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Suzanne A. Sprunger

Gianna Julian-Arnold

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Promoting and Managing Genome Innovation

Suzanne A. Sprunger & Gianna Julian-Arnold*

Introduction

What is the appropriate balance between encouraging biotechnological innovation while protecting the public from risks that accompany any new technology? A conference was convened¹ to address a concern that, as biotechnology develops at breakneck speed, even rapidly adapting legal systems² neither promote genome-related innovation effectively, nor adequately address public worries about product safety and control of genetic information. The conference was a sequel to an earlier one that focused on intellectual property and technology transfer.³

Presentation topics included societal issues raised by genomic innovation, the role of intellectual property in promoting research and development, and the effects of legal regulation of pre- and postmarket testing — as well as case studies of vaccine development, bioremediation and genome sequence database creation.

Elaine Draper made the first formal presentation, pointing out that not all innovation is necessarily good. She identified possible employment discrimination and social stratification as undesirable

* Dr. Sprunger received her B.S. (Biology) from Cornell University, Ph.D. (Genetics) from the University of Wisconsin-Madison and J.D. from Franklin Pierce Law Center (FPLC).

Ms. Julian-Arnold is an Associate with Roberts & Brownell, Tysons Corner, VA. She received her B.S. (Chemistry) from Northern Arizona University and her J.D. and M.I.P. from FPLC.

¹ October 1995. Organized by Professor Thomas G. Field, Jr. and Gianna Julian-Arnold, the conference was funded in part by the Ethical, Legal and Social Issues component of the D.O.E. Human Genome Program; Nixon, Hargrave, Devans & Doyle L.L.P., Rochester, N.Y.; and Human Genome Sciences. We are grateful for that support.

² Recent changes include, e.g., an amendment to 35 U.S.C. §§ 103 & 282, PL 104-41 § 1111, Nov. 1, 1995, (facilitating the patenting and protection of biotech processes) and amendments to FDA regulations to eliminate some hurdles for approval of biotechnology products. With regard to the latter, see Lauran Neergaard, *FDA Eases Rules for Biotech Drugs*, AP, Nov. 9, 1995, 1995 WL 4413545.

³ July 1993. *Human Genome Symposium*, 5(2) Risk (1994) (at 95-188).

consequences of genome research. Among other things, Dr. Draper suggested that statutes designed to protect employees from discrimination be extended to cover those with genetic predispositions for disease.⁴

Kate Murashige followed, acknowledging that some technologies present problems, as patents themselves sometimes do. She nevertheless stressed the importance of private risk capital in supporting research and development and patents in attracting it. She also discussed several ways the patent system fails to provide adequate incentives for certain types of inventions.⁵

Phillip Russell focused on a technology with little if any downside. He discussed how biotechnology can meet a global need for more effective vaccines. He also addressed several compelling obstacles, including various kinds of bureaucratic and logistical problems. In passing, he noted that while patent protection provides an investment incentive, it may interfere with commercial availability of logistically optimal combinations of proprietary vaccines.⁶

Brian Cunningham illustrated how policies for regulating the use of biotechnology develop in practice. From his experience, he endorsed a suggestion for a federal bioethical commission. He found such an institution to be potentially helpful in reassuring the public and shrinking the gap between the rapid development of biotechnology and the slow development of guidelines for its use.⁷

Karin Gregory⁸ discussed Institutional Review Boards (IRBs) as a means for protecting clinical subjects in premarket testing of new medical products, however derived. She suggested that one reason IRBs are needed is because investigators can have several roles: scientist, agent

⁴ Elaine Alma Draper, *Social Issues of Genome Innovation and Intellectual Property*, 7 Risk 201 (1996) (includes brief biographical information).

⁵ Kate H. Murashige, *Genome Research and Traditional Intellectual Property Protection — A Bad Fit?* 7 Risk 231 (1996) (includes brief biographical information).

⁶ Phillip K. Russell, *Development of Vaccines to Meet Public Health Needs: Incentives and Obstacles*, 7 Risk (1996) 239 (includes brief biographical information).

⁷ Brian C. Cunningham, *Impact of the Human Genome Project at the Interface between Patent and FDA Laws*, 7 Risk 253 (1996) (includes brief biographical information).

⁸ Ms. Gregory, a lawyer who also holds an M.P.H. practices in Boston.

of the drug sponsor and treating physician. She explained how IRBs, made up of both health-care professionals and lay citizens, must ensure, for example, that patients are advised of significant side effects in informed consent forms that can be understood. She also noted that IRBs may even play a role in designing or redesigning clinical studies.

Jeffrey Gibbs discussed the role of the Food and Drug Administration (FDA) in premarket testing and sanctions that it can bring to bear on those who fail to conform to legal requirements. He also discussed how action by the FDA, both before and after marketing, can have a major effect on manufacturers' potential civil liability to those who suffer adverse consequences.⁹

Michael Connolly¹⁰ presented a paper recounting how hazardous waste regulation both encourages and discourages biotechnological development. As he explained, despite the very large apparent promise of bioremediation,¹¹ it is projected to represent only about 3% of the \$1.7 trillion market in technologies used to clean up hazardous sites over the next twenty years. He also suggested ways bioremediation might be more fully exploited to improve the environment.

Finally, Robert Benson¹² related the experience of Human Genome Sciences (HGS) in attempting to recoup the costs of data generated by its affiliate, The Institute for Genetic Research (TIGR). TIGR currently concentrates on cDNA sequences that represent approximately 4% of the human genome actively used by cells to produce proteins. The information developed for human cDNAs includes both the DNA sequence and the pattern of cDNA expression in different tissues and developmental stages. He explained that much more information is generated than can be protected effectively by patents. Thus, while HGS files patent applications on commercially valuable cDNAs, it also licenses proprietary databases of genome

⁹ Jeffrey N. Gibbs, *The Human Genome, FDA and Product Liability*, 7 Risk 267 (1996) (includes brief biographical information).

¹⁰ Susan J. Timian & D. Michael Connolly, *The Regulation and Development of Bioremediation*, 7 Risk 279 (1996) (includes brief biographical information).

¹¹ The use of biological organisms or substances to convert hazardous waste into reusable or nontoxic products.

¹² Dr. Benson is Vice President, General Counsel and Secretary, Human Genome Sciences. He received his B.S. (Chemistry) and Ph.D. (Molecular Biology) from the University of Florida.

sequence information — with special efforts to make it available for scientific research in nonprofit institutions.

Conclusion

Discoveries in biotechnology are made at an extraordinary rate. As noted by several speakers whose papers appear here, such discoveries have the potential to improve our environment, health, food supply and, indeed, our world. As noted by others, these discoveries also are subject to abuse and, even when helpful, can create ethical or social problems.

The following papers offer many suggestions for promoting useful biotechnological innovation and avoiding the downside of some discoveries. The challenge is to encourage the technology and harvest its many manifestly valuable fruits while avoiding possible physical and societal damage. To that end, it is hoped that readers will find them valuable.

