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978-1-107-01191-5 - Identity, Invention, and the Culture of Personalized Medicine Patenting

Shubha Ghosh

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**IDENTITY, INVENTION, AND THE CULTURE OF
PERSONALIZED MEDICINE PATENTING**

What are the normative implications of patenting in the area of personalized medicine? As patents on genes and medical diagnoses have increased over the past decade, this question lies at the intersection of intellectual property theory, identity politics, biomedical ethics, and constitutional law. These patents are part of the personalized medicine industry, which develops medical treatments tailored to individuals based on race and other characteristics. This book provides an overview of developments in personalized medicine patenting and suggests policies to best regulate such patents.

Shubha Ghosh is a Vilas Research Fellow, Professor of Law, and Associate Director of the Initiatives for Studies in Transformational Entrepreneurship at the University of Wisconsin-Madison School of Law. He is the author of more than fifty articles and book chapters and of two leading casebooks in intellectual property law. His research is in the area of intellectual property with a focus on social justice in the design of institutions that support innovation and development.

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Preface

If I had to identify the Big Bang moment, the conception for this book was sparked by a 2005 news report about the FDA approval of BiDil, touted as the first drug specified for a particular racial or ethnic group. I have always been interested in issues of identity as a consumer of scholarship while pursuing studies of innovation, intellectual property, and the social and cultural contexts, as well as technical aspects, of markets as a producer. The BiDil news story struck me as interesting, and the topic as a bridge between my habits as a consumer and producer. But looking back over the manuscript and rereading, often painfully, the research I had brought together, I realized I owe a debt to many academic influences. Perhaps the yearning to acknowledge some of the influences reflects my misguided nostalgia. Nonetheless, acknowledge I feel I must.

First are the many teachers at St. Anselm's Abbey School and Amherst College who exposed me to the right balance of interdisciplinary thinking and rigorous questioning and analysis. Although I moved away from an engagement with the economics profession decades ago, moving toward economic analysis of the law and institutions, the graduate training at the University of Michigan formed my thinking about population studies, demography, and the commons that find expression in these pages. Thanks to the Population Studies Center of the University of Michigan, which celebrated its golden anniversary in 2011, for the positive influences. Finally, starting from my time as a student at Stanford Law School and continuing through the various schools at which I have taught, there are many legal scholars and educators from whom I have learned and still learn and whose ideas are reflected with a combination of admiration and detachment in this book. I believe in always paying back my debts in full, but I may have fallen short here.

Second are seminar participants who sat through various presentations and early fumbblings as this research project developed. I particularly would like

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to thank participants in workshops at the University of Wisconsin Business School, University of Wisconsin Law School, SMU Dedman School of Law, Howard University Law School, and sessions at the Annual Meeting of the Law & Society Association for their support. My colleague Anne Miner at the University of Wisconsin has been very supportive of this project and an encouraging colleague in general.

Third is the financial support I have received from the University of Wisconsin as a Vilas Research Fellow and from the Graduate Fellowship Committee. Recently, I had a discussion with a colleague as to whether, as professors, our teaching subsidizes our research or the other way around. I think of the job as a bundled package. But the financial backing from my university supported research trips and writing time that were not a break from teaching, but enhancements to what I do in the classroom. More important than the financial support is the assistance of Cheryl O'Connor and Bonnie Sucha of the University Wisconsin Law Library for tracking down materials and legal citations. Teresa Evans and Sue Sawatske provided guidance in the technical details of formatting the manuscript. Finally, preliminary work on this project when I was Professor of Law at Southern Methodist University's Dedman School of Law benefited from the research assistance of Ayse Guner (JD, class of 2008) and Ross Allen (JD, class of 2008).

Fourth is John Berger of Cambridge University Press, who was very patient in guiding me through the proposal process and with my questions about production. He and the many other editors and production staff at Cambridge have been a delight to work with.

Fifth, I would like to acknowledge the law journals in which preliminary versions of the ideas in this book were tested out. I would like thank the editors of the respective journals for giving me permission to reprint derivative works based on sections from the following articles:

"Why Intergenerational Equity," 2011 Wisc. L. Rev. 103–109 (2011).

"Patenting Games; or, *Baker v. Selden* Revisited," 11(4) Vanderbilt Journal of Entertainment and Technology Law 871–898 (2009).

"Race-Specific Patents, Commercialization, and Intellectual Property Policy," 56 Buffalo L. Rev. 101–187 (2008).

"The Fable of the Commons: Exclusivity and the Construction of Intellectual Property Markets," 40 U.C. Davis Law Review 855 (2007).

"Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor After *Eldred*," 19 Berkeley Technology Law Journal 1315–1388 (2005).

Writing this book allowed me to revisit the ideas of these earlier works and to synthesize them.

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Sixth is reflected in the dedication to Keith Aoki, *Wunderfreund*, who passed away unexpectedly in 2011. To describe Keith requires a neologism, a German one at that. Keith was a pathbreaking scholar and remarkable teacher as well as an incredible colleague globally, beyond the boundaries of his home institution. Keith was also the first academic I met after entering law school teaching in 1996. We shared a van ride from LAX to attend a conference at UCLA. His sincerity and inquisitiveness came through from that first encounter in which he was trying to figure me out. I will miss him.

Most importantly, Soma was a constant source of joy and our dog, Chewbacca, provided countless distractions especially when he tried to break me from the laptop with a lick to the hand, sometimes to an oddly appropriate key.