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BALANCING PUBLIC AND PRIVATE INTERESTS IN THE COMMERCIALIZATION OF PUBLICLY FUNDED MEDICAL RESEARCH: IS THERE A ROLE FOR COMPULSORY GOVERNMENT ROYALTY FEES?

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I. INTRODUCTION

The nature of publicly funded medical research has undergone a profound

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transformation over the last two decades. As part of this transformation, governments have begun to explicitly move away from their traditional gate-keeping roles in medical research, licensure and product regulation, adopting instead a stance where both public health considerations and economic activity resulting from commercialization of innovative research are equally embraced.¹ Indeed, tensions between these competing objectives can be seen in the missions and mandates of every major federal public health and granting agency in the United States, Canada, the European Union and other jurisdictions where technology transfer and commercialization are considered a vital element of national science and technology (S&T) policy.² While commercialization-oriented S&T policies have undoubtedly helped to underpin economic growth in developed nations,³ questions are beginning to emerge over whether the benefits of an increasingly privatized medical research enterprise are being equitably distributed amongst the various public and private actors responsible for marketed products.

This transformation has at least three major components, each of which revolves around a central focus on intellectual property and regulatory rights. For example, in the early 1980s legislative initiatives undertaken by the United States Congress allowing patenting and technology transfer by universities⁴ led to swift changes in the commercial orientation of scientists and their parent institutions.⁵ This was accompanied by the storied *Diamond v. Chakrabarty* decision,⁶ which broadened the category of patentable subject matter to include “anything under the sun made by man.” Along with consolidation of patent appeals before a single appellate court referred to as the Federal Circuit

¹ See Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA L. REV. 1633 (1996); Rebecca S. Eisenberg, *Lecture: Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477, 482-483 (2003-2004) [hereinafter Eisenberg (2003)]; SHELDON KRIMSKY, *SCIENCE IN THE PRIVATE INTEREST* (Rowman & Littlefield 2003).

² The approach taken in this work is focused on neither economics, law, politics nor ethics per se, but rather encompasses all social determinants of health relevant to S&T policy in a liberal democracy such as those of the United States and Canada where both market and non-market principles (such as the fundamental importance of social welfare, human rights and public health) contribute to peace, order and good governance.

³ Barry Bozeman & Daniel Sarewitz, *Public Value and Public Failure in United States Science Policy*, 32 SCI. & PUB. POL’Y, 119-136, 121 and references therein (2005) (discussing case studies and econometric studies that illustrate science is an important engine of economic growth).

⁴ Bayh-Dole Act, 35 U.S.C. §§ 200-212 (1994) [hereinafter referred to as “Bayh-Dole” or the Bayh-Dole Act”]; Stevenson-Wydler Technology Innovation Act of 1980, 15 U.S.C. §§ 3701-3715 (2000); Federal Technology Transfer Act of 1986, 15 U.S.C. §§ 3710a-3710d (2000).

⁵ Barbara J. Culliton, *The Academic-Industrial Complex*, 216 SCIENCE 960 (1982).

⁶ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

and restructuring of the United States Patent & Trademark Office (PTO) as a fee-for-service organization,⁷ this spurred an explosion in patenting by medical researchers. According to at least one patent scholar,⁸ these events together spawned the global biotechnology revolution.

Beginning in the 1990s however, a more subtle wave of privatization occurred in the form of emphasis on translational research⁹ and public-private partnerships.¹⁰ Public-private partnerships grew out of the notion that medical research was viewed as increasingly complex, global, and interdisciplinary, in turn requiring an expanded base of people, infrastructure and resources to translate basic research into commercial products. Partnerships of this nature formed a central component of Elias Zerhouni's "roadmap" on taking over the National Institutes for Health Research (NIH) in 2003,¹¹ which was mirrored by the Food and Drug Administration's (FDA) 2004 Critical Path Initiative¹² to bolster biomedical pipelines. In Canada, Alan Bernstein, then President of the Canadian Institutes for Health Research (CIHR), made commercialization and public private partnerships a central component of the new agency's mandate,¹³ and legislation establishing the agency¹⁴ goes so far as to legally mandate industrial partnerships as part of the nation's commercialization strategy.

⁷ ADAM B. JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS* (Princeton University Press 2004).

⁸ Sheila Jasanoff, *The Life sciences and the Rule of Law*, 319 J. MOL. BIOL. 891 (2002).

⁹ U.S. Department of Health and Human Services & Food and Drug Administration, *Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products* (White Paper, March 2004), available at <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html> (describing translational research as "multidisciplinary scientific efforts directed at 'accelerating therapy development' (i.e., moving basic discoveries into the clinic more efficiently)"); See also Elias Zerhouni, *The NIH Roadmap*, 302 SCIENCE 63 (2003) (describing translational research as "lab to bedside" research, also commonly known as "bench to bedside" research).

¹⁰ Jean Ettiene de Bettingnes & Thoma W. Ross, *The Economics of Public-Private Partnerships*, 30 CANADIAN PUB. POL'Y 135 (2004) (discussing public-private partnerships as encompassing a spectrum of partnerships ranging from complete privatization (e.g., private firms contracted out to provide government services using public resources) to more or less equal partnerships, depending on the nature of the partnership).

¹¹ Zerhouni, *supra* note 9, at 63-65.

¹² Mark Ratner, *Looking for Solid Ground Along the Critical Path*, 24 NATURE BIOTECHNOLOGY 885 (2006); ShaAvhree Buckman, Shiew-Mei Huang, & Shirley Murphy, *Medical Product Development and Regulatory Science for the 21st Century: The Critical Path Vision and its Impact on Health Care*, 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 141 (2007).

¹³ Alan Bernstein, *Toward Effective Canadian Public-Private Partnerships in Health Research*, 168 CMAJ 288 (2003).

¹⁴ Canadian Institutes of Health Research Act, R.S.C. ch. 6 (2006).

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Finally, and even less appreciated than the movement towards public-private partnerships, a third front of privatization has quietly advanced represented by the ever-increasing influence of industry on the legal and regulatory requirements for clinical trials and drug approval. Notably, this has included expansion of patent rights and the intrusion of provisions of patent law into legislation and regulations controlling drug approval via so-called linkage regulations¹⁵ in the United States¹⁶ and Canada,¹⁷ as well as the growth of data, market and pediatric exclusivity rights through expansion of international trade agreements such as the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). A second and related factor is the shift in these same nations from a licensing regime for biomedical products focused (to varying degrees) on the precautionary principle to one where risk management and risk-benefit considerations are central. It is no coincidence that the same firms and industry lobbying groups that were central to the evolution of the public-private partnerships model and linkage regulation regime are also those considered "clients" and "partners" by federal food and drug agencies following their switch to a fee-for-service model. Together, the basket of legal, regulatory, policy and political initiatives comprising the three waves of privatization been referred to jointly as the industrialization¹⁸ or privatization¹⁹ of medical research.

Increased emphasis by federal funding agencies on technology transfer and commercialization in the context of privatized medicine has not been without opposition. Chief among the issues raised is the growing frustration amongst some scientists and the public that industry has gained control of government purse strings, as well as national S&T policies and intellectual property practice.²⁰ Concerns such as these date back at least to the Bush-Kilgore

¹⁵ For discussion of linkage regulation in the context of the pharmaceutical and biotechnology industries, *see generally* Eisenberg (2003), *supra* note 1; Ron A. Bouchard, *Should Scientific Research in the Lead-up to Invention Vitate Obviousness Under the Patented Medicines (Notice of Compliance) Regulations: To Test or Not To Test?*, 6 CANADIAN J. LAW & TECH. 1 (2007) [hereinafter Bouchard 2007a]; Ron A. Bouchard, *Living Separate and Apart is Never Easy: Inventive Capacity of the PHOSITA as the Tie that Binds Obviousness and Inventiveness*, 4 U. OTTAWA LAW & TECH. J. (forthcoming 2007) [hereinafter Bouchard 2007b].

¹⁶ Drug Price Competition and Patent Restoration Act 1984, 21 USC § 355 (2000), commonly known as Hatch-Waxman.

¹⁷ Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 (Can.).

¹⁸ JEROME R. RAVETZ, *SCIENTIFIC KNOWLEDGE AND ITS SOCIAL PROBLEMS* (Oxford University Press 1971); Denis J. Prager & Gilbert S. Omenn, *Research, Innovation, and University-Industry Linkages*, 207 SCIENCE 379 (1980); Culliton, *supra* note 5.

¹⁹ Ron A. Bouchard & Trudo Lemmens, *Privatizing Medical Research: A "Third Way."* NATURE BIOTECHNOLOGY (forthcoming 2007).

