uspto.gov> (follow “Quick Search” under “Published Applications”; then search for “synthetic genomes”).

48. Gibson et al., *supra* note 47, at 1215–20.

Golden Rice illustrates the great promise and power of genetic engineering to enhance the genetic traits of organisms. Although rice is the major source of calories for much of the world's population,⁴⁹ its grains lack a nutrient vital to human health: beta-carotene. A biological problem precluded the use of traditional genetic techniques: Since beta-carotene is not produced in the rice endosperm (that is, the edible tissue of rice),⁵⁰ traditional selective breeding was not an option. Rather, two plant biologists, Potrykus and Beyer, realized that genetic engineering was necessary to introduce genetic traits where they previously did not exist.

Potrykus and Beyer discovered that the addition of two transgenes (that is, genes from organisms other than rice) to the rice genome led to the production of beta-carotene in the endosperm:

The first transgene encodes phytoene synthase (PSY), which utilises the endogenously synthesized geranylgeranyl-diphosphate to form phytoene, a colorless carotene with a triene chromophore. The second encodes a bacterial carotene desaturase (CRTI) that introduces conjugation by adding four double bonds. The combined activity of PSY and CRTI leads to the formation of lycopene, which is a red compound due to its undecaene chromophore.⁵¹

With the addition of these transgenes, rice endosperm is able to produce beta-carotene in significant amounts.⁵² Although the first generation of Golden Rice contained a PSY gene derived from daffodil and a CRTI gene derived from a bacterium, *Erwinia uredovora*, much greater amounts of beta-carotene were later achieved by inserting a PSY gene from maize.⁵³ By 2005, the Golden Rice genetically engineered by Potrykus and Beyer was capable of producing sufficient beta-carotene to meet even the ambitious

49. GOLDEN RICE, HUMANITARIAN BOARD, THE SCIENCE BEHIND GOLDEN RICE (2007), http://www.goldenrice.org/Content2-How/how1_sci.html.

50. *Id.*

51. *Id.* (citation omitted).

52. *Id.*

53. *Id.*

recommended daily allowances for children in rich, developed countries.⁵⁴

Golden Rice sets into high relief a crucial difference between traditional selective breeding for genetic traits, on one hand, and genetic engineering, on the other. The former can only yield organisms with heritable traits amplified from existing genes, and can only do so over multiple generations; where there is no genetic basis for a trait, that gene-based trait cannot be bred. Genetic engineering, by contrast, can create organisms with gene-based traits in organisms with no genetic basis for such traits, and can do so within a single generation.

B. Genetic Engineering of Humans

Though useful and widespread for more than thirty years as a technique for adding genetic traits to nonhuman organisms, genetic engineering was, until a decade ago, inapplicable to humans themselves. Even its successful application to a variety of fellow mammals did not justify its use in humans, largely for ethical reasons. As Lee Silver, a geneticist at Princeton University, explains,

[s]ince the 1980s, genetic engineering has been practiced with success in animals like mice, cows, sheep, and pigs. But it has yet to be applied to human beings for one simple reason—it is incredibly inefficient. With the simplest technique for adding genes to embryos, the success rate is 50 percent at best, and this is accompanied by a 5 percent risk of inducing disease-causing mutations in the animal that is born. That's not a problem for animal geneticists—who can choose the one healthy animal with a desired genetic modification from among a litter or flock—but it is unacceptable for use with humans. And with more sophisticated techniques of gene alteration, the problem just gets worse, with only one cell in a million likely to be altered in the correct way.⁵⁵

54. *Id.*

55. SILVER, *supra* note 2, at 152.

However, the discovery of mammalian cloning has made genetic engineering much more feasible in humans by removing a number of the pre-cloning technical hurdles. Silver continues:

With such a low rate of success, the direct engineering of genes within an isolated human embryo—destined to be a child—is not something that anyone would try or accept. But with cloning, the entire equation changes. Now, multiple cells grown from a single embryo could be subjected to genetic engineering. With protocols already available today [in 1998], those that appear to be engineered as desired could be recognized and picked out. Each single selected cell could be expanded by itself into a clone of cells that provides sufficient material for the confirmation of genetic integrity. Then, and only then, would one cell from this mass of cells be used by means of nuclear transformation to produce a new embryo, which would develop into a new human being, with a special genetic gift. Incredibly, within five months of the announcement of Dolly's birth, on July 25, 1997, the same team of Scottish scientists announced that they had successfully carried out this very protocol with the birth of several lambs carrying a foreign human gene. It is in the very same manner—when the techniques of cloning and genetic engineering are combined—that the human species will gain control over its own destiny.⁵⁶

Since the birth of Dolly, ethical concerns have shifted, to focus less on rates of success for genetic engineering than on whether or not humans should be genetically engineered at all. The ability of human parents to select genetic traits for their children is now more a question of when rather than if.

C. Genetic Enhancement of Humans

Humans have always welcomed enhancements to their capacities, including those made possible by new technology. As Henry T. Greely points out,

56. *Id.*

[t]he story of humanity is the history of enhancement. Stone tools, control of fire, and clothing all enhanced the success of hunter gatherers. Agriculture enhanced food supply and population size and made possible the specialization of labor. Writing systems enhanced our ability to communicate, among people and across time, and strengthened our memories; printing reduced the costs of mass distribution of information. Metallurgy and engineering, electricity and computers have all increased what humans can do and what we can be.⁵⁷

An often controversial category of enhancement is biological enhancement.⁵⁸ Biological enhancements “increase our abilities by enhancing our biological selves through new technical inventions.”⁵⁹ Examples of biological enhancement include plastic surgery that increases a recipient’s physical attractiveness, caffeine that improves a recipient’s ability to study late into the night, and anabolic steroids that accelerate a recipient’s ability to acquire muscle mass.

While biological enhancement is controversial, genetic enhancement is especially so. Many people consider genetic engineering to enhance human beings unethical, immoral, or both. However, the human desire to improve is strong, and the desire to improve one’s children permanently is an extremely powerful force. The capacity that somatic nuclear transfer, or cloning, has for genetic enhancement of one’s offspring will be highly attractive to many parents. Parents, who tend to be especially fond of providing their children with advantages, will be especially interested in making such enhancements permanent by engineering them into their offspring. Lee Silver offers the following prediction:

Genetic engineering will eventually be used by future reprogeneticists. It will begin in a way that is most ethically acceptable to the largest portion of society, with the treatment of only those childhood diseases—like sickle cell anemia or cystic fibrosis—that have a severe impact on quality of life.

57. Greely, *supra* note 1, at 88.

58. *See generally id.*

59. *Id.* at 88.

The number of parents who will desire this service will be tiny, but their experience will help to ease society's trepidation.

As the fear begins to subside, reprogneticists will expand their services to nullify mutations that have a less severe impact on a child, or an impact delayed until childhood. Predisposition to obesity, diabetes, heart disease, asthma, and various forms of cancer all fall into this category. And as the technology spreads, its range will be extended to the addition of new genes that serve as genetic inoculations against various infectious agents, including the HIV virus that causes AIDS. At the same time, other genes will be added to improve various health characteristics and disease resistance in children who would not otherwise have been born with any particular problem.

