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Impact of the Human Genome Project at the Interface between Patent and FDA Laws

Brian C. Cunningham*

*Biotechnology is nothing new, except for lawyers.*¹

The Technology

The Human Genome Project (Project) is an international effort to complete the sequencing of the 100,000 genes that comprise the human genome. Upon conclusion of the Project, estimated to occur around the year 2005 and much sooner than many realize, the genes responsible for single gene deficiency diseases, e.g., Huntington's disease and cystic fibrosis, as well as for multifactorial diseases, e.g., atherosclerosis and cancer, will have been identified.² The Project seems almost like science fiction: It is easy to think of it as not having immediate policy implications. Yet, as the Project's conclusion nears, there is little time to struggle with issues that will be raised.

The Project's progress has been matched by developments in techniques for performing human gene therapy. The first protocol was approved by the Recombinant Advisory Committee of the National Institutes of Health (RAC) in 1990. Since then, more than 200 people, in about a dozen countries, have been treated in Phase I and II clinical trials with no major side effects.³ Also, Merck has established a gene therapy division.⁴ Dr. Philip Noguchi, in charge of U.S. Food and Drug Administration (FDA) regulation of biotech products, says: "What we've seen so far is almost trivial compared to what's

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¹ Dr. Julian Davies, commenting on the information lag in the legal community, Comment, *Regulating the Environmental Release of Genetically Engineered Organisms: Foundation on Economic Trends v. Heckler*, 12 Fla. St. U. L.Rev. 891 (1985).

² Testimony of Dr. Nelson A. Wivel before the House Committee on Science, Space & Technology, Sept. 29, 1994, at 89.

³ Genesis Group Associates, Inc., *An Overview of Gene Therapy* (Feb 1995).

⁴ *Id.*

coming....”⁵ He added that the results thus far are so good that the FDA expects to see gene therapies on the market within a few years.⁶

Although information gained from the Project will find application in many fields,⁷ the combination of that information with techniques for performing germ line cell gene therapy (collectively, *genome technology*)⁸ is particularly noteworthy. In my judgment, the ability to alter the human genome for future generations, with the ability to transfer characteristics between species, will raise ethical, moral and legal issues as profound and troublesome as any faced by mankind thus far. At the same time, it is likely that tomorrow’s results of today’s research will be so far different from what we expect that our best efforts to develop policy and law will be largely confounded.

The Interface

Patent and FDA law may be said to “interface” in a couple of different ways. Legislative enactments such as the Orphan Drug Act⁹ and the Patent Term Restoration Act¹⁰ “interface” in the sense that each modifies patent law and FDA law. However, a different kind of interface may be found in the tension between the differing policies which underlie patent and FDA law. The patent system is intended to foster technological innovation and economic progress. FDA law serves different policy objectives because it is intended to protect the public’s safety and welfare. To speak of the interface between patent law and FDA law is to speak of balancing competing policy considerations.

While still a Congressman, Al Gore identified the tension between patent and FDA law when he stated:¹¹

⁵ Lauren Neergard, *U.S. Government to Streamline Gene Therapy Oversight* (A.P. May 24, 1995).

⁶ *Id.*

⁷ The first full DNA sequences of free-living organisms, two bacteria, have been determined which demonstrate the feasibility of sequencing the entire genome of ever-more complicated organisms. Dr. Craig Venter said recently that his Institute for Genomic Research can now sequence ten or more microbial genome per year. See *Genesis*, *supra* note 2.

⁸ The term, “germ line cell gene therapy,” refers to the application of gene therapy techniques to cells which are involved with reproduction, i.e. eggs and sperm.

⁹ 21 U.S.C. §§ 360aa–ee

¹⁰ 35 U.S.C. § 155A.

¹¹ Senator Al Gore, *Planning a New Biotechnology Policy*, 5 *Harv. J. Law & Tech.* 19 (1991).

The debate over biotechnology policy is at heart a debate over information policy. At one level, the debate covers how to provide intellectual property protection to the tools of biotechnology and the valuable information they produce, such as gene sequences and chromosome maps. At a different level, the debate shifts to questions of how best to distribute information to empower others and to prevent information misuses and loss of privacy. Aided by the new tools of the computer age, biotechnology is developing faster than any previous technology. In the process of development, biotechnology is creating a wider gap between practice and policy. Our growing ability to transform genetic information into new products and organisms is intended to enhance agriculture, fight pollution, and alter hereditary diseases which makes biotechnology a powerful, and threatening tool.