²⁰ *See* Mike Tyers et al., Letter, *Problems with Co-Funding in Canada*, 308 SCIENCE 1867, 1867 (2005); Wayne Kondro, *Scientists Say Genome Canada's Co-Funding Rules Stymie Good Ideas*, 309 SCIENCE 232-233 (2005).

debates leading up to Bayh-Dole.²¹ One of the more serious criticisms is that a fundamental policy emphasis on commercialization may lead to ghettoization of research lacking in commercial potential, including the possible demise of true public interest science.²² This is not a trivial concern. As noted by Art Carty,²³ then Science Advisor to the Canadian Prime Minister, one quarter of the entire federal research budget in 2005 was composed of “co-funded” grants (federal grants aimed at commercialization requiring matching industry or other funds). Similarly, a recent study of biomedical researchers in the United States²⁴ found that about 20% had industry funding, 22% had applied for a patent within the past two years and 25% participated in a “business activity,” defined as participating in negotiations of intellectual property rights, constructing a business plan, spinning out a firm, or accrual of licensing revenue. Thus, it is hardly surprising that in FY 2002 US universities brought in approximately \$1B in licensing royalties, filed 6,500 patent applications, executed 3,700 licenses and created over 400 startups.²⁵ The industrialization of publicly funded biomedical research is entirely in keeping with the growing nexus between patent law and regulatory law governing the sale and consumption of pharmaceutical products in Canada, the United States and the European Union,²⁶ whereby the traditional government “gatekeeper” role in safeguarding public health and safety is being challenged by the reach of national innovation agenda policies.²⁷

In addition to setting national research agendas, a second major concern relating to an increased emphasis on technology transfer is over the distribution

²¹ Bhavan N. Sampat, *Patenting and US Academic Research in the 20th Century: The World Before and After Bayh-Dole*, 35 RES. POL’Y 772, 777 (2006); DONALD E. STOKES, PASTEUR’S QUADRANT: BASIC SCIENCE AND TECHNOLOGICAL INNOVATION 48 (Brookings 1997).

²² SHELDON KRIMSKY, *SCIENCE IN THE PRIVATE INTEREST* (Rowman and Littlefield 2003).

²³ Arthur J. Carty, Letter, *Co-Funding in Canada: Another View*, 309 SCIENCE 874, 874-875 (2003).

²⁴ John P. Walsh, Charles Cho, & Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002 (2005).

²⁵ ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS LICENSING SURVEY FY 2002 (2003); David J. Trigg, *Patenting the Sun: Enclosing the Scientific Commons and Transforming the University-Ethical Concerns*, 63 DRUG DEVELOPMENT RES. 139, 142 (2005).

²⁶ Joel Lexchin, *Intellectual Property Rights and the Canadian Pharmaceutical Marketplace: Where Do We Go from Here?*, 35 INT’L J. HEALTH SERVICES 237 (2005); Edward Hore, *A Comparison of US and Canadian Laws as They Affect Generic Pharmaceutical Drug Entry*, 55 FOOD & DRUG L. J. 373 (1992); Andrew A. Caffrey & Jonathan M. Rotter, *Consumer Protection, Patents and Procedure: Generic Drug Market Entry and the Need to Reform the Hatch-Waxman Act*, 9 VA. J.L. & TECH. 1 (2004); Valerie Junod, *Drug Marketing Exclusivity Under United States and European Union Law*, 59 FOOD & DRUG L.J. 479 (2004).

²⁷ Eisenberg (2003), *supra* note 1.

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of risks and benefits arising from commercialization of publicly funded biomedical research. In other words, are the benefits of publicly funded medical research distributed equitably amongst the various public and private actors responsible for its production, construction and use?²⁸ Public “inputs” to clinical product development include clinical trial participation, provision of tissue samples, tissue and organ donation, provision of genomic, proteomic and other “omic” information, general taxation tied to public health, as well as philanthropy and other donations for cause-specific medical research. Indeed, it is becoming increasingly clear that public contributions and risk allocations may not always be rewarded by reasonable access to the resulting products of research. Furthermore, public health has become increasingly exposed to risks from industry malfeasance designed to maintain market share and profit margins.²⁹ Nor are profits from monopoly-priced products directly shared with either funding governments or the public, even though significant profits are realized increasingly by universities and research institutes.³⁰ As such, the full impact of the push for technological innovation by domestic government has not been fully appreciated until now, as it has only recently become apparent that inequalities in distribution of benefits derived from privatized research require some rethinking in order to avoid policy failure.³¹ Here, I contend that the distribution of the benefits of commercialization are skewed towards private firms and universities and against the public interest, and that a legitimate and economically efficient solution to this imbalance includes

²⁸ See generally BRUNO LATOUR, *SCIENCE IN ACTION: HOW TO FOLLOW SCIENTISTS AND ENGINEERS THROUGH SOCIETY* (Harvard University Press 1987); STATES OF KNOWLEDGE: THE CO-PRODUCTION OF SCIENCE AND SOCIAL ORDER (Sheilla Jasanoff ed., Routledge 2004).

²⁹ See generally RAY MOYNIHAN & ALAN CASSELS, *SELLING SICKNESS: HOW THE WORLD'S BIGGEST PHARMACEUTICAL COMPANIES ARE TURNING US ALL INTO PATIENTS* (GrayStone Books 2005); MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* (Random House 2004); JEROME KASSIRER, *ON THE TAKE: HOW MEDICINE'S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH* (Oxford University Press 2004); JOHN ABRAMSON, *OVERDOSED AMERICA: THE BROKEN PROMISE OF AMERICAN MEDICINE* (Harper Collins 2004); JAY S. COHEN, *OVERDOSE: THE CASE AGAINST THE DRUG COMPANIES* (Penguin 2001); CHARLES MEDAWAR, *MEDICINES OUT OF CONTROL?: ANTI-DEPRESSANTS AND THE CONSPIRACY OF GOODWILL* (Aksant Academic Publishers 2004); JERRY AVORN, *POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS* (Alfred A. Knopf 2004); PHILIP J. HILTS, *PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION* (Alfred Knopf 2003); see also Trudo Lemmens, *Leopards in the Temple: Restoring Scientific Integrity to the Commercialized Research Scene*, 32 J.L. MED & ETHICS, 641, 645 (2004) (“When huge profits lure, and pressure mounts to bring novel drugs or therapies quickly to the market, potential risks may be perceived somewhat more lightly, and inclusion or exclusion criteria may become more flexible.”).

³⁰ ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, *AUTM LICENSING SURVEY FY 2005* (2005), available at [http://www.autm.net/events/File/US_LS_05Final\(1\).pdf](http://www.autm.net/events/File/US_LS_05Final(1).pdf).

³¹ Bozeman & Sarewitz, *supra* note 3.

levying compulsory government royalty fees on successful commercial products that were made possible by public contributions.

II. BENEFIT SHARING: ALLOCATING THE SPOILS OF COMMERCIALIZATION

This article addresses the question of whether the benefits from an enhanced focus on technology transfer and commercialization are equitably distributed amongst the various public and private actors responsible for the successes (and failures) of the system. In S&T policy literature, this concept is sometimes referred to as benefit sharing. For purposes of this article, "commercialization" refers to commercial development of biomedical products for sale to the public developed in whole or in part using tissues, data, information or other resources contributed by the public.³² "Benefit" means a good contributing to the well-being or value of individuals, communities and firms, and "benefit sharing" refers to balancing creation of biomedical products using public resources with equitable sharing of benefits derived from those products via monetary and non-monetary vehicles. Note that the definition of benefit sharing extends well beyond the mere provision of monopoly-priced products in the marketplace and covers both tangible and intangible benefits of medical research.

Benefit sharing has received increased attention lately, largely in the context of genetic research. However, the notion that the benefits of medical research should be shared equitably can be legitimately extended to cover all medical research owing simply to the evolution of clinical science itself from a relatively communitarian activity aimed at the global public good to an increasingly commercial one. The alternative is "benefit hoarding," whereby the benefits of a policy designed to provide aid to the general public are captured preferentially by a subset of the population. In the present context, benefit hoarding would refer to the asymmetric capturing of the benefits of publicly funded medical research by the private or public sector. Under such conditions, policy failure is said to occur.³³ As described by Bozeman,³⁴ failure of public policy occurs when neither the market nor public sector provides needed goods and services required to achieve core public values or when public values are not reflected in social relations. This approach differs from a pure market failure approach in that it requires of government something more than a focus on achieving market efficiency. It accords with

³² Definitions adapted from the Human Genome Organization (HUGO), Ethics Committee Statement on Benefit-Sharing (April 9, 2000), <http://www.hugo-international.org/hugo/benefit.html>.

³³ See Barry Bozeman, *Public Value Failure: When Efficient Markets May Not Do*, 62 PUB. ADMIN. REV. 145 (2002); Bozeman & Sarawitz, *supra* note 3; Giovanni Dosi, Luigi Marengo, & Corrado Pasquali, *How Much Should Society Fuel the Greed of Innovators? On the Relations Between Appropriability, Opportunities and Rates of Innovation*, 35 RES. POL'Y 1110 (2006).

³⁴ Bozeman & Sarewitz, *supra* note 3, at 4.

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the view³⁵ that needed goods are not, and should not, be freely tradable commodities when there is a socially recognized need. In the present context, the public values at stake are first, an equitable distribution or allocation of the benefits of publicly funded medical research and second, reasonable access by the public to affordable medical therapies funded by the public purse. Obviously, the strength of this argument will vary from jurisdiction to jurisdiction depending on the emphasis on free market principles and how strongly the generation, licensure and marketing of medical products are regulated. Even so, almost all liberal democracies recognize that the state has a significant role in promoting equitable access to needed social goods, based in part on the notion that egalitarian justice requires market forces to be restricted in some capacity in order to promote their distribution. This idea, referred to by Walzer as “complex equality,”³⁶ is particularly relevant to the issue of public health given that clinical research, as well as the patenting, licensing and marketing of biomedical products are strongly regulated in most developed nations and because biomedical products are generally derived from publicly funded research aimed at the global common good.³⁷

The question of benefit sharing is therefore a timely one for scientific, political and economic leaders, as the changing face of medical research is being accompanied by a similar shift in public expectations with regard to the results of medical research, owing in large part to controversies relating to the safety and efficacy of marketed drugs. While it is undoubtedly true that the push for translational research has resulted in a number of life-saving medicines and therapeutic interventions and that large scale innovation in clinical research would not occur in the absence of some form of government or public subsidy,³⁸ the question remains as to whether the distribution of

³⁵ MICHAEL WALZER, *SPHERES OF JUSTICE: A DEFENSE OF PLURALISM AND EQUALITY* (Basic Books 1983).

