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Ethics of Nanobiotechnology at the Frontline

Wei Zhou[†]

I. INTRODUCTION

Nanobiotechnology promises a wide variety of medical applications. Some of the proposed applications include more efficient and specific drug delivery, systems microsurgic devices that find and destroy viruses or cancer cells, and inexpensive and high throughput diagnostic devices. If nanobiotechnology can fulfill its promises, its impact on society and market will be profound. One optimistic industry report projects that nanobiotechnology will have an overall market impact of nearly $300 billion within the next 12 years.[1] Motivated by the commercial implications, business executives, industrial research scientists and venture capitalists are quickly moving nanotechnology research from academic laboratories into industrial research programs.[2] In some areas, industrial researchers are pursuing research that may lead to commercial products in the near future. Despite its potential impact on the society, ethical issues related to nanobiotechnology are not well understood, particularly by the industrial decision-makers.

II. WHAT IS NANOBIOTECHNOLOGY?

For a meaningful discussion of the legal and ethical implications of an emerging technology, it would be helpful to have a working definition of the underlying technology. While all emerging technologies tend to be difficult to define, nanotechnology is a rare

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1. Mehr, *Nanobiotechnology*, D&MD Executive Briefing (2002), *available at* http://www.bioportfolio.com/cgi-bin/acatalog/9072_toc.pdf.

2. Companies that may be conducting nanotechnology research include Aclara, Arryx, Caliper, Carbon Nanotechnologies, Cell Robotics International, EngeneOS, Fluidigm, Gyros, HandyLab, Life Sensors, Luna nanoMaterials, MemGen, Metrigenix, MicroCHIPS, Micronics, NanoBio, Nano-C, NanoCarrier, Nanogem, Nanoprobe, Nanospectra, NanoSphere, Nanostream, Ntera, Quantum Dot, SurroMed, Targetsome, U.S. Genomics, etc. *See id.*

field that has "produced so much confusion."[3]

"Nanotechnology" has become a buzz word for the science and technology pertaining to visualization, manipulation, and control of materials at the nanometer scale.[4] A nanometer is one billionth of a meter. An atom is about one third of a nanometer wide.

According to one definition, nanotechnology focuses on a scale.[5] This is a very unusual definition of a technology field because other technologies tend to be defined by a key technology or breakthrough. For example, microelectronic technology is powered by photolithographic manufacturing of integrated circuits; genetic engineering technology is based upon recombinant DNA; and the Internet is enabled by packet switching network/networking protocols/ample supply of computers, and made popular by the World Wide Web. In fact, nanotechnology, according to various definitions, may encompass many technologies that can operate on the nanometer scale. The broadness in scope presents difficulties for understanding the legal and ethical implications of nanotechnology because nanotechnology may represent a collection of technologies, each of which may have different characteristics and applications.

Some ethical discussions have been focused on the field of molecular nanotechnology.[6] Technologies related to the mechanical control over the arrangement of atoms are often referred to as molecular nanotechnology. American physicist and Nobel Laureate Richard Feynman[7] introduced the concept of manipulating matter on an atomic scale and its implications in his classic talk at the American Physical Society's 1959 annual meeting.[8] Additionally, physicist K.

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3. Jeffrey M. Perkel, *Nanotech Dreams*, THE SCIENTIST, March 1, 2002 *at* http://www.the-scientist.com/yr2002/mar/profile_020304.html (last visited Apr. 20, 2003).

4. *Id.*; Drexler, *Introduction to Nanotechnology in Prospects, in* NANOTECHNOLOGY: TOWARD MOLECULAR MANUFACTURING 1 (Markus Krumenacker & James Lewis eds., 1995).

5. *See, e.g.*, Perkel, *supra* note 3 (quoting Chad A. Mirkin, George B. Rathman Professor of chemistry and director of Institute of Nanotechnology at the Northwestern University. "It is a field that focuses on a scale rather than a material. So, it affects everything.").

6. *See, e.g.*, Frederick A. Fiedler & Glenn H Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. CAL. INTERDISC. L. J. 593 (1994); David D. Friedman, *Future Imperfect* (Oct. 6, 2002) (draft), *at* http://www.daviddfriedman.com/future_imperfect_draft/future_imperfect.html.

7. Richard Feynmann shared the 1965 Nobel Prize in Physics with Sin-Itiro Tomonaga and Julian Schwinger "for their fundamental work in quantum electrodynamics, with deep-ploughing consequences for the physics of elementary particles." *See* The Nobel Prize in Physics 1965, Nobel e-museum, *at* http://www.nobel.se/physics/laureates/1965/index.html (last modified June 16, 2000).