Development of genome technology will outpace needed public policy which will be required to cope with consequences. According to Mr. Gore, "From the printing press to the atomic bomb, human kind reveals a penchant to pioneer first and plan later. It is a simple truth that technology develops faster and further than policy."¹² No matter how safe and well controlled technology may be, public opinion will be driven by lack of knowledge, lack of trust of science and government and a tendency to believe that things are worse than what the public is told. Therefore, the question is: How does society ensure that its governmental and social institutions manage the future course of evolution with enough wisdom to avoid catastrophic mistakes?

The real risk of genome technology is not whether appropriate clinical trials can be designed, nor how or where inserted DNA integrates into the host cell or any other such events. The real risk may be illustrated by recalling the incident which led to the Asylomar Conference and creation of the NIH's Guidelines for Research Involving Recombinant DNA Molecules (Guidelines).¹³ In 1971 Dr. Paul Berg, then at Stanford University, now a Nobel Laureate, was planning an experiment which involved the transfer of DNA from an animal tumor virus to a virus which can infect *E Coli*, a common human intestinal bacteria. Robert Polack, a researcher, heard about the

¹² *Id.*

¹³ 48 Fed. Reg. 24556 (1983).

proposed experiment and advised Berg that if the new virus were to escape from the laboratory it might survive in human intestinal bacteria, exposing humans to a tumor-causing DNA which might even result in a cancer epidemic. After months of soul searching, Dr. Berg finally decided not to conduct his experiment.¹⁴

This reminds us that no matter how well controlled and safe experiments are, the unexpected may happen. If it does, consequences could cause public opinion to galvanize to make further research more difficult. Another serious incident is the now infamous rooftop experiments a company conducted with an engineered bacterium on trees on its roof without first obtaining regulatory approval. Of this, Mr. Gore said, "The injury to the industry far exceeded any possible injury to the environment. Not only was good risk assessment missing, but so were candor, judgment, and perception."¹⁵ Dr. French Anderson recently well summarized public concern by saying, "[T]he vast majority of people still do not know what genetic engineering is all about and they are frightened by it. I do know what genetic engineering is all about and I am frightened by it."¹⁶

The Difficulty of Setting Policy

It is not easy to establish policy that deals with implications of genome technology; value systems, risk tolerance levels and capacity for understanding technology all vary widely. Neither public debate nor the existing regulatory apparatus is well suited to resolving differences that emerge from the moral and social plurality in the U.S. In 1984, the Office of Technology Assessment reported:¹⁷

There is little reason to believe that differences in opinion about the appropriateness of human gene therapy will resolve spontaneously, or even after extensive public discussion. Where there is no agreement on what decision to make, the only alternative is a *process* for making the decision. Government agencies must demonstrate that the process is rational and fair. (Emphasis added)

¹⁴ See Comment, *supra* note 1 at 897.

¹⁵ See Gore, *supra* note 10 at 22.

¹⁶ Dr. W. French Anderson, *Editorial — Big Changes at the RAC! 5 Human Gene Therapy* 1309 (1994).

¹⁷ U.S. Congress, Office of Technology Assessment, *Human Gene Therapy — A Background Paper*, at 30 (1984).

Whatever process is adopted must involve professionals from many disciplines, must be open to the public and must be insulated from political pressures.

The best hope of setting policy to deal with the implications of genome technology is to use an effective process for gathering necessary information and subjecting that information to appropriate and thorough consideration to formulate recommendations for appropriate bodies. The following examination of processes currently used by industry and government reveals that a new process will be required.