³⁶ *Id.* (discussing the theory of “complex equality,” which claims the standard of just equality is not a discrete material or moral good, but rather one that is distributed according to its particular social meaning. Hence, no good (private knowledge; patented or marketed products) is allowed to dominate or distort the distribution of other goods in the same sphere or goods in other spheres (affordable health care or medical products). Egalitarian justice is a normative moral standard as opposed to a Platonic standard in the form of a universalized abstraction).

³⁷ Kay Dickersin & Drummond Rennie, *Registering Clinical Trials*, 290 *JAMA* 516, 517 (2003); see generally Catherine De Angelis et al., *Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors*, 351 *NEJM* 1250 (2004); Catherine De Angelis et al., *Is This Trial Fully Registered? A Statement from the International Committee of Medical Journal Editors*, 352 *NEJM* 2436 (2005); Christine Laine et al., *Clinical Trial Registration: Looking Back and Moving Forward*, 356 *NEJM* 2734 (2007); Ida Sim et al., *Clinical Trial Registration: Transparency is the Watchword*, 367 *LANCET* 1631 (2006).

³⁸ Bozemand & Sarewitz, *supra* note 3, at 3 (discussing the notion that “delegitimation of science as a source of authority leaves the economic role of science [and S&T policy] as the

benefits from publicly funded research is so skewed to the private sector so as to attract policies based on the principal of reciprocity. Indeed, one issue common to most public opinion surveys over the last decade is that the public depend strongly on government to protect their best interests, including avoiding undue influence by industry. As discussed in detail below, concerns of this nature encompass mission or regulatory creep whereby government agencies are captured by the industries they regulate,³⁹ a concern expressed specifically in the context of federally-funded medical research⁴⁰ and licensure of the resulting commercial products.⁴¹

III. GROUNDS SUPPORTING DISTRIBUTIVE REALLOCATION

A. *The Market for Biomedical Technologies*

The term “biomedical products” encompasses both small molecule pharmacotherapeutic products and biotechnological products. Pharmacology refers to the science relating to drugs and, in particular, how chemical substances interact with living systems. When such substances have medicinal properties they are referred to as pharmaceuticals or drugs. Drugs are typically small molecules that have discrete agonist or antagonist effects at specific receptors or other molecular targets. The field of pharmacology encompasses drug composition, drug properties, interactions, toxicology, and desirable effects that can be used in therapy of diseases. The term “biotechnology” refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

The market for traditional small molecule pharmaceuticals is substantial and growing rapidly. According to the IMS World Review 2004, the global pharmaceutical market grew from \$173B in FY 1990 to \$466B in FY 2003,

only one that no longer demands a defense” and that the only thing that does matter “is economic growth.” On this basis, it is “sufficient to know that . . . science ‘works,’ and works quite well enough to contribute robustly to economic growth.”); Dosi et al., *supra* note 33, at 1110 and 1118 (discussing “profit-motivated innovators are fundamental drivers of the ‘unbound Prometheus’ of modern capitalism” and the general acceptance in the innovation literature that “some private expectation of ‘profiting from innovation’ is and has been throughout the history of modern capitalism a necessary condition for entrepreneurs and business firms in order to undertake expensive and time-consuming search for innovations themselves.”); *See also* Robert E. Litan, Lesa Mitchell, & E.J. Reedy, *Commercializing University Innovations: Alternative Approaches* (NBER Working Paper, May 16, 2007), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=976005.

³⁹ Michele Boldrin & David K. Levine, *The Economics of Ideas and Intellectual Property*, 102 PNAS 1252 (2005).

⁴⁰ Michael M.E. Johns, Mark Barnes, & Patrick S. Florencio, *Restoring Balance to Industry-Academia Relationships in an Era of Institutional Conflicts of Interest*, 289 JAMA 741 (2003); Lemmens, *supra* note 29.

⁴¹ Bouchard & Lemmens, *supra* note 19.

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with an estimated compounded annual growth rate of 5-8% for FYs 2004-2009.⁴² A 2002 survey of Fortune 500 firms demonstrated that the return on capital in the pharmaceutical industry has far exceeded that for an index of all Fortune 500 firms since 1970.⁴³ Median profits as a percent of revenue for all firms were approximately between 4-5% for FYs 1970, 1980, 1990 and 2000, whereas those in the pharmaceutical sector were approximately between 9-18% for the same years, notwithstanding the substantial reduction in drug approval times over the same term.⁴⁴ Like the market for small molecule pharmaceuticals, the market for newer biotechnological products is also rapidly growing. Revenues of publicly-traded biotechnology companies surpassed \$60B in 2005 for the first time in the sector's history, up 18% over 2004 revenues.⁴⁵ The market capitalization of biotechnology firms in FY 2004 was \$410B and \$18B in the United States and Canada, respectively. These statistics are particularly significant in the context of privatized medicine because biotechnology-based products often originate in publicly funded university labs and research institutes.

Figures such as those above suggest that biomedical products have become a necessity in developed and developing nations. In particular, pharmaceuticals and biotechnologies have become standard therapies for the treatment and prophylaxis of a wide variety of acute and long-term diseases. Yet essential drugs are unavailable to an estimated one-third of the global population⁴⁶, with many people lacking access to affordable medications in nations with high GDPs per capita such as the United States and Canada.⁴⁷

Although the public undoubtedly benefits from improved access to drugs, the issue of benefit-sharing is not restricted to access alone. The relevance of fiscal balancing in discussions of benefit sharing is underscored in light of the fact that firms outside the biomedical industry typically do not expect to profit from combination products without first paying in some fashion for the components making up the product,⁴⁸ in-licensing or outright acquisition of technology by firms in telecommunications or mining industries being

⁴² IMS HEALTH, IMS WORLD REVIEW (2004).

⁴³ *Pharmaceutical Industry Ranks as Most Profitable Industry-Again*, PUBLIC CITIZEN, Apr. 18, 2002, <http://www.citizen.org/pressroom/release.cfm?ID=1088>.

⁴⁴ EUROPEAN GENERIC MEDICINES ASSOCIATION, A BITTER PILL TO SWALLOW: MYTHS AND REALITIES OF THE PHARMACEUTICAL INDUSTRY (2003).

⁴⁵ ERNST & YOUNG, BEYOND BORDERS: GLOBAL BIOTECHNOLOGY REPORT (2006).

⁴⁶ See Michael R. Reich, *The Global Drug Gap*, 287 SCIENCE 1979, 1979 (2000) (discussing global inequities in the provision of "essential medicines" as defined and calculated by the World Health Organization).

⁴⁷ Section III.G *infra*. See also WORLD BANK, 2002 WORLD ECONOMIC DATA RELATING TO "PROSPERITY GAP" IN DEVELOPED NATIONS: WORLD DEVELOPMENT INDEX 2002 (2003); CARMEN DENAVAS-WALT ET AL., U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2003 (2004); Bozeman & Sarewitz, *supra* note 3, at 1-2 and references therein.

⁴⁸ Kare Berg, *The Ethics of Benefit Sharing*, 59 CLINICAL GENETICS 240 (2001).

excellent examples. Benefit sharing as used here is thus deemed to encompass the notion that private firms capitalizing on publicly funded research should return a portion of profits or other in-kind benefits accruing from this research to the public (or government as public agent) responsible for making the relevant research and product development activities possible in the first place.⁴⁹

B. "Inherent" Tensions between Public and Private Interests

A major premise of this article is that public and private interests in the commercialization of medical research are at odds with one another to a certain degree. It is often claimed in policy and political⁵⁰ circles that innovation and commercialization of biomedical products fuels the economy and results in increased generalized prosperity and productivity for the public at large. While the economic literature generally supports commercialization-oriented S&T policies and programs as an effective engine for national economic growth, there is nevertheless growing evidence to suggest that prosperity ensuing from such policies and programs is not enjoyed by all members of the public equally. Moreover, when the notion of individual prosperity is constructed in relation to public health issues per se, empirical evidence supports a conclusion that the direct health benefits of research are often inaccessible to large swaths of the public. To paraphrase Martone, once the marketplace has exclusive rights over the funding, development and licensure of biomedical products it can redefine the human person standards that create demand for products the market can itself develop⁵¹. It is undoubtedly true that the public benefits from the commercialization of publicly-funded research, particularly in the context of life-saving therapies. However, when viewed a broader social perspective, the benefits of this research are often

⁴⁹ See Daryl Pullman & Andrew Latus, *Clinical Trials, Genetic Add-Ons, and the Question of Benefit-Sharing*, 362 LANCET 242, 242 (2003) ("Benefit-sharing refers to the view that commercial sponsors should return a portion of the profits or other in-kind benefits that accrue from this research to those who made the research possible in the first place or perhaps to humankind more broadly."); HUGO Ethics Committee, *Statement on Benefit-Sharing*, THE HUMAN GENOME ORGANISATION, Apr. 9, 2000, http://www.hugo-international.org/Statement_on_Benefit_Sharing.htm.

⁵⁰ See *Reinventing Innovation and Commercialization Policy in Ontario* (Institute for Competitiveness & Prosperity Working Paper No. 6., 2004); BRIAN GUTHRIE & TREFOR MUNN-VENN, CONFERENCE BOARD OF CANADA, SIX QUICK HITS FOR CANADIAN COMMERCIALIZATION: LEADERS' ROUNDTABLE ON COMMERCIALIZATION (2005), and CANADIAN GOVERNMENT EXPERT PANEL ON COMMERCIALIZATION, PEOPLE AND EXCELLENCE: THE HEART OF SUCCESSFUL COMMERCIALIZATION (2006); GUTHRIE & MUNN-VENN, *supra* note 50.