The final frontier will be the mind and the senses. Alcohol addiction will be eliminated, along with tendencies toward mental disease and antisocial behavior like extreme aggression. Visual and auditory acuity will be enhanced in some to improve artistic potential. And when our understanding of the genetic input into brain development has advanced, reprogneticists will provide parents with the option of enhancing various cognitive attributes as well. . . .

In the short term . . . most genetic enhancements will surely be much more mundane [than potentially extraordinary enhancements]. They will provide little fixes to all of the naturally occurring genetic defects that shorten the lives of so many people. They will enrich physical and cognitive attributes in small ways. And as the years go by over the next two centuries, the number and variety of possible genetic extensions to the basic human genome will rise exponentially—like the additions to computer operating systems that occurred during the 1980s and 90s. Extensions

that were once unimaginable will become indispensable . . . to those parents who are able to afford them.⁶⁰

Lee Silver envisions that the availability of genetic enhancement will have great effects on society. In fact, he predicts the emergence of a social, political, economic, and even reproductive barrier between the genetically enhanced (“GenRich”) and those without genetic enhancements (“Naturals”):

[A] difference has emerged [among humans] that is sharp and easily defined. It is the difference between those who are genetically enhanced and those who are not. The GenRich . . . all carry synthetic genes. Genes that were created in the laboratory and did not exist within the human species until twenty-first century reproductive geneticists began to put them there. The GenRich are a [future] hereditary class of genetic aristocrats.⁶¹

The future course of human genetic enhancement is unlikely to lead to a scenario exactly like that proposed by Lee Silver. Nevertheless, it is highly probable that genetic enhancement of some kind—whether narrow in scope and relatively uncontroversial in nature, such as ameliorating genetic diseases, or broader in scope and more controversial, such as expanding the potential abilities of humans beyond their non-genetically enhanced baselines—will occur in the near future.

Humans have attempted to enhance themselves for millennia. Enhancement is an unsurprising and rational goal because it confers, or is perceived to confer, advantages. Becoming faster, stronger, healthier, more attractive, or cleverer are all obvious temptations, especially in a society where competition can decide who receives scarce resources such as acceptance to prestigious schools, academic scholarships and awards, remunerative jobs, high social status, financial prestige, and desirable mates. Existing individuals might wish such enhancements for themselves, though successfully conferring genetic traits that might undergird such enhancements

60. SILVER, *supra* note 2, at 277–78.

61. *Id.* at 5.

would be technologically difficult. However, enhancing one's children would be far more feasible, even with existing biotechnology, since enhancing genes could be introduced into embryos early enough to ensure that all subsequent cells carry the enhanced genotype.

Parents will often make extreme efforts to ensure the success of their children, sometimes even sacrificing themselves in favor of their offspring's survival. If genetic enhancement were to raise the probability that their children might thrive in a highly competitive world, at least some, and probably many, parents would be willing to choose genetic enhancement for their children. Furthermore, if some parents chose to enhance their offspring, other parents, who might otherwise have opted not to enhance, would feel pressure to ensure that their own offspring did not begin life at a genetic disadvantage relative to the genetically enhanced children of other parents.

In the language of evolutionary biology, the strategy of not enhancing one's offspring while others enhance their offspring might be an unstable strategy. The societal implications could also be destabilizing. Philosopher Jürgen Habermas has observed that genetic enhancement of some but not others might threaten "the essentially symmetrical relations between free and equal human beings."⁶² However, in the likely absence of governmental intervention in reproductive decision-making, parents will perform the fearful calculus about whether or not to attempt to enhance their children genetically. Michael Sandel explains the stark choice that may face parents:

Pointing to the possible effects of bioengineering on humility, responsibility, and solidarity may be persuasive to those who prize those virtues. But those who care more about gaining a competitive edge for their children or themselves may decide that the benefits to be gained from genetic enhancement outweigh its allegedly adverse effects on social institutions and moral sentiments.⁶³

62. JÜRGEN HABERMAS, *THE FUTURE OF HUMAN NATURE* 23 (2003).

63. MICHAEL J. SANDEL, *THE CASE AGAINST PERFECTION: ETHICS IN THE AGE OF GENETIC ENGINEERING* 95 (2007).

Human genetic enhancement will almost certainly become a technological reality in the near future, and it is vital to consider how the law will regulate access to it. Currently, although drug regulation laws may police the safety and efficacy of genetic enhancements intended for the market, it is the patent system that will largely determine who gains access to those genetic enhancements that are approved.

III. PATENTS AND GENETIC ENHANCEMENT⁶⁴

A. *The Patent System*

The Patent Act⁶⁵ requires patent applications to satisfy several statutory requirements before they can become patents. Beyond a number of procedural requirements, there are several substantive requirements, principally those of novelty,⁶⁶ nonobviousness,⁶⁷ utility,⁶⁸ disclosure,⁶⁹ and claims.⁷⁰

Patents are expensive and take a long time to obtain. On average, an applicant for a patent pertaining to a complex technology will spend more than eleven thousand dollars simply to file a patent application,⁷¹ and, after filing, considerably more to obtain enforceable patent rights.⁷² The examination system of the United States Patent and Trademark Office (“USPTO”), the agency where patent applications are examined by technically skilled examiners before a patent can issue, acts relatively slowly. Patent prosecution

64. This section is adapted from Torrance, *supra* note 13, at 1091–1101.

65. 35 U.S.C. §§ 1-2071 (2006).

66. *Id.* § 102.

67. *Id.* § 103.

68. *Id.* § 101.

69. *Id.* § 112.

70. *Id.*

71. Thomas C. Fiala & Jon E. Wright, *Preparing and Prosecuting a Patent that Holds Up in Litigation*, in PATENT LITIGATION 2006, at 515 (PLI Patents, Copyrights, Trademarks, and Literary Property Course Handbook Series No. 9001, 2006) (“For example, based on the AIPLA Report of the Economic Survey 2005, the average expected charge in 2004 for preparing and filing a utility patent application was \$11,218 for a relatively complex electrical or computer application and \$12,373 for a relatively complex biotechnology/chemical application.”).

72. Interview with Craig Smith, Partner, Fish & Richardson P.C. (Mar. 5, 2007).

(the process through which a patent application must pass prior to issuance as a patent) generally takes from two-and-a-half to five years,⁷³ with the duration of prosecution rising with the complexity of the technology involved.