Industry Decision Process

By chance I have played a significant role in some important events in biotechnology that have been most criticized. In 1980 and 1981, while employed in-house, I represented Monsanto in its negotiations with Genentech for a license to develop and sell bovine growth hormone (BGH). Approved for administration to dairy cattle to promote increased milk production, BGH has caused considerable controversy and opposition. Some groups claim that milk from cows to which it is administered is unsafe notwithstanding regulatory approval. Others argue that the cost of BGH will further disadvantage small farmers who cannot afford it. According to Al Gore, "These early product choices indicate that little thought was given to which initial products would increase confidence in biotechnology."¹⁸

In the mid-80's, as General Counsel of Genentech, I was responsible for directing that company's lobbying. I helped formulate and implement a plan to respond to the potential additional regulation of biotechnology and the Environmental Protection Agency's announced intention to regulate biotechnology under the Toxic Substances and Control Act.¹⁹ The company was concerned that additional regulation might impose unnecessary and costly burdens at a time when it was still struggling to reach the market with its first products. Consequently, Genentech effectively made the argument that prior to implementing new regulations, agencies ought to gather more information from affected companies and thoroughly reconsider their roles. According to Mr. Gore, "Political interference in agency decision-making effectively

¹⁸ Gore, *supra* note 11 at 25-26.

¹⁹ 15 U.S.C. §§ 2601-2629.

prevented the 1986 Coordinated Framework from laying a clear path from the lab to the marketplace.”²⁰

While General Counsel of Genentech, I participated in decisions that led to FDA’s being sued to try to prevent it from giving market approval for a competitor’s product in contravention of a period of exclusivity awarded to Genentech under the Orphan Drug Act for its first product.²¹ As to this, Mr. Gore said:²²

Early legal decisions have focussed on the debate over technology and the right to exercise it experimentally. Future legal debates will be over the policies to implement the technology....

These roles have afforded a detailed view of processes by which corporate America, large and small, makes choices and sets policies.

Corporate officers and employees are as caring and sensitive as average Americans. They have families and personal concerns. Yet, they work for organizations that expect loyalty to their objectives — ones driven to a large extent by financial markets. Anyone who tries to depart from corporate objectives by favoring social values over financial goals is apt to be labeled “not a team player” and reminded that such a course will likely to negatively affect the company’s stock price. The assumption is that stock price is paramount.

Indeed, stock prices often appear to be of paramount importance to shareholders, financial analysts and the financial press. Although not totally ignoring social concerns and policies, corporate decision makers do tend to act to maximize corporate financial goals rather than to advocate the point of view of society at large. They expect, perhaps need, others to do so. Whether such corporate behavior is good or bad does not matter because that behavior is not likely to change. “Others,” whomever they are, need to step in and play a role. However, it would be counter productive for those “others” to intervene in a manner regarded by industry as antagonistic to its interests. Industry can mount highly effective lobbying efforts to derail such efforts, even those based on the very best intentions.

²⁰ Gore, *supra* note 11 at 25-26.

²¹ As it turned out, that litigation was the opening salvo in massive intellectual property litigation between Genentech and the worldwide pharmaceutical industry.

²² Gore, *supra* note 11 at 25-26.

In fact, the direction of biotechnology has been set in sterile laboratories and closed board rooms, in court chambers and politically-charged White House meetings.²³ The decisions to develop ice-minus, herbicide resistant plants, and BGH created intense public opposition to biotechnology and lent credibility to those who argued that biotechnology would make things worse before it made them better. In their rush to develop this new technology, companies have paid insufficient attention to the fact that the public will involve itself eventually in decisions affecting their communities with or without an invitation. The public still perceives that its involvement comes well after decisions have been made concerning product selection and investment. It can hardly be denied that meetings held to persuade the public to accept products such as BGH are qualitatively different from meetings to discuss what kinds of biotechnology products could help local communities and economies.²⁴

The biotechnology industry can and should do better. It ought to be at the forefront of fostering a rational discussion of genome technology and its implications for social policy. If such a discussion does not begin soon, events will overtake the opportunity. Announcements of experiments made too soon, whether successful or unfortunate, will catch the public's attention with the potentially destructive consequences of fear, mistrust and backlash.

Regulatory Process

Regulation of gene transfer therapies by the FDA has been an exercise of fitting the existing system to the new technology. Dr. Kessler has said that while the FDA's regulatory approach may be modified in light of additional knowledge about risks and benefits, "[n]evertheless, early clarification of the agency's plan to apply its existing regulatory framework to products for somatic-cell and gene therapy is more prudent than waiting until the field has matured."²⁵

²³ *Id.* at 21.

²⁴ *Id.* at 26-27.

²⁵ David Kessler et al., *Regulation of Somatic-Cell Therapy and Gene Therapy by the Food and Drug Administration*, 329 *New Eng. J. Med.* 1169 (1993).