⁵¹ Marilyn Martone, *The Ethics of the Economics of Patenting the Human Genome*, 17 J. BUS. ETHICS 1679 (1998); see also Timothy Caufield, *Sustainability and the Balancing of the Health Care and Innovation Agendas: The Commercialization of Genetic Research*, 66 SASKATCHEWAN L.R. 629 (2003).

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highly diffuse in nature compared to the specific and discrete nature of public contributions to commercial research. Therefore, direct benefits to the public are speculative rather than particularized. The speculative nature of medical research must also be grappled with by economic actors responsible for pushing commercialization forward, such as venture capitalists, angel investors, shareholders and, increasingly, technology transfer offices.⁵² The question remains, however, as to whether the nature and degree of risk assumption by various public and private actors (and thus their risk-benefit ratios) justifies the current benefit allocation landscape.

The “private interest” in biomedical commercialization is, for the most part, said to be aimed at efficient wealth maximization for stakeholders.⁵³ Indeed, under most federal, state and provincial corporate/commercial statutes, corporate directors are under a legal obligation to maximize shareholder value. Moreover, as recently discussed by Dosi and colleagues⁵⁴ in the context of innovation-based S&T policies, it is undisputed that profit-seeking firms are the drivers of the “unbound Prometheus” of capitalism. Under market failure theory,⁵⁵ even where the results of publicly funded research retain some aspects of a public good through a relatively restricted intellectual commons,⁵⁶ the output of such research cannot be a free good, since private firms (or technology transfer offices) must intervene in order to transform basic knowledge into applied knowledge, the latter of which constitutes patentable subject matter as well as marketable products.⁵⁷

⁵² Robert Litan, Lesa Mitchell, & E.J. Reedy, *Commercializing University Innovations: Alternative Approaches* (National Bureau of Economic Research, Working Paper JEL No. O18, M13, 033, 034, 038, May 16, 2007) available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=976005.

⁵³ See Michael A. Heller & Rebecca S. Eisenberg, *Can Patent Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698, 700 (1998) (discussing first the situation that “research in the biomedical sciences is increasingly likely to be ‘private’ in one or more senses of the term—supported by private funds, carried out in a private institution, or privately appropriated through patents, trade secrecy, or agreements that restrict the use of materials and data” and second, that private firms are “more likely to use intellectual property to maintain a lucrative product monopoly that rewards shareholders and funds future product development”).

⁵⁴ Dosi et al., *supra* note 33, at 1110-1111 (citing, for the proposition indicated in the text: Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in NATIONAL BUREAU COMMITTEE FOR ECONOMIC RESEARCH, *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY* (Richard Nelson ed., Princeton University Press 1962); DAVID LANDES, *THE UNBOUND PROMETHEUS: TECHNOLOGICAL CHANGE AND INDUSTRIAL DEVELOPMENT IN WESTERN EUROPE FROM 1750 TO THE PRESENT* (Cambridge University Press 1969).

⁵⁵ Bozeman & Sarewitz, *supra* note 3, at 2-3; Dosi et al., *supra* note 33, at 1111-1112.

⁵⁶ See *infra* Section III.C.

⁵⁷ See Keith Pavitt, *National Policies for Technological Change: Where are the Increasing Returns to Economic Research?*, 93 PROC. NAT’L ACAD. SCI. USA 12693, 12695

From a broader social perspective, economic inefficiencies arise from the race to be the first to patent over competitors working in the same field with high innovation costs. As noted by Martin & Scott, society is concerned simply that innovation occurs, whereas individual firms are concerned that *they* win the innovation race⁵⁸ An innovation race left to its own devices is therefore ultimately about the drive to minimize economic efficiencies: firms typically do not undertake socially desirable projects due to high transaction costs and the risks and uncertainties associated with them. As noted above, this has been the traditional rationale offered to support public-private partnerships in medical research. Inefficiencies of this nature may be compounded by the practice of monopoly or regulatory creep where federal agencies involved in oversight of highly regulated industries (such as pharmaceuticals and biotechnology) enable rent-seeking behavior by key industrial players rather than safeguarding the public interest.⁵⁹

By contrast, the “public interest” in biomedical research is said to be traditionally focused on issues relating to public health and well-being independent (though not exclusively so) of transaction costs. An argument typically advanced in bioethics literature⁶⁰ is that individuals consent to participate in clinical trials and donate money, tissues and organs (before and after death) generally for the public good even if that good is sometimes in relation to discrete patient populations. Indeed, the public good nature of medical research was the primary grounds offered by the medical community

(1996) (“[A]lthough the output of R&D activities have some characteristic of a public good, they are certainly not a free good, since their application often require [sic] further investments in technological application, such as R&D expenditures, patenting, and skill levels.”).

⁵⁸ Stephen Martin & John T. Scott, *The Nature of Innovation Market Failure and the Design of Public Support for Private Innovation*, 29 RES. POL’Y 437, 443 (2000).

⁵⁹ See Michele Boldrin & David K. Levine, *The Economics of Ideas and Intellectual Property*, 102 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES 1255 (2005) (discussing the effect of monopoly creep on regulatory agencies); Dosi et al., *supra* note 33, at 1115 (discussing importance of regulatory capture in heavily regulated industries where innovation is strongly tied to intellectual property rights); Baker has catalogued “anti-social” rent-seeking behaviours enabled by monopoly profits, including an increased firm focus on marketing and government lobbying over research and development, concealed or distorted research findings, conflicts of interests in the FDA approval and NIH funding processes, undue influence over physician prescribing habits via pharmaceutical representatives, skewing the direction of research funding towards patentable findings, and an increased emphasis on “me too” drugs and line extensions. Dean Baker, *The Reform of Intellectual Property*, 32 POST-AUTISTIC ECON. REV., available at <http://www.paecon.net/PAERreview/wholeissues/issue32.htm> (July 2005).

⁶⁰ See Berg, *supra* note 48; Jasper Bovenberg, *Whose Tissue Is It Anyway?*, 23 NATURE BIOTECHNOLOGY 929 (2005); Kai-Lit Phua, *The Human Genome Project and Genetic Research: What Are the Implications for Ethics and Equity?*, 14 CRITICAL PUB. HEALTH 191 (2004); Rahul K. Dhanda, *Bioethics in Biotechnology: From Pain to Gain*, 63 DRUG DEV. RES. 93 (2005); Triggle, *supra* note 25.

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in favour of mandatory clinical trial registration,⁶¹ and public contributions of this nature often yield large repositories of biological samples and data ultimately intended to benefit humankind in general as well as more discrete patient advocacy groups or genetically diverse communities. The results in either case are inevitably deemed to be for the public good, and “solidarity” considerations of this nature permeate the mandates and mission statements of both the NIH and CIHR.⁶² To this effect, it has been suggested⁶³ that solidarity constitutes a strong moral duty in the context of public health research.

One of the major sources of commercial product development is the so-called scientific commons.⁶⁴ When it comes to the commons, private and public interests in commercialization as viewed under the lens of market failure theory diverge dramatically. The public interest is in the maintenance of an open, free, and continually evolving intellectual commons, whereas the private interest seeks to gain control of and restrict access to the commons for its own goal of profit maximization.⁶⁵ Similarly, the public “deposit” into the commons is intellectual, ethical, political and financial whereas the private “withdrawal” from the commons is primarily through the acquisition and exercise of intellectual property rights (e.g., patent monopolies, data, market and pediatric exclusivity under TRIPS and related trade agreements, and exclusive licenses).⁶⁶ Public interactions with the commons are governed by

⁶¹ See sources cited *supra* note 37.

⁶² See *infra* notes 90-97 and accompanying text.

⁶³ Kadri Simm, *Benefit Sharing: An Inquiry Regarding the Meaning and Limits of the Concept in Genetic Research*, 1 GENOMICS, SOC’Y, & POL’Y 29, 34 (2005) (discussing the notion that the justification for some form of compensation in the context of benefit-sharing “is a moral one- those who have the power and are able to act in alleviating suffering have the moral obligation of doing so, based on concepts of solidarity and justice.”). See also Ruth Chadwick & Kare Berg, *Solidarity and Equity: New Ethical Frameworks for Genetic Databases*, 2 NATURE REVIEW GENETICS 310 (2001).

⁶⁴ See *infra* notes 90-97 and related discussion.

⁶⁵ See Richard R. Nelson, *The Advance of Technology and the Scientific Commons*, 361 PHIL. TRANSACTIONS ROYAL SOC’Y LONDON 1691, 1692, 1697 (2003) (discussing the benefits of keeping scientific discoveries open to the public); Nicholas S. Argyres & Julia Porter Leibeskind, *Privatizing the Intellectual Commons: Universities and the Commercialization of Biotechnology*, 35 J. ECON. BEHAV. & ORG. 427, 436 (1988) (noting that privatization of medical research could lead to “erosion of the standards of open science” and “commercially-motivated privatization has been seen as adding a powerful new incentive to withhold knowledge.”); Trigg, *supra* note 25, at 143 (describing how monopoly patents “prevent innovation, . . . limit medical access, raise costs to the patient unnecessarily, create unacceptable conflicts of interest, and cannot be considered as anything but totally contrary to the public interest.”).