Once a patent is actually issued by the USPTO, the term of a patent is almost always significantly less than the theoretical twenty-year term because of time spent in patent prosecution or regulatory approval. Even with patent-term extension to compensate for unreasonable federal agency review, the average enforceable lifetime of a patent lasts only about fifteen to seventeen-and-a-half years. If a patent owner decides to enforce the right to exclude others from making, using, selling, offering to sell, or importing a patented invention, the average cost of patent litigation can rise above \$5 million, depending on the amount of damages at issue.⁷⁴ Additionally, patent litigation involves a significant degree of unpredictability, at least in part due to the proliferation of judicial barriers and available defenses to patent infringement.⁷⁵

73. *Id.* The USPTO Performance Report for fiscal year 2006 reports an average patent pendency time (defined as time from filing until patent issued or application abandoned by applicant) of 31.1 months and shows that this figure has been increasing over the past few years. See U.S. PATENT & TRADEMARK OFFICE, DEP'T OF COMMERCE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2006, at 22 (2006), available at <http://www.uspto.gov/web/offices/com/annual/2006/2006annualreport.pdf>. However, the average pendency times estimated by the USPTO are likely underestimates. Kristen Osenga, *Entrance Ramps, Tolls, and Express Lanes—Proposals for Decreasing Traffic Congestion in the Patent Office*, 33 FLA. ST. U. L. REV. 119, 130 (2005) (“[T]he average prosecution (or pendency) time for an ultimately successful patent is 3.6 years, with a median of 2.7 years. Anecdotally, the time period . . . varies by technology and ranges from twenty-four to thirty-six months for chemical and mechanical arts and thirty-six to sixty months for electrical and software arts” (footnote omitted)).

74. Fiala & Wright, *supra* note 71, at 522.

In comparison, the average estimated costs associated with litigating a patent in 2005 as reported by [AIPLA Report of the Economic Survey 2005] were: \$769,562 for a patent infringement suit in which less than \$1 million was at risk; \$2,637,179 for a suit in which between \$1 and \$25 million was at risk; and \$5,175,753 for a suit in which more than \$25 million was at risk.

Id.

75. See David J.F. Gross & Shawn T. Gordon, *Claim Construction, Patent Infringement, and the Growing Importance of the Claim Vitiating Defense*, in PATENT LITIGATION 2005, at 45, 51 (PLI Patents, Copyrights, Trademarks, and Literary Property Court Handbook Series No. 6578, 2005) (“[T]he Federal Circuit has erected several independent barriers to finding infringement under the doctrine of equivalents, but the most foreboding of such barriers may be

Patent rights have attracted an increasing amount of controversy from the public in recent years. This is especially true where gene patents are concerned. This controversy is one of the factors that has led to suggestions about open source biology as an alternative approach.

B. The Patent Quid Pro Quo

Among the rights a patent confers to the patent owner is the right to exclude others from making, using, selling, offering to sell, or importing the claimed invention during the term of the patent, or from inducing or contributing to such infringement.⁷⁶ The patent term is twenty years from the filing date of the patent application.⁷⁷ In return for the limited monopoly right to exclude, an inventor must provide the public with a full disclosure of the claimed invention.⁷⁸

According to 35 U.S.C. § 112, a patent applicant must provide a detailed and explanatory disclosure of the claimed invention:

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 of carrying out his invention.⁷⁹

This disclosure requirement is often conceived as part of a bargain between inventor and society. In return for monopoly rights to exclude others from making, using, offering to sell, or selling the

the doctrine of claim vitiation.”); Douglas R. Nemeo, *Current Trends in Equitable Defenses to Patent Infringement: Prosecution Laches and Inequitable Conduct*, in *PATENT LITIGATION 2004*, at 1147, 1155 (PLI Patents, Copyrights, Trademarks, and Literary Property Court Handbook Series No. 3149, 2004) (“This article . . . compares several recent Federal Circuit decisions on inequitable conduct, and explores how these cases, together with *Symbol Technologies*, suggest an inclination by the Federal Circuit toward more vigorous policing and enforcement of the rules of conduct before the PTO.”).

76. 35 U.S.C. §§ 154(a)(2), 271(a)–(b) (2006).

77. *Id.* § 154(a)(2).

78. *Id.* § 112.

79. *Id.*

patented invention within the United States, or importing the patented invention into the United States,⁸⁰ the patentee contributes new information to the metaphorical public storehouse of knowledge. Although information about how to practice the claims is of limited immediate usefulness in the face of the patent owner's right to exclude others during the term of a patent, the teachings in a patent do provide society with new knowledge or techniques. These new teachings may help other inventors to develop other, unrelated inventions, improvements on the claimed invention, or noninfringing alternatives that directly compete with the claimed invention.⁸¹ In addition, once the patent term expires, so does the patent owner's right to exclude others from freely practicing the claimed invention.⁸² The disclosure requirement functions to assist in ensuring the fairness of the bargain made between inventor and society by ensuring that the public storehouse of knowledge receives reliable, new information⁸³ to justify toleration of the deadweight loss to society caused by the patent owner's monopoly exclusion right. As the Supreme Court has pronounced, the disclosure requirement is "the *quid pro quo* of the right to exclude."⁸⁴

The first paragraph of 35 U.S.C. § 112 outlines the disclosure requirement.⁸⁵ An applicant for a patent must provide "a written description of the invention."⁸⁶ This disclosure requirement has several purposes. First, it serves a notice function, by providing the public with a specific indication of what the inventor considers to be his or her invention. Second, the disclosure requirement represents the very core of the patent bargain and is "arguably the most

80. *Id.* §§ 154(a)(2), 271(a)–(b).

81. Note that these informational amenities all lessen the deadweight loss to society incurred by the monopoly exclusion rights conferred by the patent grant.

82. 35 U.S.C. § 154(a)(2) (2006) ("[The patent] grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States.").

83. Patent applications are published within about eighteen months of filing. *Id.* § 122(b)(1)(A) ("[E]ach application shall be published . . . promptly after the expiration of a period of [eighteen] months from the earliest filing date.").

84. *J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974)).

85. 35 U.S.C. § 112 (2006).

86. *Id.*

important patent doctrine after obviousness.”⁸⁷ It is crucial for ensuring that society receives an adequate description of inventions in exchange for tolerating the monopoly right to exclude others granted to inventors.⁸⁸ One of the paramount purposes of the disclosure requirement is

to provide the assurance that the public will, in fact, receive something in return for the patent grant. This consideration is, of course, the full and complete disclosure of how to make and use the claimed invention. Thus, the patent adds a measure of worthwhile knowledge to the public storehouse. The incentive to give this added measure of knowledge to the public, which clearly promotes the progress of the “Useful Arts,” is the primary justification for the existence of the patent system.⁸⁹

A patent application claiming a new gene (or any other invention) must disclose “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.”⁹⁰ Furthermore, as explained in *In re Wright*,

[a]lthough not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without “undue experimentation.”⁹¹

C. Promoting Progress in the Useful Arts

Legal authority for a patent system is provided by the United States Constitution. Specifically, Article I, Section 8, clause 8 states that “The Congress shall have power . . . to promote the progress of

87. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 982 (Fed. Cir. 2002) (Radar, J., dissenting) (addressing the enablement requirement).

88. In economic terms, the enablement requirement, along with the written description and best mode requirements, may be viewed as attempts to minimize the deadweight loss to society attending the monopoly right conferred by a patent.

89. *In re Argoudelis*, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring).

90. 35 U.S.C. § 112.