Thus for the short term, technologies such as gene therapy will be dealt with as drugs or biologics in the same manner as other therapies, although approval to test gene therapies in patients has been more rigorous than any other medical area. A synthetic polynucleotide sequence intended to alter a genetic sequence in human somatic cells after administration to the patient is classified as a drug, so that an NDA

The RAC reviews all proposals for NIH funded research projects pursuant to the Guidelines. The Guidelines were intended to monitor biotechnology research until more was known about the safety of the organisms produced through genetic engineering. These Guidelines have been revised over the years in a manner characterized as demonstrating the gradual rise of technology to prominence over policy development to the point that the RAC has "virtually relaxed itself out of a job."²⁶

The RAC responded to the recommendations of the President's Commission in its 1982 report, *Splicing Life*,²⁷ by establishing the Human Gene Therapy Subcommittee to review proposals involving the use of rDNA techniques on human beings and to continue to explore issues that would be posed by the extension of these techniques into genetic enhancement and germline gene therapy.²⁸ The Subcommittee has not yet addressed germline gene transfer proposals because it lacks time.²⁹ Recent reorganization of responsibilities with the FDA should leave it with more time to devote to such issues.

Patent Office Process

The U.S. Patent and Trademark Office (PTO) was founded in the age of, and evolved its rules and policies in connection with, mechanical engineering arts.³⁰ It has struggled to accommodate biology, traditionally considered a "soft science." Patents are supposed to promote dissemination of knowledge; they are not designed to safeguard public well-being. Nevertheless, the application of patent law to biotechnology was initially subjected to ethical and legal

is required. A retroviral vector containing a gene to be administered intravenously into the patient will be classified as a biologic, requiring a PLA and ELA (establishment license application). A retroviral vector containing a gene and intended to modify cells *ex vivo* is considered a biologic intended for further manufacture; hence, both a PLA and ELA will be required. *See* 58 Fed. Reg. 53248 (1993).

²⁶ *See* Gore, *supra* note 11 at 20.

²⁷ President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Splicing Life: A Report on the Social and Ethical Issues of Genetic Engineering with Human Beings*.

²⁸ Testimony of Alexander M. Capron before the Senate Committee on Labor & Human Resources, Oct. 14, 1993, at 113.

²⁹ *See* 59 Fed. Reg. 34496 (1994) (Appendix M to NIH Guidelines).

³⁰ William D. Noonan, *Patenting Medical Technology*, 11 J. Leg. Med. 263 (1990).

controversies similar to those that delayed recognition of earlier medical patents: Scientists debated rDNA's safety; "extremists" sued to prevent the issuance of patents for genetically modified organisms (GMOs); "religious leaders claimed that the sanctity of life was being cheapened; and animal rights groups decried that animals were being tormented."³¹ The PTO was initially reluctant about GMOs and cells on the ground that they were unpatentable "products of nature."³² Perhaps the real reason was simply that they are alive.

The Supreme Court's 1980 *Chakrabarty* decision³³ caused the PTO to implement a policy of broad patent protection for microorganisms, plants and multicellular organisms, including animals.³⁴ However, a decision of the Court of Appeals of the Federal Circuit in 1987 that polyploid oysters were patentable³⁵ was followed shortly by a PTO notice announcing that although the Commissioner considered "nonnaturally occurring nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. Sec 101," claims for such organisms drawn so broadly as to potentially include human beings were regarded as excluded from patentability due to antislavery dictates of the 13th Amendment to the U.S. Constitution.³⁶

It is difficult to know what to think about this. It may be motivated by a concern about interference with "humanness," i.e., that the essential part of a person should not or cannot be owned by another, and that ownership in some part of the human body will violate that principle. Yet the patenting of implantable or implanted medical devices do not seem to have generated the same concerns. Alternatively, the PTO may be agreeing with those who construe the 13th Amendment as prohibiting the imposition of any restraint on

³¹ *Id.* at 294-295.

³² *Id.* at 295-296.

³³ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

³⁴ The first patent for a genetically modified organism (GMO) issued in 1988 on a transgenic mouse modified to be useful in studying cancer. See Noonan, *supra* note 29 at 297.