⁶⁶ Congressional hearings were held on this topic in 1981 and 1982, resulting in the Twentieth Century Fund Report. See Nicholas Wade, *Background Paper to TWENTIETH CENTURY FUND TASK FORCE ON THE COMMERCIALIZATION OF SCIENTIFIC RESEARCH, THE SCIENCE BUSINESS* 17, 47 (1984) (describing, *inter alia*, the nature and effects of the research funding agreement between Massachusetts General Hospital and Hoechst); Argyres

intellectual and cultural synergies and discourses. By contrast, private interactions with the commons are governed by competition among rivals.⁶⁷ Given these diverging public and private interests, it is reasonable to conclude from a public values perspective⁶⁸ that publicly-funded intellectual property should be managed to ensure private economic benefit but also the broadest public benefit.⁶⁹

To some degree, the tension between public and private interests arises from the mandates and enabling legislation of federal agencies responsible for public health administration and funding of biomedical research. For example, the Preamble of the Canadian Institutes of Health Research Act makes clear that the CIHR aims to fund healthcare research for the benefit of public health.⁷⁰ In particular the Parliament of Canada expressly recognized:

that Canadians value health as central to happiness and fulfilment . . . that excellence in health research is fundamental to improving the health of Canadians and of the wider global community, and that investment in health and the health care system is part of the Canadian vision of being a caring society.⁷¹

However, in addition to public good goals and mechanisms, further provisions of legislation create significant tension between public and private interests within the rubric of Canadian health research. For example, the Preamble also states that:

Parliament believes that health research institutes should be created to coordinate, focus and integrate health research based on . . . the creation of new scientific knowledge based on research that meets the highest

& Liebeskind, *supra* note 55, at 435. (noting that “incentives to commercialize new knowledge depend critically on the existence of property rights to that knowledge on the part of the investor. Thus, the intention of the Bayh-Dole Act was to facilitate the commercialization of university-generated knowledge by allowing for the formation of IP rights to that knowledge, and their transfer to private parties.”).

⁶⁷ See Argyres & Liebeskind, *supra* note 55, at 431 (“Private firms . . . often keep new discoveries secret in order to gain competitive advantage over rivals. Universities can be thought of . . . as having made a partly-implicit, partly explicit contract with society to store, create and disseminate knowledge in exchange for financial support.”).

⁶⁸ Bozeman & Sarewitz, *supra* note 3, at 2 (discussing the notion that “if we assume that science’s benefits and costs affect citizens in very different ways and to different degrees, and that those benefits and costs are in turn affected by the composition of society’s science portfolio, then public value questions emerge as at least as important as economic ones.”).

⁶⁹ See Sara Boettinger & Alan B. Bennet, *Bayh-Dole: If We Knew Then What We Know Now*, 24 NATURE BIOTECHNOLOGY 320, 323 (2006) (noting that US public policy should “require that public policy funded research results be managed in a way that preserves the opportunity to mobilize new technologies to meet humanitarian needs of the world’s poorest people in addition to meeting the commercial needs of the developed world.”).

⁷⁰ Canadian Institutes of Health Research Act, R.S.C., ch. 6 (2000).

⁷¹ *Id.*

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international standards of excellence, and the application of that knowledge to the development and implementation of innovative policy and practice.⁷²

Thus, under the text of the enabling legislation, not only does the Minister of Health have jurisdiction for improving the public health of Canadians, it also provides the Minister (rather than the Minister of Industry) with jurisdiction to ensure that healthcare research is aimed at enhancing economic development in relevant sectors (e.g., pharmaceuticals, biotechnology).

Analogous tension between public and private interests in medical research exist in the United States. As recently reviewed by Sampat,⁷³ debates over the purpose and methods of technology transfer and commercialization have been ongoing for well over a century, having their roots, inter alia, in the Research Corporation founded by Fedrick Cottrell of the University of California and continuing well into the Bush-Kilgore debates leading up to the passage of Bayh-Dole. A good litmus test for the tenacity of the two sides can be seen in the nature of the NIH mission, which has the agency acting simultaneously as the traditional “gatekeeper” of public health research while also fostering innovation and ensuring a high return on investment:⁷⁴

NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.

The goals of the agency are as follows:

1. foster fundamental creative discoveries, innovative research strategies, and their applications as a basis to advance significantly the Nation’s capacity to protect and improve health;
2. develop, maintain, and renew scientific human and physical resources that will assure the Nation’s capability to prevent disease;
3. expand the knowledge base in medical and associated sciences in order to enhance the Nation’s economic well-being and ensure a continued high return on the public investment in research; and
4. exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

It is clear from mission statements such as these that federal funding agencies in the United States and Canada have taken the initiative, indeed the jurisdiction, to play the role of “facilitator” in underwriting both federal

⁷² *Id.*

⁷³ Sampat, *supra* note 21.

⁷⁴ About NIH, <http://www.nih.gov/about/> (last visited April 6, 2007).

research funding with an eye to the public good and the economic outputs of research. Similar tensions play out in the mandates and policy positions taken by the FDA and its Canadian counterpart, the Therapeutics Products Directorate (TPD) of Health Canada with regard to drug regulation⁷⁵ and the increasing emphasis by both the NIH and CIHR on facilitating innovation and translational research via public-private partnerships.

The above discussion illustrates that there are certain real tensions between public and private interests in commercialization that are by now well entrenched in the enabling legislation, missions and mandates of all American and Canadian health research funding and regulatory agencies as well as in patent scholarship. The tension is real in the sense that the doubling of the budget for the NIH between 1998 and 2002 was premised on the promise of health benefits for the public even though healthcare became increasingly unaffordable to larger swaths of the public and the public returns on health research remain difficult to document empirically.⁷⁶

However, there is also good historical evidence⁷⁷ to the effect that universities and research institutes were never pure “ivory towers” of basic research and that there has been a strong historical interplay of public and private interests in the medical research enterprise. With this and Bozeman’s theory of public policy failure⁷⁸ in mind, we therefore cannot say with certainty that public and private interests in commercialization are *inherently* and *irretrievably* in conflict. We are in a position, however, to say that public and private interests in commercialization do meaningfully conflict with one another *to the degree* that the benefits of commercialization are skewed (or in the words of Bozeman, “hoarded”) by one of the enterprise partners thus giving rise to conditions of policy failure.

C. The Scientific Commons

The scientific commons is the starting point for any analysis of benefit sharing in relation to public research. Indeed, the power of innovation and market-stimulated research is widely seen as dependent on the strength of the “open” basic science base from which firms draw for their product development activity.⁷⁹ The concept of openness has been articulated as “the

⁷⁵ Trudo Lemmens & Ron A. Bouchard, *Regulation of Pharmaceuticals*, in CANADIAN HEALTH LAW & POLICY 311-365 (Jocelyn Grant Downie, Timothy A. Caufield, & Colleen M. Flood eds., 3d ed. 2007) [hereinafter Lemmens & Bouchard 2007a].

⁷⁶ Section III.G, *infra*. See also, Bozeman & Sarewitz, *supra* note 3.

⁷⁷ See generally STOKES, *supra* note 21; Sampat, *supra* note 21; Nathan Rosenberg & Richard R Nelson, *American Universities and Technical Advance in Industry*, 23 RES. POL’Y 323 (1994).

⁷⁸ Bozeman, *supra* note 33; Bozeman & Sarewitz, *supra* note 3.

⁷⁹ See Nelson, *supra* note 55, at 1697 (“[T]he fact that most of scientific knowledge is open, and available through open channels is extremely important. This enables there to be at any time a significant number of individuals and firms who possess and can use the

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republic of science”⁸⁰ or “communitarian aspect of science”⁸¹ and entails some form of discourse between scientists and the greater public in relation to the production (if not construction) of valuable scientific knowledge and the practical benefits to be drawn from it.⁸² For example, two recent reports⁸³ on how management values research output concluded that industry obtains the lion’s share of benefit through open rather than closed channels. In particular, research emanating from universities frequently enables firms to solve technical problems rather than initiate new projects. Thus, as far as empirical data suggest, open channels between academia and industry are necessary for efficient and optimal productivity. Under this theory, erosion of the commons would be detrimental to innovation. Indeed, Nelson has correctly argued that this aspect of the scientific commons is critical to productivity in downstream efforts to advance technological solutions to applied problems.⁸⁴

Much has been written about the importance of an open exchange of various forms of tacit and focal⁸⁵ (or codified⁸⁶) knowledge in the life sciences and the

scientific knowledge they need in order to compete intelligently. . .”).

⁸⁰ Michael Polanyi, *The Republic of Science*, 1 MINVERVA 154 (1967).

⁸¹ BERNARD BARBER, *SCIENCE AND THE SOCIAL ORDER* (1953); THOMAS KUHN, *THE STRUCTURE OF SCIENTIFIC REVOLUTIONS* (1962); WARREN O. HAGSTROM, *THE SCIENTIFIC COMMUNITY* (1965); ROBERT K. MERTON, *THE SOCIOLOGY OF SCIENCE* (1973).

⁸² See Jasanoff, *supra* note 8.

⁸³ See Wesley M. Cohen et al., *Links and Impacts: The Influence of Public Research on Industrial R&D*, 48 MGMT. SCI. 1, 21 (2002) (concluding that “a large share [of industrial R&D projects] made use of research findings from public research . . .”); Ajay Agrawal & Rebecca Henderson, *Putting Patents in Context: Exploiting Knowledge Transfer at MIT*, 48 MGMT. SCI. 44, 59 (2002) (discussing “the well-established idea that patents are a relatively small channel for the transfer of knowledge out of the university.”).