91. *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”⁹² Congress has relied on this explicit constitutional authority to offer statutory patent protection for inventions since the original Patent Act of 1790.⁹³

“[T]o promote progress of science and the useful arts,” the availability of patent protection provides an incentive for inventors to invest their valuable time and efforts on the development of technological innovations. By virtue of the monopoly right that a patent confers, investments in developing new and useful compositions, devices, and methods have an opportunity of yielding profits because inventors can exclude all others from making, using, selling, offering to sell, or importing their inventions for a substantial period of time. A particular advantage of this incentive system is that Congress need not offer inventors financial rewards for new inventions because, based on the right to exclude others, patent owners can directly extract monopoly rents from consumers wishing to make or use patented inventions. The monopoly pricing that the patent system allows does inflict a deadweight loss on society. However, the monopoly endures only for a limited period of time (that is, twenty years from the filing date of a utility patent or Patent Cooperation Treaty application), after which the right to exclude others is lost, and competition can drive down prices. Counteracting the deadweight loss to society, the disclosure of a patent application delivers informational benefits to society as soon as it is published (that is, usually about eighteen months following the patent application’s priority date).⁹⁴

The patent system is commonly assumed to promote scientific and technological progress.⁹⁵ By conferring to inventors a limited monopoly right to exclude, the patent system should create incentives for scientific technical innovation additional to those incentives that would exist in the absence of available patent protection. The United

92. U.S. CONST. art. I, § 8, cl. 8.

93. Patent Act of 1790, ch. 7, 1 Stat. 109 (1790).

94. *See supra* note 83.

95. Here, “scientific” and “technical” are intended to be interpreted broadly to include all fields entitled to patent protection, including biological, chemical, physical, electrical, mechanical, software, athletic, business, and financial innovations.

States Constitution explicitly recognizes that the goal of the patent system is “[t]o promote the progress of . . . useful arts.”⁹⁶ In theory, potential inventors will respond to the incentive created by the patent system by choosing to allocate more time, energy, and other resources into inventing “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”⁹⁷ than would otherwise be the case.

The hypothesis that the patent system spurs innovation (hereinafter, the “Innovation Hypothesis”) has been tested by a number of different approaches by both economists and legal thinkers. Some of these have established theoretical frameworks to explain why the patent system should promote innovation. Others have attempted to estimate the additional quantum of innovation created by the availability of patent protection by using a number of distinct approaches: designing mathematical models of technological innovation; attempting directly to measure levels of innovation in a single economy; and comparing rates of innovation between countries offering strong patent protection and countries offering weak, or no, patent protection. Still others have questioned the basic assumption that the patent system does indeed promote innovation, suggesting, instead, that patents may lead to fewer inventions, at least under certain circumstances. Thus far, there is surprisingly little clear evidence that patent systems promote innovation.

The introduction to *Patents in the Knowledge-Based Economy*,⁹⁸ a 2003 publication of the National Academies Press, discusses recent work addressing whether the theory is valid: “There are theoretical as well as empirical reasons to question whether patent rights advance innovation in a substantial way in most industries.”⁹⁹ For example, the benefit of the patent monopoly might be outweighed by the cost of the disclosure the patent system requires,¹⁰⁰ and “where technological advances build upon one another cumulatively, as is

96. U.S. CONST. art. I, § 8, cl. 8.

97. 35 U.S.C. § 101 (2006).

98. PATENTS IN THE KNOWLEDGE-BASED ECONOMY (Wesley M. Cohen & Stephen A. Merrill eds., 2003).

99. Wesley M. Cohen & Stephen A. Merrill, *Introduction*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 1, 2 (Wesley M. Cohen & Stephen A. Merrill eds., 2003).

100. *Id.*

increasingly the case, broad patent protection on upstream discoveries may slow the rate of technical change by impeding subsequent innovations.”¹⁰¹ On the whole, the authors argue, the “literature on the impact of patents on innovation must be considered emergent.”¹⁰² There has been “little systematic empirical analysis of the impact of patents on innovation.”¹⁰³ One reason for this is limited data in some areas; another is that “the effect of patent policy has many dimensions” and it has therefore been challenging to determine how a particular policy actually affects innovation.¹⁰⁴

Mazzoleni and Nelson provide a useful framework for organizing theories about the patent system. They suggest that the answer to the question, “What are the social benefits and costs of awarding patents for inventions?” is not simple or well settled, though “[m]any economists and patent lawyers seem to think” that it is.¹⁰⁵ They propose four broad theories about the purposes served by patents:

1. The anticipation of patents provides motivation for useful invention: we will call this the “invention motivation” theory.
2. Patents induce inventors to “disclose” their inventions when otherwise they would rely on secrecy, and in this and other ways facilitate wide knowledge about and use of inventions: we will call this the “invention dissemination” theory.
3. Patents on inventions induce the needed investments to develop and commercialize them: this we call the “induce commercialization” theory.
4. Patents enable the orderly exploration of broad prospects: we call this the “exploration control” theory.¹⁰⁶

The authors recognize that these purposes are not necessarily mutually exclusive, and may overlap, but some versions of the theories do conflict. The first three theories have a long history,

101. *Id.* at 3 (citations omitted).

102. *Id.*

103. *Id.* at 2.

104. *Id.* at 3–4.

105. Roberto Mazzoleni & Richard R. Nelson, *Economic Theories About the Benefits and Costs of Patents*, 32 J. ECON. ISSUES 1031, 1031 (1998).

106. *Id.* at 1033.

whereas the fourth theory is of relatively recent vintage.¹⁰⁷ The authors also make the useful observation that theories about the costs and benefits of patents are often based on assumptions (not always explicit) about certain “context conditions”:

1. The nature and effectiveness of means other than patents to induce invention and related activities. These “other means” may be as diverse as government grants and contracts or strong first mover advantages.
2. Whether the group of potential inventors is likely to work on diverse and non-competing ideas, or whether the group is likely to be focused on a single alternative or a set of closely connected ones. Basically the issue here is whether or not more inventing input yields more useful inventing output or mainly duplication of effort and waste.
3. The deterrent effect of the presence of patents on unauthorized use of a technology and on the transaction costs involved in licensing an invention.
4. Whether the multiple steps in the invention, development, and commercialization of a new technology tend to proceed efficiently within a single organization, or whether efficiency is enhanced if different organizations are involved at different stages of the process.
5. What we will call the topography of technological advance, by which we mean the manner in which inventions are linked to each other temporally, and as systems in use.

At least some of these conditions are partly endogenous to the nature of the patent system. They are themselves influenced by the strength and scope of the patent protection within a field of technology. . . .

. . . In any case, the implications of the theories are very sensitive to the assumed context conditions.¹⁰⁸

107. *Id.*

108. *Id.* at 1033–34.

Later, they make the point that different theories probably apply in different domains: “The proposition we now want strongly to espouse is that the appropriate question about these diverse theories is not ‘Which theory is the correct one?’ but rather, ‘Where do the different theories apply?’”¹⁰⁹ The empirical work necessary to answer this question has not yet been done.