8. Richard Feinman, *There is Plenty of Room at the Bottom*, ENGINEERING AND

Eric Drexler contributed significantly to the theoretical thinking about molecular nanotechnology. Drexler proposed the concept of "assemblers" which are molecular machines that are capable of building other molecular machines.[9] He also suggested "replicators" which are assembler-like devices that could create exact copies of themselves. Such replicators may enable inexpensive mass production of any device. However, not all scientists view the future in the same way as Drexler. For example, Nobel laureate Richard E. Smalley once declared that Drexler's devices "will never become more than a futuristic daydream."[10]

While it is still not possible to control and manipulate matter on an atomic scale at will, recent scientific discoveries suggest that certain rearrangement of atoms are achievable and may offer practical applications. For example, new forms of the element carbon—called fullerenes— can be produced by vaporizing carbon condenses in an atmosphere of inert gas to form the soccer-ball-like fullerenes arrangement of carbon atoms. In addition, it has been possible to produce thin tubes with closed ends, nanotubes, arranged in the same way as fullerenes. The new materials are the basis of much of the emerging nanotechnology industry.[11]

Nanobiotechnology is the application of nanotechnology to the life sciences and may include the application of biotechnology to nanotechnology (e.g., using biological means to manipulate materials on the nanometer scale). Many areas of biomedical applications have been suggested. At a conference organized by National Institutes of Health's Bioengineering Consortium, the following areas were identified for research in the coming years: synthesis and use of nanostructures; applications of nanotechnology in therapy; biomimetic nanostructures, which are synthetic products developed from an understanding of biological systems; biological nanostructures; electronic biological interface; devices for early detection of diseases; instruments for studying individual molecules; and nanotechnology for tissue engineering.[12]

SCIENCE, February 1960, *at* http://www.zyvex.com/nanotech/feynman.html.

9. *See* K. ERIC DREXLER, ENGINES OF CREATION-THE COMING ERA OF NANOTECHNOLOGY (1986).

10. R.E. Smalley, *Of Chemistry, Love and Nanobots*, SCIENTIFIC AMERICAN, Sept. 2001, at 285.

11. PETER HARRIS, CARBON NANOTUBES AND RELATED STRUCTURES : NEW MATERIALS FOR THE TWENTY-FIRST CENTURY (Cambridge University Press 2000).

12. Malsch, *Biomedical Applications of Nanotechnology*, THE INDUSTRIAL PHYSICIST, June/July 2002, at 15.

In the diagnostic area, much of the research has been focused on biochips, which are devices that contain many biological sensors.[13] Nanotechnology has been proposed to increase the density of sensors on the biochips[14] and to provide alternative detection mechanisms.[15] In the therapeutic advances, one potential near term application may be in drug delivery. Many researchers are working on using nanoparticles as vehicles for efficient drug delivery.[16] From a long term prospective, some researchers envision nanorobotics that are capable of navigating throughout the body, repairing injuries, destroying tumors and even performing gene therapy.[17]

A. Ethical Issues and Nanobiotechnology

There are at least two important reasons for discussing ethical issues at this early stage of technology development. One is to anticipate ethical problems such as "preventable harms, conflicts about justice and fairness, and issues concerning respect for persons likely to arise from specific nano initiatives."[18] The second aim is "to foster sensitivity to ethical issues and responsibility at every level of decision making by both technical and policy people."[19]

Despite the great interest in understanding the legal and ethical implications of nanobiotechnology, there seems to be a lag in ethics research in nanotechnology.[20] There are significant research funds available for studying the ethics of nanotechnology. Unfortunately, as Mynyusiwall et al. recently reported, research funds have not been spent and ethics publications are lagging behind the science.[21] For example, the National Nanotechnology Initiative allocated $16 –28

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13. *See generally* Perkel, *supra* note 3.

14. R. Piner, J. Zhu, F. Xu, S. Hong, C. A. Mirkin, *'Dip-pen' Nanolithography*, 283 SCI. 661 (1999).

15. *See, e.g.*, Quantum Dot Corporation website, *at* http://www.quantumdot.com; Nanotheraputics website *at* http://www.nanosphere.com.

16. *See* Celia M. Henry, *Drug Delivery*, 80(34) C&E NEWS 39 (2002), *at* http://pubs.acs.org/cen/coverstory/8034/8034drugdelivery.html; Majeti N. V. Ravi Kumar, *Nano and Microparticles as Controlled Drug Delivery Devices*, 3(2) J. PHARM. PHARMACEUT. SCI. 234 (2000), *at* http://www.ualberta.ca/~csps/JPPS3(2)/M.Kumar/particles.htm.