⁸⁴ Nelson, *supra* note 55, at 1697-1698 (discussing the notion technological advances are an “evolutionary process,” that there are “great advantages of having multiple paths explored by a number of different actors” and that the “communitarianism of scientific knowledge is an important factor in its productivity in downstream efforts to advance technology.”).

⁸⁵ See Michael Polanyi, *The Republic of Science: Its Political and Economic Theory*, 1 MINVERVA 54 (2003). For application of tacit and focal knowledge in the pharmaceutical sciences, see Bouchard 2007b *supra* note 15, at 24 (discussing Polanyi’s view that while knowledge is generally assumed to be public, it is to a very great extent personal, and thus subject to a significant “tacit” dimension. Focal knowledge is knowledge about an object or phenomenon that is “in focus” in the objective realm and as such it must be converted to tacit personal knowledge in order to be used pragmatically as a tool to understand or improve on what is in focus. That which is tacit is complimentary to that which is focal, yet both can vary from one context to another. From a commercialization perspective, the relevant information or knowledge about how to solve a particular pharmaceutical problem comprises traditional prior art sources such as textbooks, literature, conference proceedings (focal knowledge) but also more practical and intuitive details of how such information is put into practice in an actual laboratory and how that knowledge is passed on from one person to the next in a personal sense (tacit knowledge).

application of these forms of knowledge in what Stokes referred to as practical “considerations of use.”⁸⁷ The use-oriented benefits of a freely open scientific commons have been described as analogous to a “non-contentious use” in that they are deemed to be for the benefit of the public good and can be used freely by the public without eroding the quality of the commons.⁸⁸ In the case of a purely open public intellectual good, there is no “tragedy of the commons.”⁸⁹

Several factors operate iteratively to close or “erode” the commons. First, under market failure theory, it is necessary to transform public goods (knowledge) into private goods (patented technology/biomedical products). This transformation self-determines incentives for its own production by pulling the levers of the available legal-regulatory regime.⁹⁰ For firms to capitalize on information in the commons, it is therefore necessary to restrict its open character via acquisition of intellectual property rights (primarily patent and licensing rights) and regulatory rights (primarily data, market and pediatric exclusivity provisions, such as those under TRIPS).⁹¹ Combined

⁸⁶ See David A. Wolfe et al., *Global Networks and Local Linkages: An Introduction*, in GLOBAL NETWORKS AND LOCAL LINKAGES: THE PARADOX OF CLUSTER DEVELOPMENT IN AN OPEN ECONOMY 1, 9 (David A. Wolfe & Matthew Lucas eds., 2005) (discussing the notion that the life sciences industry is heavily dependent on forms of knowledge the authors refer to as synthetic and analytical knowledge. “Synthetic knowledge” is knowledge directed to finding technical solutions to specific problems and particularly important for product development, while “analytical knowledge” refers to intellectual skills underpinning analysing and synthesizing information, e.g., those required for constructing rational and/or cognitive models.).

⁸⁷ Donald Stokes in *Completing the Bush Model: Pasteur’s Quadrant*, in SCIENCE THE ENDLESS FRONTIER 1945–95: LEARNING FROM THE PAST, DESIGNING FOR THE FUTURE 3, 6, 8, 9, 12 (conference, December 9, 1994, Center for Science, Policy, and Outcomes, Columbia University, New York), <http://www.cspo.org/products/conferences/> (paraphrasing Vannevar Bush’s description of the “practical purposes” of science in *Science: The Endless Frontier*).

⁸⁸ Nelson, *supra* note 55, at 1700 (“The ‘public good’ concept of economists is much more directly relevant to analysis of the appropriate domain of public science, or at least the range where ‘communalism of knowledge’ should apply. For our purposes here, the most salient aspect of the economists’ public good concept is that a public good is ‘non-contentious in use.’ By that it is meant that, unlike a standard economic good, like a peanut-butter sandwich, which either you or I, but not both, can eat (although we can split it), a public good can be used by all of us at the same time without eroding the quality for any of us.”).

⁸⁹ Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243 (1968). The term “tragedy of the commons” refers to the degradation of communal resources due to the self-interest of free riders who use or destroy more than their fair share of common property to the detriment of the common good.

⁹⁰ Dosi et al., *supra* note 33, at 1112; See the end of Section III.D. for a discussion of the impact on the existing intellectual property-regulatory regime on innovation and commercialization in the biomedical sciences.

⁹¹ See e.g. Eisenberg (2003), *supra* note 1 (describing “FDA-conferred exclusivity”); Junod, *supra* note 26, at 479-480 (“Generic companies can enter the [drug] market only

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with so-called “linkage regulations” which tie patent protection to product licensure by the FDA or TPD, these property rights result in accumulation of extended periods of monopoly rights and market exclusivity.⁹² Given the increasing periods of patent and market exclusivity achievable by rights “stacking,” it is perhaps not surprising that it has become a bone of contention that rights of this nature can lead to reduced access by the public to innovative medicines and therapies.⁹³ This is a particularly onerous issue in cases where patients have contributed the very data, information or samples required for product development.⁹⁴

Second, lack of access of competitors to a common scientific database may result in significant economic inefficiencies and social costs due to competitors duplicating entire fields of practical research in order to be “first to invent.”⁹⁵ This is because information in the commons is restricted and use of such knowledge by rivals is kept secret, which not only increases the costs of production but also that of the final product to consumers. Moreover, duplication occurs not only at the level of pre-clinical research, but also during Phases 1-3 clinical trials, with attendant risks to patients enrolled in such studies.⁹⁶ Ironically, avoidance of this situation is what led most governments

when the various protections sheltering the pioneer drug have expired. The most important of these protections undoubtedly is the one conferred by a patent, but patents are not the only protection against generic competition: nonpatent exclusivity plays an increasingly important role The practical consequence is to postpone the second applicant’s market entry; in particular, generic competition is delayed for the duration of marketing exclusivity.”).

⁹² See Eisenberg (2003), *supra* note 1, at 483 (discussing the scenario that linkage regulations such as the Hatch-Waxman Act “blur the functional distinction between drug regulation and patents” by “directing PTO to take regulation into account in determining patent term and directing FDA to take patents into account in approving drugs” and allowing “the PTO to grant patent term extensions of up to five years to compensate for marketing delays during the regulatory review period prior to the first permitted commercial marketing of a new drug.”).

⁹³ Lexchin, *supra* note 26.

⁹⁴ See generally, Sections III.E. and III.F. and Bovenberg, *supra* note 60.

⁹⁵ Sim et al., *supra* note 37, at 1631; Zarin et al., *Issues in the Registration of Clinical Trials*, 297 JAMA 2112, 2112 (2007); Alison Tonks, *Registering Clinical Trials*, 319 BMJ 1565, 1566 (1999).

⁹⁶ Trudo Lemmens & Ron A. Bouchard, *Intellectual Property, Regulatory and Ethical Issues Relating to Mandatory Clinical Trial Registration*, in THE GLOBAL FORUM UPDATE ON RESEARCH FOR HEALTH 14 (4th ed., forthcoming. 2007) [hereinafter Lemmens & Bouchard 2007b] (discussing the notion that mandatory clinical trial registration “operates to enhance scientific and economic efficiencies in the conduct and interpretation of clinical trials, which should serve to reduce firm transaction costs and thus lower drug prices” by minimizing “patient risk in clinical trials by avoiding unnecessary duplication of efforts and minimizing situations where harm to patients has been documented but not reported while on the other hand encouraging appropriate replication and confirmation of results.”).

in developed countries to institute some form of data or market exclusivity.⁹⁷ Thus, erosion of the commons forces the public to bear multiple costs, including fiscal and well-being costs.

Third is the increasingly “collapsed discovery path” in the field of biomedical research. As articulated by Orsenigo, this refers to the fact that emphasis on patenting has shifted due to various legal and policy developments from in-house industrial research and development to that conducted by basic researchers at universities as the primary source for discovery of patentable and commercially valuable inventions.⁹⁸ As a result of this shift and the corresponding increase in public expenditures, one might argue that the public has a larger stake in flow-through profits than was previously true.

A fourth issue that may impact the distributive effects of commercialization is the apparent emergence of a “scientific anticommons.”⁹⁹ According to this theory, an anticommons has evolved in recent years due to the increase in patenting of publicly funded biomedical technologies under the Bayh-Dole Act, and the resulting over-patenting has led to underuse of scarce resources because competitors are restricted by strong intellectual property rights.¹⁰⁰ In addition to the sheer volume of patents granted, the purported anticommons has evolved due to the proliferation of so-called “upstream” patents on processes, principals and technologies that were previously unpatented or deemed to be unpatentable. Collection of useable property rights under such conditions is “brutal and slow,”¹⁰¹ and is associated with increased economic inefficiencies due to increased transaction costs and the slowing down of innovation. While intellectual property rights by necessity increase prices and restrict use, development of an anticommons pushes both of these costs well beyond the point of efficiency which private arrangements¹⁰² can do little to mitigate.¹⁰³ This will be particularly true of pharmaceutical and biotechnology

⁹⁷ Junod, *supra* note 26.

⁹⁸ See generally LUIGI ORSENGIO, *THE EMERGENCE OF BIOTECHNOLOGY* (St. Martin's Press 1989).

⁹⁹ See generally Heller & Eisenberg, *supra* note 53.

¹⁰⁰ The problem is not simply a public interest one, because under-utilization of scarce resources occurs to the detriment of patent owners, albeit to a lesser degree than for institutional researchers who either have no interest in pursuing commercialization or have yet to do so.