Numerous other approaches have been taken to analyze the question of what effects patents have on promoting or retarding innovation. For example, Landes and Posner suggest a theoretical approach that incorporates insights from other forms of intellectual property law: “[A] more illuminating way of thinking about the patent system is as a response to economic problems inherent in trade secrecy and market structure.”¹¹⁰ Much more work will be required before stronger causal links can be drawn between patents and innovation. In the meantime, existing empirical evidence does not demonstrate the patent system to be superior to open source approaches at generating innovation in general. The relationship between patents and genetic innovation, however, may be an exception.

D. Promoting Progress in the Genetic Arts

In 1998, Heller and Eisenberg raised the specter that patents claiming genes risked causing a “tragedy of the anticommons”:

[T]he recent proliferation of intellectual property rights in biomedical research suggests . . . an “anticommons” in which people underuse scarce resources because too many owners can block each other. . . . [Unless privatization of biomedical research is managed properly,] more intellectual property rights may lead paradoxically to fewer useful products for improving human health.¹¹¹

109. *Id.* at 1044.

110. WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 294 (2003).

111. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698, 698 (1998).

Heller and Eisenberg envisioned a particular risk of incurring a tragedy of the anticommons with respect to patents claiming genes, fragments thereof, or polypeptides.¹¹² Without careful limitation of patents on such categories of inventions, Heller and Eisenberg feared the creation of “a tragedy of the anticommons through a proliferation of fragmented and overlapping intellectual property rights.”¹¹³ Subsequently, others have also suggested that patents claiming genes might inhibit, rather than promote, genetic innovation.¹¹⁴

However, a tragedy of the anticommons in gene patents has been difficult to substantiate. To the contrary, the best available evidence appears to discount its existence. Caulfield et al. have summarized the evidence:

The results of [surveyed] empirical efforts have been fairly consistent. First, the effects predicted by the anticommons problem are not borne out in the available data. The effects are much less prevalent than would be expected if its hypothesized mechanisms were in fact operating. The data do show a large number of patents associated with genes. A recent study found that nearly 20% of human genes were associated with at least one US patent, and many had multiple patents. Another study estimated that in the United States over 3,000 new DNA-related patents have issued every year since 1998, and more than 40,000 such patents have been granted. But despite the large number of patents and the numerous, heterogeneous actors—including large pharmaceutical firms, biotech startups, universities and governments—studies that have examined the incidence of anticommons problems find them relatively uncommon. These studies span both academics and industry, and include data from the United States, Germany, Australia and Japan.¹¹⁵

112. *Id.* at 699.

113. *Id.* at 701.

114. *E.g.*, Gaia Vince, *Gene Patents “Inhibit Innovation,”* NEW SCIENTIST, July 23, 2002, <http://www.newscientist.com/article/dn2580gene-patents-inhibit-innovation.html> (reporting conclusion of the Nuffield Council on Bioethics’s discussion paper on gene patents, cited *supra* note 46).

115. Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene*

As the authors conclude, “although there may have been good reasons for concern, the feared problems [predicted to be caused by the tragedy of the anticommons] have not widely manifested.”¹¹⁶ Similarly, a recent comprehensive survey of human gene patent litigation in United States courts concludes that gene patents have not caused a tragedy of the anticommons in the United States.¹¹⁷

In their recent study of the role that the patent system plays in spurring innovation, James Bessen and Michael J. Meurer suggest the patent system may indeed promote innovation in the pharmaceutical/biotechnology industry.¹¹⁸ As they have stated, “The evidence is certainly consistent with the notion that patents encourage American pharmaceutical” research and development.¹¹⁹

E. Exclusion from Genetic Enhancement

By conferring on their owners the right to exclude parents from access to genes that could enhance their children, gene patents have powerful implications for the distribution of genetic enhancement within society. In essence, the right to exclude may bar at least some parents from the opportunity to genetically enhance their children. Like more conventional drugs and other medicines, access to genetic enhancements would likely be mediated through pricing mechanisms. The more valuable the enhancement a gene offered, the more expensive access to that gene would be for parents eager to ensure the best genes for their children.

It is true that the right to exclude tends to last for only twenty years from the filing date of the patent application, resulting in free access to any gene after its corresponding patent expires. However, just as with other rapidly advancing fields of technology, genetic enhancements too will surely improve rapidly over time. As a

Patenting Controversies, 24 NATURE BIOTECHNOLOGY 1091, 1092 (2006) (footnotes omitted).

116. *Id.* at 1093.

117. Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295 (2007).

118. BESSEN & MEURER, *supra* note 5, at 85–88.

119. James Bessen & Michael J. Meurer, Do Patents Stimulate R & D Investment and Promote Growth? (Mar. 13, 2008), <http://www.patentlyo.com/patent/2008/03/do-patents-stim.html>.

consequence of such advances, a genetic enhancement that was once cutting-edge may become obsolete, or even positively deleterious, by the time its patent protection expires. In fact, it would be unsurprising if improvements in genetic enhancement advanced, at least in part, in order to surmount prevailing levels of genetic enhancement; a genetic enhancement shared by many or all depreciates any relative advantage conferred by that enhancement. One might even expect a sort of genetic-enhancement arms race to ensue, with those able to afford doing so opting to arm their children with the latest and greatest genetic enhancements to maintain their advantages over children with no, or lesser, genetic enhancements.

It is not difficult to imagine how the patent system could assist in achieving a division between GenRich and Naturals. In fact, by its mediation of access to genetic enhancements, patent law holds the potential to affect the future course of human evolution. Patent law could act as a direct force for differentiating genetically enhanced humans from those lacking genetic enhancements via two distinct mechanisms: (1) creating an incentive to discover, synthesize, and develop new genetic enhancements; and (2) by limiting access to those genetic enhancements.

IV. OPEN SOURCE AND GENETIC ENHANCEMENT

A. Open Source Biology

Open source biology offers an alternative approach to the proprietary model of biomedical research that currently predominates in the United States and many other countries. The origins of open source, however, are found within the arena of computer software. Open source software is “computer source code publicly available for licensees to use, modify, and redistribute, provided that these licensees make their enhancements available to others on the same terms.”¹²⁰ More specifically, to be considered open source by the Open Source Initiative, an organization viewed by many as a

120. Donna M. Gitter, *Resolving the Open Source Paradox in Biotechnology: A Proposal for a Revised Open Source Policy for Publicly Funded Genomic Databases*, 43 HOUS. L. REV. 1475, 1477 (2007).

guardian of the open source movement, a particular set of software code must be made available under a license that satisfies the Open Source Definition (“OSD”).¹²¹ The OSD includes requirements such as free redistribution, availability of source code, free redistribution of derivative works, non-discrimination against potential users or fields of use, and technology neutrality.¹²² Steven Weber has articulated a simpler, tripartite definition: (1) “Source code must be distributed with the software or otherwise made available for no more than the cost of distribution”; (2) “[a]nyone may redistribute the software for free, without royalties or licensing fees to the author”; and (3) “[a]nyone may modify the software or derive other software from it, and then redistribute the modified software under the same terms.”¹²³ There have been a number of notable successes in open source software, including the Linux operating system, the Apache web-server, and the mySQL database system.¹²⁴

In the realm of biology, the success of open source as a viable challenger to the existing, proprietary model of research and development remains unproven. Nevertheless, several initiatives are seeking to demonstrate the power of the open source biological approach. Richard Jefferson has been a pioneer in developing an open source system for research and development in biology. For example, his institution, CAMBIA, offers a number of technology platforms designed to make the genetic modification of crops easier, while minimizing risks of infringing existing patents.¹²⁵ Furthermore, CAMBIA’s Biological Innovation for Open Society (“BiOS”) initiative seeks to replicate the success of open source software in biology: “Similar to the ethos of the Free Software movement, the BiOS Initiative is not about cheap or free stuff, either pharmaceuticals or food. It’s about creating the freedom to innovate based on what has come before, and the freedom to deliver the fruits of such innovation with few constraints.”¹²⁶ Another open source

121. Open Source Initiative Homepage, *supra* note 8.

122. The Open Source Definition, *supra* note 9.

123. STEVEN WEBER, THE SUCCESS OF OPEN SOURCE 5 (2004).

124. *Id.* at 6.