17. Perkel, *supra* note 3.

18. V. Weil, *Ethical Issues in Nanotechnology*, *in* SOCIETAL IMPLICATIONS OF NANOSCIENCE AND NANOTECHNOLOGY 193 (M. Roco & W.S. Bainbridge eds., National Science Foundation 2001).

19. *Id.*

20. Mnyusiwalla, et al., *'Mind the Gap': Science and Ethics in Nanotechnology*, NANO TECHNOLOGY 14:R9-R13, *available at* http://www.utoronto.ca/jcb/pdf/nanotechnology_paper.pdf (Feb. 17, 2003).

21. *Id.*

million to study societal implications, but less than half of the amount was spent.[22] The National Science Foundation did not award a single project proposing to study the social impact of nanotechnology, even though it was charged with the responsibility to spend $8 million in this research area. Apparently, no one submitted a meritorious research grant proposal.

While anticipating all the ethical issues arising from nanotechnology and its application is difficult, some ethical issues are so commonplace in any emerging technology that we can safely assume that we will encounter the same issues for nanotechnology. Such areas include environment and safety, equity, and potential conflict of interest arising from the interactions among government, industry, and universities, and intellectual property ownership.

Additionally, as expected, we are seeing increasingly critical examinations concerning the safety of nanotechnology in terms of material toxicity and potential harm to the environment.[23] Small nanoparticles may enter the human body but the health implications are yet unknown. In the nanobiotechnology area, the public may have legitimate reasons to be concerned about the safety of employing viruses as nanotechnology tools. Also, because of the short history of nanotechnology and its unparalleled power, we should be particularly concerned about any unforeseen adverse effects.

The lack of meritorious ethics research proposals may be related to the difficulty in identifying or anticipating ethical issues that are unique to nanobiotechnology, particularly its near term applications. Some researchers have examined the social implications of distant and controversial molecular nanotechnology.[24] However, the focus on the futuristic world of molecular nanotechnology has also been criticized for illogically extrapolating current research.[25]

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22. *Id.*

23. Robert A. Freitas Jr., *Could Medical Nanobots be Carcinogenic?*, IMM REPORT NUMBER 33: NANOMEDICINE (2002), *available at* http://www.imm.org/Reports/Rep033.html (last updated Oct. 29, 2002).

24. For those who are interested in the world of assemblers and replicators, visit Prof. Friedmann's web site at http://www.daviddfriedmann.com; *see also* Bill Joy, *Why the Future Doesn't Need Us*, WIRED MAGAZINE, Apr. 2000, *at* http://www.wired.com/wired/archive/8.04/joy.html.

25. Stanford Biophysicist Steven Block was quoted as saying, "Nobody has a clue how to build a nanoassembler, much less get one to reproduce." Gary Stix's view may represent the critics. He stated in a special issue of Scientific American on Nanotechnology (NT) that "there has emerged a cult now of futurists who foresee NT as a pathway to a technological utopia: unparallel prosperity, pollution free industry, even something resembling eternal life." Robert F. Service, *Is Nanotechnology Dangerous?*, SCIENCE, November 24, 2000, at 1526.

Nevertheless, the potential social implications of assemblers and replicators are fascinating areas. The intellectual discussion about assemblers and replicators in the futuristic nanoworld may offer insights in many areas including ethics of near-term nanotechnology. On the other hand, focusing on the ethics discussion on the long-term potentials is not enough. Ethics discussion about near-term applications is clearly needed to guide further development of nanotechnology applications. Ethics researchers and legal scholars should be encouraged to study the many ethics issues arising from the near term nanotechnology research and commercialization.

Next, two examples will be used to illustrate some of the ethical questions we may face in the near term. The first example is a nanotechnology-powered era of personal genomics. The second example is the issue related to the patenting of nanotechnology.

1. Nanotechnology-Powered Personal Genomics

Many nanotechnology companies currently are focusing their research on developing more efficient and inexpensive genetic analysis devices. The experience of the microarray industry may provide a glance of what nanotechnology can do to change the way genetic information is obtained. In the last decade, microarray technology particularly, photolithographic, or combinatorial synthesis of genetic probes, has greatly advanced the acquisition of genetic information by shrinking the feature size of genetic probes.[26] For commercially available GeneChip® probe arrays, each of the genetic probes on a microarray occupies a feature of eighteen microns. Hundreds of thousands of probes may be synthesized on a single chip to interrogate a large amount of genetic information.