¹⁰¹ See Heller & Eisenberg, *supra* note 53, at 698. (“Once an anticommons emerges, collecting rights into usable private property is often brutal and slow,” (citing DOUGLAS G. BAIRD, ROBERT H. GERTNER, & RANDAL C. PICKER, *GAME THEORY AND THE LAW* (Harvard Univ. Press 1994)).

¹⁰² See Heller & Eisenberg, *supra* note 53, at 700 (discussing transaction costs of bundling rights).

¹⁰³ See Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 *LAW & CONTEMP. PROBS* 289, 297-298 (2003) (noting that agreements to bundle intellectual property rights have yet to reduce costs in biomedical research).

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firms due to the now entrenched emphasis on accumulating strong patent and other intellectual property rights and a reduced willingness to cooperate in private arrangements to reduce costs and speed up innovation.

Fifth, additional inefficiencies may also arise because the public will not be able to “maximize benefits of publicly funded research” either because of the effects of upstream patenting or under conditions that favour discrete patent owners who receive varying kinds of subsidies for their product development activities. As noted by Nelson,¹⁰⁴ the former may occur either because of enhanced upstream patenting on “research tools” or under conditions where progress towards a particular advance involves “transgressions” of patents held by a number of other parties (e.g., the patent thicket described by Heller & Eisenberg). As to the latter, the deadweight loss on monopoly-priced pharmaceutical products can amount to up to 0.5% GDP, well in excess of all other subsidized industries.¹⁰⁵ Under any view of the social costs of innovation, this is a potentially staggering loss of taxpayer (rather than government or funding agency) return on investment. Further, public institutions absorb much of the costs of increased transaction costs to the public, particularly for early stage research efforts prior to technology transfer.¹⁰⁶ These inefficiencies may be amplified under conditions of public-private partnerships, where both groups have divergent if not conflicting agendas that further drive up both direct and indirect costs to the public and slow down product development. For example, public institutions may be more interested in maintaining a commons or facilitate access to affordable versions of products whereas private interests will only be interested in maintaining market share and/or monopoly pricing schemes. Thus, both erosion of the commons or development of an anticommons have the potential to significantly increase the economic costs and risk allocations for public actors, and it would appear that neither is matched by a corresponding public benefit.¹⁰⁷ The result is an even greater asymmetric distribution of risks and

¹⁰⁴ Nelson, *supra* note 55, at 1703.

¹⁰⁵ DEAN BAKER & NORIKO CHATANI, CENTER FOR ECONOMIC AND POLICY RESEARCH, PROMOTING GOOD IDEAS ON DRUGS: ARE PATENTS THE BEST WAY? THE RELATIVE EFFICIENCY OF PATENT AND PUBLIC SUPPORT FOR BIO-MEDICAL RESEARCH (2002).

¹⁰⁶ Heller & Eisenberg, *supra* note 53, at 700. (discussing “High transaction costs may be an enduring impediment to efficient bundling of intellectual property rights in biomedical research” [because] many upstream patent owners are public institutions with limited resources for absorbing transaction costs and limited competence in fast-paced, market-oriented bargaining.”).

¹⁰⁷ There is however a caveat to this position. Substantial empirical evidence is not widely available as yet to support the anticommons hypothesis. For example, some commentators found that while complaints were made by holders of multiple licenses, the licenses were for the most part freely available. See John P. Walsh, Ashish Arora, A. & Wesley M. Cohen, *The Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill eds., 2002); Richard A. Epstein & Bruce Kuhlik, *Is There a Biomedical*

benefits undertaken by private and public actors than would otherwise occur within a merely inefficient commons.

Whether one accepts the erosion model or the anticommons model, or some combination of both, an important reason to assume that the present commercialization regime will remain the status quo for some time is that the vast majority of universities have already made substantial adaptive accommodations in order to maximize profits, including establishment of adaptive administrative routines and policies, technology transfer offices, and spinout firms.¹⁰⁸ As noted by Argyres & Porter Liebeskind,¹⁰⁹ these organizational adaptations are in conflict with the long-standing philosophical and cultural championing by universities and certain federal policy-makers of intellectual independence through maintenance of the commons. This has led predictably to inefficiencies in organizational adaptations and thus profits realized by universities from a market failure perspective,¹¹⁰ and thus the need for policies and behaviors more in line with business interests and less faithful to the historical model of an open scientific commons.

Based on the above, it is reasonable to conclude the commercialization juggernaut is gaining, rather than losing steam, and that a return back to a primarily open commons or even a more open licensing scheme is unlikely to occur absent substantial federal policy intrusion.¹¹¹ To this end, university administrators are not likely to allow development of practices away from maximizing revenues gleaned from intellectual property¹¹² even if such policies are now acknowledged to be against the public interest. In fact, recent work in the area appears to extend the proposal by Argyres & Porter Liebeskind by conflating the two issues together. For example, in the work of Litan et al.,¹¹³ technology transfer and commercialization are seen as entrenched and beneficial norms within the university community to the

Anticommons?, 27 REGULATION 54 (2004).

¹⁰⁸ See Argyres & Liebeskind, *supra* note 65.

¹⁰⁹ *Id.* at 427 (“We argue that [universities’ recent attempts to adapt their policies and organizational arrangements in order to accommodate the commercialization of university biotechnology research] have been severely hampered because internal and external parties have sought to enforce universities’ adherence to their historic commitment to create and sustain an ‘intellectual commons’ for the benefit of society at large.”).

¹¹⁰ See generally *id.*; Litan, *supra* note 52; Bozeman & Sarewitz, *supra* note 3; Dosi et al., *supra* note 33.

¹¹¹ See Nelson, *supra* note 55, at 1704 (discussing the notion that while it is universities that conduct and are best positioned to place research in the commons, these institutions “are not in general supporting the idea of a scientific commons, except in terms of their own rights to do research” because they “have become a major part of the problem, avidly defending their rights to patent their research results, and license as they choose.”).

¹¹² See *id.* at 1706 (“Many university administrators and researchers certainly would resist [a revision of Bayh-Dole] on the grounds that [such a revision] would diminish their ability to maximize financial returns from their patent portfolio.”).

¹¹³ See e.g. Litan, *supra* note 52.

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inherent benefit of society. Consequently, there is no discussion over whether these norms should be strongly supported for example by producing a greater volume of commercialization activities rather than focussing on return on investment considerations. The position of these authors is typical of the resistance by supporters of commercialization to the Mertonian norms of universalism, communalism and disinterestedness¹¹⁴ and the maintenance of an open commons in favour of a more profit-minded approach to medical research. Resistance of this nature by researchers, universities and, increasingly, federal funding agencies to contemplation of the deeper social value of their work has been evident throughout the entire history of Bayh-Dole in discussions of recoupment and other legislative mechanisms such as march-in and reasonable pricing clauses designed to increase the social value of research.¹¹⁵

Finally, some form of benefit sharing is strongly supported by the commercial nature of the uses to which the scientific commons is put by industry and university technology transfer offices. What empirical research exists demonstrates that the majority of drugs identified by government health agencies, public interest groups and, importantly, firms themselves as “the most medically and commercially significant” in the years since the second world war were developed using substantial public resources.¹¹⁶ This research further demonstrates that publicly funded research is responsible for the riskiest and most costly research, with firm entry largely after identification of a marketable target. For example, one prominent NIH study revealed that public research was responsible for development of the five best-selling drugs of 1995, each of which had sales in excess of \$1B per year. 85% of the research on the compounds was done at public institutions, and publicly-funded researchers contributed to product development by discovering basic

¹¹⁴ ROBERT K. MERTON, *THE SOCIOLOGY OF SCIENCE* (1973); *see also* BERNARD BARBER, *SCIENCE AND THE SOCIAL ORDER* (1953); THOMAS KUHN, *THE STRUCTURE OF SCIENTIFIC REVOLUTIONS* (1962); WARREN O. HAGSTROM, *THE SCIENTIFIC COMMUNITY* (1965).

¹¹⁵ *See* Section IV.B.

¹¹⁶ NATIONAL INSTITUTES OF HEALTH, *NIH CONTRIBUTIONS TO PHARMACEUTICAL DEVELOPMENT* (Feb. 2000); Iain M. Cockburn & Rebecca Henderson, *Public Private Interaction and the Productivity of Pharmaceutical Research*, (NBER Working Paper #6018, April 1997); Alice Dembner, *Public Handouts Enrich Drug Makers, Scientists*, *BOSTON GLOBE*, April 5, 1998, at A5; James Love, *Comments on Trade and Pharmaceutical Policies: A Perspective from the United States Consumer Movement*, HAI Seminar: World Trade Organization/GATT, *Pharmaceutical Policies and Essential Drugs* October 4, 1996, available at <http://www.cptech.org/pharm/bielefeld.html>; *see also* Jeff Gerth & Sharyl Gay Stolberg, *Medicine Merchants: Birth of a Blockbuster Drug Makers Reap Profits on Tax-Backed Research*, *N.Y. TIMES*, April 23, 2000, at A1; PUBLIC CITIZEN, *RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY’S R&D “SCARE CARD”* (July 2001); DEAN BAKER & NORIKO CHATANI, CENTER FOR ECONOMIC AND POLICY RESEARCH, *PROMOTING GOOD IDEAS ON DRUGS: ARE PATENTS THE BEST WAY? THE RELATIVE EFFICIENCY OF PATENT AND PUBLIC SUPPORT FOR BIO-MEDICAL RESEARCH* (2002).

phenomena and concepts, developing new techniques and assays, and participating in clinical applications of the drugs. Similarly, an MIT study of the 21 most important drugs introduced from 1965 to 1992 demonstrated that public funds were used to discover and develop 14 of the 21 compounds, and an investigation by the *Boston Globe* demonstrated that public research funds were involved in 45 of the 50 best-selling drugs in the United States from 1992 to 1997. Finally, a study by the Center for Study of Responsive Law demonstrated that the United States government funded clinical trials and other research for 34 of the 37 cancer drugs approved for marketing in the United States between 1955 and 1992, and that half of all FDA “priority drugs” approved for marketing between 1987 and 1991 had benefited from a significant federal government role in funding research on the drug. The study also showed that government focuses its research investments on drugs which represent the largest gains in therapeutic value and which treat the most severe illnesses.