125. CAMBIA’s 3D Vision, <http://www.cambia.org/daisy/cambia/about.html> (last visited Mar. 17, 2009).

126. CAMBIA, THE CAMBIA BIOS INITIATIVE: BIOLOGICAL INNOVATION FOR OPEN

initiative, the International HapMap Project (“IHMP”), is a “partnership of scientists and funding agencies from Canada, China, Japan, Nigeria, the United Kingdom and the United States to develop a public resource that will help researchers find genes associated with human disease and response to pharmaceuticals.”¹²⁷ The HapMap (or map of haplotypes) “is a catalog of common genetic variants that occur in human beings.”¹²⁸ One of IHMP’s major goals is to avoid the development of a patent thicket in haplotype research. Instead of patenting the haplotypes they discover, IHMP participants contribute their data to the IHMP genetic database; “[b]y making this information freely available, the [IHMP] will help biomedical researchers find genes involved in disease and responses to therapeutic drugs.”¹²⁹ Rather than require licenses for access to its database, “[d]ata generated by the [IHMP] can be downloaded with minimal constraints.”¹³⁰ However, the IHMP does not oppose patent applications on genes shown to possess specific utility “as long as this action does not prevent others from obtaining access to data from the [IHMP].”¹³¹

The Tropical Diseases Initiative (“TDI”) has proposed an open source biology model to promote innovation in treatments for tropical diseases that disproportionately affect people in the developing world.¹³² Despite the devastation such diseases cause among people in some of the poorest and most vulnerable countries in the world, few drugs are developed to treat these diseases.¹³³ Even so, proponents of the TDI have acknowledged the role of the patent system in promoting innovation in biomedical research, noting that

SOCIETY 5 (2006), available at <http://www.bios.net/daisy/bios/2029/version/default/part/AttachmentData/data/BiOS%20Initiative%20Phase%202006-2008.pdf>.

127. International HapMap Project Homepage, <http://www.hapmap.org> (last visited Mar. 17, 2009).

128. What Is the HapMap?, <http://www.hapmap.org/whathapmap.html.en> (last visited Mar 17, 2009).

129. About the HapMap, <http://www.hapmap.org/thehapmap.html.en> (last visited Mar. 17, 2009).

130. *Id.*

131. Data Release Policy, <http://www.hapmap.org/datareleasepolicy.html> (last visited Mar. 17, 2009).

132. Maurer, Rai & Sali, *supra* note 7, at 184.

133. See Welcome to the Tropical Disease Initiative, http://www.tropicaldisease.org/?page_id=6 (last visited Apr. 7, 2009).

“patent incentives and commercial pharmaceutical houses have made Western health care the envy of the world.”¹³⁴ These proponents have also noted that “[t]o date, open-source methods have made little headway beyond software.”¹³⁵

On a superficial level, open source may appear to be especially relevant to inventions like genes. Genes, like software code, are built from a definable vocabulary of commands that, once executed, produce some result. The genetic vocabulary of commands consists of the deoxyribonucleotides, A, T, G, and C, and the results are the synthesis of ribonucleic acids (“RNA”) or polypeptides (which form proteins). Genes may be discovered, isolated, and altered. Genes and artificial chromosomes may also be designed synthetically. In fact, just as blocks of software code for carrying out particular functions are freely available, the “Registry of Standard Biological Parts” makes “BioBricks,” or biological molecules, available to those conducting biological research or engineering projects.¹³⁶ While it is true that many have the requisite knowledge and skill to isolate, sequence, manipulate, and even synthesize genes, acquiring these requisites and securing access to the considerable facilities and resources needed to accomplish successful genetic engineering makes the prospect of achieving a viable system of open source genetics much more challenging than the comparable model that exists for open source software.

B. Limitations of Open Source Biology

To design and write software code, one need only have knowledge, skill, and access to a computer. To isolate, sequence, design, or synthesize genes, one needs knowledge, skill, access to expensive equipment, expensive supplies (for example, chemical reagents), and expensive technical personnel. Genetic research is orders of magnitude more expensive than software coding. The romantic image of a lone software coder coming up with an

134. Maurer, Rai & Sali, *supra* note 7, at 183.

135. *Id.* at 184.

136. See Registry of Standard Biological Parts Main Page, http://partsregistry.org/Main_Page (last visited Mar. 2, 2009).

important new hack may not translate well to the world of biological research. Biological knowledge and skill are uniquely difficult to develop. One must not only study theory, but learn practical skills in a well appointed molecular biology laboratory. Carrying out laborious, time-consuming, and often unsuccessful experiments is a *sine qua non* of attaining a solid basis in genetics.

There are significant barriers to entry into such laboratories. Access is usually reserved for students formally studying biology, professional biologists who have already attained a recognized academic degree (for example, Ph.D. or M.D.), and skilled laboratory technicians. Laboratories are usually quite conscious of security for several reasons: laboratories often view themselves as in competition with other laboratories to be the first to publish important new discoveries, which can be an important factor in career success; confidentiality is necessary to preserve patent rights prior to the filing of a patent application, which is widely viewed within academia and industry as a potential, though admittedly uncommon, path to riches; laboratories often contain equipment, chemicals, or organisms that are expensive or can be dangerous if handled by the untrained; and much biological research is considered controversial, attracting protestors and saboteurs.

Biological laboratories are very expensive to set up and to maintain. Chemical reagents are often quite expensive, and must constantly be restocked. Specialized machines, such as centrifuges, automated DNA-sequencers, PCR thermocyclers, autoclaves, and powerful computers, along with laboratory renovations necessary to house them safely and computers to run the equipment, can cost hundreds of thousands or even millions of dollars. Life-support equipment and technologies needed to keep laboratory organisms alive add additional expense. Establishing a new molecular biology laboratory for a principal investigator often costs the host institution millions of dollars.