Nanotechnology promises even smaller feature sizes and much higher densities of probes. If the probe feature size can be reduced to the nanometer scale, a small glass slide containing billions of probes can be potentially manufactured at a low cost. Such slides can be used to interrogate the entire human genome in a single assay. While there are many manufacturing, biochemical, software, and detection technology obstacles to overcome before the nanobiochip becomes a reality, it is closer to reality than many believe. If nanomicroarrays become a reality, the social implications may be profound. What nanomicroarrays can potentially do is to make genomic information readily available to the majority of the population at a very low cost,

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26. *See* Affymetrix website, *at* http://www.affymetrix.com.

thus making genomic information ubiquitous. This raises the following questions: Will the technologies that can make genomic information ubiquitous, change the societal view on privacy and other ethics concerns? Will there be a division between genomic information haves and have-nots? Will genetic discrimination be of a concern if it turns out that no one has a perfect genome (i.e. everyone has a set of bad genes)? Will the development of personal genomic technology profoundly change the way we interact with each other? These issues need to be discussed so that ethics become a part of the decision matrix for many research and commercialization decisions on the pathway to the era of a nano-powered personal genomics.

2. Intellectual Property and Freedom to Operate

Universities and private research organizations are patenting nanotechnology at an increasing rate. According to a Derwent ITP survey, in 2000 alone, there were 1200 patents covering various aspects of nanotechnology.[27] Therefore, another issue that the fledging nanotechnology industry may soon face is how to maintain freedom of operation for a large number of innovators, while rewarding innovations with patent rights.

There are a number of reasons why freedom to operate can be a serious problem for the fledging nanotechnology industry. Nanotechnology has become a high visibility technology that is pursued in a large number of academic and industrial laboratories, which may result in a large number of patent owners, each having some right to exclude others from practicing various aspects of the technology. In addition, patents that cover traditional products may also contain generic claims covering the product concept, not limited by the scale and manufacturing technology. Such patent claims will cover nanotechnology products as well. As a result, for an entity to commercialize a nanotechnology product, it may potentially have to obtain permissions from a large number of patent owners. How industry and society resolve the freedom to operate problem may be dependent upon our understanding of many ethical and legal questions relating to equity and fairness, nondiscriminatory license practice, incentive to innovation, division and aggregation of legal rights among other questions.

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27. Press Release, Derwent Information, *Derwent Responds to Rise in Nanotechnology Patents with a New Service, at* http://www.derwent.com/press/2002/press4.html (March 25, 2002).

B. Ethical Discussion in Industrial Nanotechnology Research Decision-Making

As mentioned earlier, the second aim of discussing ethical issues is to foster sensitivity among executives, research scientists, and other decision-makers to ethical issues. The second aim is perhaps even more important than theoretical discussion of the ethical issues a nano society may face. What ethical issues the society is going to face and how the society is going to address them may be somewhat dependent upon how the scientific researchers and executives make decisions on research and commercialization priorities.

Much of the industrial research and product road maps are kept confidential and out of the reach of academic social scientists and philosophers of ethics. The decision makers at the frontline are often pursuing a particular pathway to products and focusing their attention on the immediate technical challenges. It is difficult to incorporate ethical implications in the decision-making processes unless the decision-makers are thoroughly educated about how to evaluate ethical issues.

For the publicly supported nanotechnology research programs, such as the National Nanotechnology Initiative, it may be a good idea to include social scientists and humanistic scholars in the social process of setting visions for nanotechnology to ensure that ethical issues are considered.[28] This could set a precedent for private research programs whereas it is much more difficult to incorporate social scientists in the decision making process.

Some corporations retain ethics advisory boards consisting of experts who are familiar with ethical issues. The ethics advisory boards can evaluate major research decisions and should be a great mechanism to incorporate ethics in the research decision process. But, it is unlikely that corporate ethics advisory boards will be involved in the day-to-day decision making process. Therefore, it is critical to engage research scientists, research managers, corporate attorneys, and executives in a discussion of potential legal and ethical issues, so that important issues can be addressed in sync with scientific research and technology development.

III. CONCLUSION

Nanobiotechnology promises many powerful applications that may have profound social implications. Ethics research on the

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28. *Id.* at 12.

nanotechnology applications is needed to provide guidance for the decision-makers. However, the research on the ethics of nanotechnology, particularly for the short-term applications, is lagging behind science. Therefore, it is important to encourage ethics researchers to produce quality research proposals on ethical issues and to have the public involved in the discussion of the social impact of nanotechnology. It is also of critical importance to have the industrial decision-makers engaged in the ethics discussion so that ethics consideration will become a part of the often private corporate research decision-making process.