³⁵ *Id.*

³⁶ See *id.* at 297. According to patent practitioners, examiners routinely reject claims to a transgenic mammal if the claims could include a human being. They require that any claim directed to a non-plant multicellular organism of such scope should include the limitation "nonhuman."

freedom.³⁷ Although it is difficult to see how a patent covering gene therapy could interfere with a person's freedom or liberty, perhaps it may be said that the loss of a property right in one's body or the assignment of some type of property right to another results in a social inferiority or subjugation in the sense that becoming property of another kills what is human in us.³⁸

Does the PTO have the authority to make new policy by introducing a constitutional limitation to patentability? May it apply the policy differentially to different types of technology? The Supreme Court in *Chakrabarty* said that Congress intended statutory subject matter to "include anything under the sun that is made by man" and that living organisms are patentable.³⁹

The PTO has generally avoided analysis of the social consequences of inventions because the grant of a patent does not give inventors the right to make, use or sell their inventions. On the contrary, other agencies, the States or Congress can limit use of inventions. These other venues are better equipped to conduct necessary fact gathering and investigations of social consequences. The PTO has no procedures for data gathering or legal analysis except with regard to patentability.⁴⁰ Hence, moral and ethical considerations would be explored by patent examiners untrained to do so.⁴¹

Jeremy Rifkin's Foundation for Economic Trends, together with a broad coalition of mainstream religious leaders, has recently filed a petition with the PTO to impose a moratorium on the issuance of patents for living organisms. The petition has been described as "an idea whose grandiose vision — to stop an entire industry in its tracks — utterly belied its likely impact in the real world." On the other hand, the reaction of the PTO and the biotechnology industry were only too

³⁷ Current federal court decisions construe the 13th Amendment to include prohibitions against racial discrimination, leading to speculation that it may protect against any conduct which restricts freedom, whether imposed by government, private individuals, or environmental conditions, the only criteria being a loss of internal potential or social inferiority. See Robin M. Silva, *Somatic Gene Therapy and the 13th Amendment: Patentability, Constitutionality, Morality* 25–32 (1995) (unpublished manuscript).

³⁸ *Id.*

³⁹ 447 U.S. 309.

⁴⁰ See Silva, *supra* note 37 at 53.

⁴¹ *Id.* at 57.

predictable. The same author described the reactions by the PTO as “dismissally out of hand;” the Biotechnology Industry Organization, as a “clayfooted organization, which drew a ‘Jesuitical’ distinction between ownership and patent monopoly;” and by BioCentury, a trade journal, that made an effort at “explaining away this latest attack by scientific infidels and religious philistines,” as being more problematic than the petition’s criticisms because it revealed an inclination to avoid examining the real issue that “the evolution of ethics and patent laws that applies to patenting genes and living organisms has been haphazard and largely unexamined.”⁴²

Judicial and Congressional Process

The Supreme Court in *Chakrabarty* rejected the Government’s listing of potential social consequences as irrelevant to its decision and suggested that Congress was a more suitable forum for those issues, saying that:⁴³

we are without competence to entertain these arguments — either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution with the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.

However, Congress has not effectively legislated in this area. In fact, it has only worsened the situation by proposing amendments which would restrict the scope of patents issuable for animals and restricting the collection of royalties on transgenic animals⁴⁴ and has cut PTO funding. Congress seems curiously unsupportive of biotechnology.⁴⁵ Its proposals designed to bring regulatory order to biotechnology have met vigorous opposition from industry and the Administration.⁴⁶ It

⁴² Russ Hoyle, *Don’t Dismiss Rifkin’s Damning of Gene Patents*, 13 *Biotechnology* 643 (1995).

⁴³ 447 U.S. 317.

⁴⁴ See Noonan, *supra* note 30 at 318.

⁴⁵ *Id.*

has been my experience that it is much easier to prevent legislation than to accomplish it. However, it may be worse if Congress does pass legislation. Among other risks, legislation might impede research without good reason.⁴⁷ Yet, absence of legislation has forced agencies to retrofit existing, inadequate legislation to deal with policy issues surrounding recombinant DNA and has slowed innovation due to industrial concerns over the lack of a clear regulatory path.⁴⁸

Need for a National Commission

Issues raised by biotechnology in the 1980's were trivial compared to those to be raised by genome technology. To resolve those issues effectively and fairly, we must develop a coherent moral and ethical basis for decisions in several areas, including patent and FDA law.