Highly skilled and, consequently, highly compensated laboratory technicians are required to maintain and run a successful and productive molecular biology laboratory. In addition, successful laboratories create entire ecosystems of researchers and other personnel, from professors or other principal investigators to visiting scholars, postdoctoral fellows, doctoral students, master's students,

undergraduate students, and various specialized technicians and other support staff. High-quality genetic research of the sort that is most likely to lead to the discovery or synthesis of valuable new genes relies upon these ecosystems for productivity, efficiency, and success. One would be hard-pressed to identify successful geneticists who act alone, without extensive education, training, and experience, or conduct their research using inexpensive or informal facilities. Although the proverbial garage entrepreneur may one day include the geneticist, that day has yet to arrive, and will not likely arrive in the near future.

Another factor limiting open source biology is the need to exchange not just pure information, as can be done with the code of which computer software is comprised, but also physical elements, such as vectors, cells, or organisms. One can transmit, receive, and share computer code cheaply, instantly, and without a breath of institutional or government fiat. By contrast, exchange of biological materials must be done under strict conditions necessary to preserve the integrity of those materials, and must comply with safety protocols mandated by norms of the research community, rules of host institutions, and laws and regulations imposed by governments or their agencies. Such precautions add significantly to the cost and delay involved in such exchanges. In Coasian terms, transaction costs involved in genetic research are much more burdensome than those involved in software.

Translating genetic research into products also entails significant costs in both time and money. Before a biological molecule or method can reach the market, the United States Food and Drug Administration must approve its safety and efficacy. This regulatory process can be extremely expensive, sometimes costing a company tens or hundreds of millions of dollars to complete. And there is no *a priori* guarantee that the results of the regulatory process will yield a green light for marketing the product or process. By contrast, there are few regulatory restrictions on implementing computer code; once it is ready to test, it can usually be posted to the Web or otherwise distributed without governmental permission.

For reasons outlined above, open source biology may be most appropriate and effective when applied to upstream research tools rather than downstream applications of biology, like medicinal

drugs.¹³⁷ Furthermore, the above reasons temper assumptions that the practice of biological research conforms to Mertonian ideals of collaboration, sharing, and the pursuit of knowledge for its own sake.

A final potential limitation of open source biology involves the creation of incentives for innovation. An orthodox economic analysis of open source biology suggests that, in the absence of incentives created by proprietary rights, rates of biological innovation would be lower than for a system in which patent protection was available for inventions. As Steven Weber explains,

Coca-Cola sells bottles of soda to consumers. Consumers use (that is, drink) the soda. Some consumers read the list of ingredients on the bottle, but that list of ingredients is surprisingly generic. Coca-Cola has a proprietary formula that it will not divulge, on the bottle or anywhere else. This formula is the knowledge that makes it possible for Coke to combine sugar, water, and a few other readily available ingredients in particular proportions with a secret flavoring mix and produce something of great value. The point is that the bubbly liquid in your glass cannot be reverse-engineered into its constituent parts. You can buy Coke and you can drink it, but you can't *understand* it in a way that would let you reproduce the drink, or improve upon it and distribute your cola drink to the rest of the world.

Standard economics of intellectual property rights provides a straightforward account of why the Coca-Cola production regime is organized this way. The core problem of intellectual property is supposed to be about creating incentives for innovators. Patents, copyrights, licensing schemes, and other means of “protecting” knowledge ensure that economic rents are created and that some proportion of those rents can be appropriated by the innovator. If that were not the case, a new and improved formula would be immediately available in full and for free to anyone who chose to look at it. The person who invented the formula would have no special and defensible

137. See Gitter, *supra* note 120, at 1478; see also Yann Joly, *Open Source Approaches in Biotechnology: Utopia Revisited*, 59 ME. L. REV. 385, 394 (2007).

economic claim on a share of the profits that might be made by selling drinks engineered from the innovation. And so the system unravels, because that person no longer has any rational incentive to innovate in the first place.¹³⁸

If rates of innovation would indeed be lower under a system of open source genetics than they would be for a system in which patent protection were available, then the implications for genetic enhancement would be complicated.

V. OPEN SOURCE VERSUS PROPRIETARY GENETIC ENHANCEMENT

An open source model of genetic research and development likely would have a significant influence on the trajectory of human genetic enhancement. This trajectory likely would be markedly different from that occurring within a proprietary patent-based system. Comparing the likely outcomes for human genetic enhancement that would obtain under open source genetics and proprietary systems yields several predictions. Comparing a proprietary system with an open source genetics system yields the following three predictions: (1) rates of genetic innovation likely would be higher in a proprietary system than in an open source genetics system; (2) access to genetic innovations likely would be democratized in an open source genetics system as compared with in a proprietary system; and (3) combining predictions (1) and (2), an open source genetics system likely would yield a lower rate of genetic innovation, leading to a lower number of possible genetic enhancements, but those genetic enhancements that existed would be more widely available.

Open source genetics would decrease rates of genetic enhancement innovation. There is little evidence to demonstrate that open source models of biology do, or would, spur innovation more than the prevailing patent system does. In fact, positive evidence suggesting that patent systems do, indeed, increase rates of innovation in bioscience, coupled with the dearth of evidence that open source genetics does so, suggests that proprietary systems would tend to yield more inventions related to genetic enhancement.

138. WEBER, *supra* note 123, at 3–4.

Since an open source genetics system would reduce the prospects that inventors could reliably recoup their considerable investments in research and development, fewer enhancing genes would tend to be discovered or synthesized. By contrast, a patent system allows geneticists to appropriate monopoly rents accruing from enhancing genes that they invent.

Fewer genetic enhancement inventions would offer fewer potential options for enhancement, even to people with the wherewithal to gain access to the full array of existing genetic enhancement inventions. The potential degree to which parents could enhance their children would tend to be relatively lower than it would be under a proprietary system. One result would be to minimize the genetic distance between maximally genetically enhanced people and those without genetic enhancements. A smaller degree of potential genetic enhancement would yield smaller extremes in the genetic inequality within society. If genetic inequality arising from unequal access to genetic enhancement technologies tends to increase societal conflict and strife, then the existence of fewer genetic enhancement inventions could have beneficial societal effects by promoting stability and solidarity.

On the other hand, the existence of fewer potential genetic enhancements could serve to thwart the ambitions of those members of society who value, and could afford access to, genetic enhancements. Though societal utility might increase through avoidance of extremes of genetic inequality, fewer potential genetic enhancements could lower the utility of genetically ambitious individuals. Furthermore, if genetic enhancements serve any general role in raising the standard of living for at least some people, then the lowered rates of genetic enhancement innovation would probably detract from this goal.

If countries other than the United States offered superior patent protection for genetic enhancement inventions, research and development into genetic enhancement—along with much of the economic value such inventions could generate—might be expected to move out of the United States and into such countries. This result could harm the biotechnology industry of the United States, while simultaneously promoting it in other countries with more favorable attitudes towards genetic engineering. Furthermore, parents wishing

to genetically enhance their children could travel to more genetically innovative countries to ensure the genetic enhancement of those children. This result could erode at least some of the salutary implications of open source genetics in the United States, while simultaneously ensuring that spending on genetic enhancement research and development would tend to go offshore.

Access to genetic enhancement innovations would become democratized in an open source genetics system as compared with proprietary systems. If genetic enhancements were made available at lower than the monopoly prices possible under a patent system, or without the restrictions made possible by the patent grant, access to the possibility of genetically enhancing one's children would be democratized and more widely spread among members of society. More parents would choose to have their children genetically enhanced. More children would tend to share the same genetic enhancements. And the genetic inequality that would almost certainly pertain under a patent system would likely not pertain under an open source genetics system.

One corollary of this democratization of access to genetic enhancements would be the relative lack of advantages that might have been conferred by more exclusive genetic enhancements, because fewer children would be without the same genetic enhancements. On the other hand, democratization of genetic enhancement would probably lead to fewer available opportunities for genetic enhancement. The lessened ability to appropriate monopoly rents under an open source genetics system would likely lead to lower rates of genetic enhancement innovation. In other words, more members of society would have the option of enhancing their children with a relatively smaller number of potential genetic enhancements.

A scenario of fewer available genetic enhancements spread more evenly among members of society would tend to foster societal solidarity. Commentators as philosophically disparate as Michael J. Sandel, Francis Fukuyama, and Lee Silver have worried about the effects that genetic enhancement might have on how individual members of society view their connectedness and sense of common purpose with other members of society. Sandel sees a threat to "a willingness to share the fruits of good fortune through institutions of

social solidarity.”¹³⁹ Fukuyama sees advances in genetic enhancement as a dangerous threat to the essence of our humanity: “Human nature shapes and constrains the possible kinds of political regimes, so a technology powerful enough to reshape what we are will have possibly malign consequences for liberal democracy and the nature of politics itself.”¹⁴⁰ And Silver speculates that genetic enhancement—a technology whose application he views as inevitable—has the potential to separate the GenRich from the Naturals to “the final point of complete polarization.”¹⁴¹ In the face of such anxieties about the societal effects of genetic enhancement, the prospect that open source genetics could deliver more equitable access to relatively fewer potential genetic enhancements could be viewed as desirable from a society-wide perspective. Open source genetics would seem to have a better chance of avoiding deep societal fissures between the genetically enhanced and unenhanced.

On the other hand, wider access to existing genetic enhancements could increase the proportion of those in society who choose to enhance their children genetically. Instead of a relatively smaller societal experiment in human genetic enhancement carried out only among those people with the resources to afford patented genetic enhancements, open source genetics could allow and facilitate a much more widespread human genetic enhancement experiment encompassing a much larger proportion of the population. Adverse health or societal effects that might have been isolated within a relatively smaller group of affluent enhancers would instead be risked on many more members of society.

An open source genetics system would lead to relatively fewer potential genetic enhancements that were relatively more widespread among members of society. Open source genetics would tend to lead to relatively fewer genetic enhancement inventions, but access to those existing genetic enhancements would be more widely available to members of society. In other words, more people would be able to

139. SANDEL, *supra* note 63, at 96.

140. FRANCIS FUKUYAMA, OUR POSTHUMAN FUTURE: CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION 7 (2003).

141. SILVER, *supra* note 2, at 6.

choose from a relatively smaller menu of genetic enhancements for their children.

Equal or increased rates of genetic enhancement innovation. Despite evidence suggesting that patent systems tend to yield relatively larger rates of biotechnological innovation than open source genetics would tend to do, one ought to consider the possibility that open source genetics might equal, or even increase, rates of genetic enhancement innovation. If open source genetics were able to provide incentives for genetic enhancement innovation equal to, or greater than, those currently provided by the patent system, society would be faced with a double challenge. Not only would rates of genetic enhancement innovation be relatively high, but access to those genetic enhancements would also be relatively widespread. Although many proponents who promote open source models of biology might simultaneously hesitate to support human genetic enhancement, the result of open source genetics might be an acceleration of human genetic enhancement.

Some commentators would welcome just such a future. John Harris, for example, has described the advantages of genetic enhancement technologies as follows: “For the first time in human history we face the prospect of a truly open future, involving perhaps infinite sequential as well as simultaneous opportunities, and stretching, open-ended, before the individual in . . . an unprecedented but truly liberating pathway.”¹⁴² Thus, if open source genetics were to lead to relatively high rates of genetic enhancement innovation, the results might be the application of the fruits of open source genetics on a scale as grand as the human population. Harris’s “open-ended” and “truly liberating pathway” would hold implications of seismic proportions for the future of human society, and even future human evolution. To those who oppose human genetic enhancement, the prospect of open source genetics that achieves high rates of genetic enhancement innovation may be a Pandora’s Box of societal risks that ought to remain unopened. Even so, current evidence suggests that open source genetics would not be capable of achieving rates of

142. JOHN HARRIS, ENHANCING EVOLUTION: THE ETHICAL CASE FOR MAKING BETTER PEOPLE 71 (2007).

genetic enhancement innovation to rival those achieved by patent systems.

CONCLUSION

Open source has been championed by many scholars as a superior system for promoting innovation, not only in software but latterly in biology.¹⁴³ Though software code and genes appear superficially similar in the sense that they both serve as algorithms for the production of specified results, the former may be more conducive to the open source model of innovation than the latter. Nevertheless, if an open source model of genetics were adopted, the model could have significant effects on the future of human genetic enhancement. If open source genetics were unsuccessful or counterproductive in promoting genetic innovation, the result would be slowed discovery and development of genetic enhancements. Yet, if open source genetics were successful in spurring genetic innovation, at least two results would be likely: (1) acceleration in the rate of innovation in new genetic enhancements, and (2) acceleration of the widespread adoption of genetic enhancements. By contrast, proprietary patent protection for genetic enhancements would tend to spur genetic innovation, but would tend to limit access to those genetic enhancements through discriminatory mechanisms such as price and favoritism.

Open source genetics likely would offer different societal outcomes for genetic enhancement than would proprietary patent systems. Furthermore, the societal implications of an open source genetics approach to genetic enhancement likely would not have the simple, salutary effects many in the open biology movement tend to assume. Rather, open source genetics might lead to more widespread genetic enhancement than would proprietary patent approaches, though the potential pool of available genetic enhancements likely would be smaller. A proprietary patent approach would likely ensure high rates of genetic enhancement innovation, research, and development, and efficiently mediate access to genetic enhancements

143. See, e.g., Maurer, Rai & Sali, *supra* note 7, at 184–85; CAMBIA's 3D Vision, *supra* note 125.

but likely would allow access to genetic enhancements to fewer members of society. With both open source genetics and proprietary patent approaches, there remains the prospect that genetic enhancement might lead to human evolutionary change.

Public policy and the law must grapple with the implications of genetic enhancement before current technological possibilities become societal realities. Open source genetics offers a significant alternative to the prospect of the patent system as a substantial arbiter of parental decisions regarding genetic enhancement of their offspring. Open source genetics holds the potential to democratize accessibility of genetic enhancements, while discouraging high rates of genetic enhancement innovation. However, the implications that open source genetics has for the future of human society—and even human evolution—are not clearly more beneficial than the implications the patent system would have. It is certain that the implications that open source genetics and proprietary patent systems have for future human genetic enhancement should be subjected to thorough analysis and debate prior to the imminent arrival of human genetic enhancement technologies.