Neither the FDA nor the RAC has even begun to address the questions which will be raised by genome technology. They have attempted only to fit somatic cell gene therapy within the existing regulatory framework.⁴⁹ Nor can existing patent law answer such questions as how to clearly and concisely describe a living creature sufficiently to meet the enabling requirement, what scope of enforcement would apply to potentially infringing organisms or nucleic acid sequences or questions of ownership of biological materials.⁵⁰ And if patentability is to turn on whether an invention claims a human body part, how does the PTO go about addressing the question of what it is that makes up personhood? If one has a plastic replacement part, does it make one a different person? Is that part personal property or something else? Does one cease to be human if it is not the original version or if someone else has a property right to a body part? Is the body indivisible from that which makes personhood?

The President's Commission addressed genetic manipulation and noted concerns about the possibility of self-perpetuating "mistakes," a concern that stems from the fact that hybrid life forms may be able to reproduce themselves, especially animal-human hybrids. This raises the

⁴⁶ See Gore, *supra* note 11 at 26-27.

⁴⁷ See OTA, *supra* note 17 at 16.

⁴⁸ See Gore, *supra* note 11 at 26-27.

⁴⁹ See *supra* note 25 and accompanying text.

⁵⁰ See Noonan, *supra* note 29 at 299.

question of which characteristics are uniquely human and whether the wrong lies in bestowing some but not all of those characteristics on the new creation or in denying purely human makeup to the being that might otherwise have resulted from the human genetic material. The possibility that some aspect of humanness might be changed:⁵¹

rightly evokes profound concerns and burdens everyone with an awesome and inescapable responsibility — either to develop and employ this capability for the good of humanity or to reject it in order to avoid potential undesirable consequences.

Thus far, the RAC has served as a surrogate for a national commission on bioethics. But it is not enough. Professor Capron has called for establishing a new commission on bioethical issues to encourage interdisciplinary participation, provide public authority for its statements and permit scholarly consideration required for this subject matter.⁵² In his vision, the commission could serve as a catalyst to force a closer look at ways that health care decisions have traditionally been made; forum to air differences, articulate broad areas of existing agreement, and reassure those forced to make bioethical decisions such as patients, professionals and public servants — as well as a important player in engendering and encouraging the process by which a vibrant and ever-developing society reexamines, revises and reaffirms its system of values and beliefs.⁵³

Professor Capron correctly proposes that a national commission begin as soon as possible. He points out that it should be federal because issues transcend state borders. Acknowledging that some decisions will be made by courts, he correctly observes that courts look to legislatures for guidance. While legislation will be needed, demands on legislative bodies are already overwhelming, and their inherently political atmosphere risks polarization despite large likely agreement. Also, administrative bodies, too, are already overtaxed.⁵⁴

⁵¹ President's Commission, *supra* note 27 at 53–70.

⁵² See Capron, *supra* note 28 at 111–113.

⁵³ *Id.*

⁵⁴ *Id.*

Conclusion

I close with an excerpt from the 1938 C. S. Lewis novel, *Out of the Silent Planet*.⁵⁵ Outspoken in his criticism of science and English society in the early 20th Century, Lewis' book deals with efforts to colonize Mars.

This comes from a scene in which the hero is traveling with an intelligent Martian.⁵⁶

Then, as his hunger ebbed, the sense of his situation returned with dismaying force. The huge, seal-like creature seated beside him became unbearably ominous. It seemed friendly; but it was very big, very black, and he knew nothing at all about it. ... And was it really as rational as it appeared?

It was only many days later that Ransom discovered how to deal with these sudden losses of confidence. They arose when the rationality of the hross tempted you to think of it as a man. Then it became abominable — a man seven feet high, with a snaky body, covered, face and all, with thick black animal hair, and whiskered like a cat. But starting from the other end you had an animal with everything an animal ought to have — glossy coat, liquid eye, sweet breath and whitest teeth — and added to all these, as though Paradise had never been lost and earliest dreams were true, the charm of speech and reason. Nothing could be more than disgusting the one impression; nothing more delightful than the other. It all depended on the point of view.



⁵⁵ Reprinted by Easton Press, 1994.

⁵⁶ *Id.* Ch. 8.