While reports of this nature do not, and cannot, make quantitative statements about exactly what fraction of the resulting products were funded by the public purse, they do illustrate clearly that a significant proportion of the funds and risk necessary to underwrite strong firm innovation and product development are derived using public resources. Consequently, there seems little question that publicly funded research remains one of the major, if not the major, sources of risk-intensive innovative products notwithstanding shifting patterns in public and private research funding.¹¹⁷ As the privatization of medical research moves forward, the distinction between public and private contributions will become harder to determine owing to the legal nature of public-private partnerships and the effect thereof on disclosure of confidential financial information. Experience has shown that this will almost certainly benefit for-profit entities far more than the public when it comes time to assess the relative research and development contributions of each partner to actual product development.¹¹⁸

In summary, there is significant evidence to suggest that the scientific commons is eroding and that there is at least the potential for development of an anticommons. In addition, there is significant evidence that these developments place undue (or at least very substantial) health and economic risks on the public. Moreover, the lion’s share of high risk product development looks to be funded by the public rather than in-house firm research and development. As such, a substantial percentage of the costs and risks of erosion appear to be borne by the public while, conversely, the bulk of the economic benefits appear to be realised by private firms and their

¹¹⁷ National Science Board, Science and Engineering Indicators 2006 (Feb. 23, 2006), <http://www.nsf.gov/statistics/seind06/>.

¹¹⁸ U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS (U.S. G.P.O. 1993).

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university partners.¹¹⁹

D. Intellectual Property and Regulatory Rights

In their analysis of the role of patent law in generating and maintaining the current commercialization landscape in the United States, Jaffe and Lerner noted:

In the last two decades, . . . the role of patents in the U.S. innovation system has changed from fuel for the engine to sand in the gears. Two apparently mundane changes in patent law and policy [creation of CAFC and PTO service fee arrangement] have subtly but inexorably transformed the patent system from a shield that innovators could use to protect themselves, to a grenade that firms lob indiscriminately at their competitors, thereby increasing the cost and risk of innovation rather than decreasing it.¹²⁰

Despite this somewhat pithy observation on the costs and risks of the patent system, the authors argue that economic analysis does not support abolishing patent legislation¹²¹ and that a condition of so-called “rational ignorance” will continue dominating PTO practices,¹²² suggesting patents will continue to be issued to broadly conceived subject matter and with broad scope. Indeed, under the prospect theory of patents posited by Kitch, broad patent rights are required for economic efficiency in the patent system, in turn giving rise to incentives regarding the scope of research from the perspectives of both

¹¹⁹ Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227 (2001) (discussing how, in light of the profitability of the pharmaceutical industry and the range of inputs to product development by the NIH and other public agencies, how “It is difficult, therefore, to characterize the industry that is consistently the most profitable in the United States as risky.”).

¹²⁰ ADAM B. JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS 1* (Princeton University Press 2004) (National Bureau of Economic Research Summary available at <http://www.nber.org/books/innovation6/jaffe-lerner8-9-05.pdf>).

¹²¹ *Id.* at 1, 51; *see also* Dosi et al., *supra* note 33 at 1113 (citing FRITZ MACHLUP, *AN ECONOMIC REVIEW OF THE PATENT SYSTEM* (U.S. GPO 1958) (“If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.”)).

¹²² JAFFE & LERNER, *supra* note 7, at 10 (citing Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1501 (2001) (discussing how, in light of the notion that “while the basic theory of patent law posits that a patent’s value lies in the patentee’s enforcement of the right to exclude competitors, or alternatively to compel a license fee,” data demonstrate that only 2% of issued patents are litigated and only 0.2% reach the courtroom)); *see also* Dan Burk & Mark Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1591 & n.46 (2003).

researchers and investors.¹²³ For Kitch, future prospects opened up by patent claims are more efficient under conditions where a single party is in control of the resource than under conditions of rivalry, notwithstanding the potential availability or loss of substitutes.

As for the United States FDA, which has in the past set the tone for food and drugs regulation globally, it asserted in its recent Critical Path report that there is a major problem “translating” basic research into commercial products and that commercial product development has not kept pace with basic science.¹²⁴ The FDA has taken the firm position that “there is currently an urgent need for additional public-private work on applying [biomedical] technologies.”¹²⁵ The need to push translational research has been paralleled in Canada in recent years both through CIHR and Canadian Foundation for Innovation (CFI) funding schemes and Health Canada’s “Blueprint” for its new progressive licensing framework for drug approval.¹²⁶ Large-scale commercialization-based S&T projects such as these confirm that the push for commercialization has expanded from the patent domain well into the regulatory domain.¹²⁷ Together, they suggest a necessary maintenance of broadly constructed patent and licensing rights concomitant with erosion of the intellectual commons in favour of economic benefits from commercialization, notwithstanding potentially increased transaction costs to competitors in the form of royalty payment demands by holders of broad patent rights and an increased risk of being sued by potential rivals.¹²⁸

According to Lunney,¹²⁹ the case law in the United States is generally

¹²³ Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 266 (1977).

¹²⁴ See U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES AND FOOD AND DRUG ADMINISTRATION, CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS 1 (2004), available at <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf> (“[T]here is growing concern that many of the new basic science discoveries made in recent years may not quickly yield more effective, more affordable, and safe medical products for patients. This is because the current medical product development path is becoming increasingly challenging, inefficient, and costly.”).

¹²⁵ *Id.* at 15.

¹²⁶ HEALTH CANADA HEALTH PRODUCTS AND FOOD BRANCH, BLUEPRINT FOR RENEWAL: TRANSFORMING CANADA’S APPROACH TO REGULATING HEALTH PRODUCTS AND FOOD (2006), http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/hpfb-dgpsa/blueprint-plan_e.pdf.

¹²⁷ Eisenberg (2003), *supra* note 1.

¹²⁸ See JAFFE & LERNER, *supra* note 7, at 29 (describing “waste and uncertainty that hinder and threaten the innovative process.”); Bouchard 2007b, *supra* note 15 (discussing Supreme Court of Canada case law to the effect that enhanced litigation over an lowered bar for obviousness creates an “undue commercial risk zone” for the public in the context of pharmaceutical patents).

¹²⁹ See generally Glynn Lunney, *E-Obviousness*, 7 MICH. TELECOMM. & TECH. L. R. 363

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favourable to Kitch's view that broad intellectual property rights are required for wealth maximization in the commercialization arena. As noted above, following on earlier decisions by the United States PTO to allow patents on naturally occurring subject matter that had been "purified and isolated,"¹³⁰ federal courts have applied *Chakrabarty* over the years to gradually whittle away resistance to broad patent rights, particularly those associated with subject matter. For example, it has been claimed that the Federal Circuit has extended the Supreme Court's expansive approach to patent scope while relaxing threshold requirements for both utility and nonobviousness.¹³¹ Indeed, despite apprehension by patent scholars and anxious bloggers over the implications of the United States Supreme Court's decision in *KSR International v. Teleflex, Inc.*¹³² over changes to the requirements for patentability, little has happened over the last few years to change this situation. It has been suggested that this practice has now been institutionalized by the United States PTO in part due to "laxity" and the conflict of interest of PTO review resulting from its relatively recent fee-for-service structure.¹³³ Similar criticisms have been levelled at the FDA and TPD for implementing user fees in the context of product licensure.¹³⁴ The result of these changes is that the likelihood of court challenges on issues of subject matter, obviousness or utility is reduced.¹³⁵ The result is encouragement of "imaginative claiming strategies" and unprecedented levels of patenting.¹³⁶ Given the potential global reach of the United States PTO practices and related jurisprudence, it would appear that, at least for the moment, broad patent scope rights attaching to biomedical inventions, and thus an emphasis on wealth maximization in the biomedical industry, are here to stay.

Broad intellectual property rights have become entrenched in economic analyses of innovation despite the theoretical and empirical limitations of

(2001); For an example of corresponding Canadian case law, see *Monsanto Canada Inc. v. Schmeiser*, [2004] S.C.R. 902.

¹³⁰ See *Parke-Davis & Co. v. HK Mulford & Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911); see also *Merck & Co. v. Olin Mathieson Chem. Corp.* 253 F.2d 156 (4th Cir. 1958).

¹³¹ Rai & Eisenberg, *supra* note 103, at 290 (discussing requirements for utility); Lunney, *supra* note 129; Bouchard 2007a and 2007b, *supra* note 15 (discussing requirements for obviousness in the telecom and biomedical sciences, respectively).

¹³² *KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727 (decided April 30, 2007).

¹³³ See JAFFE AND LERNER, *supra* note 7, at 29-31 (describing the weakening of the patent system in the wake of the creation of the Federal Circuit and the change to the USPTO as a fiscally independent unit).

¹³⁴ Lemmens & Bouchard 2007a, *supra* note 75, at 318, 327-328 (discussing implementation of user fees by the FDA and TPD and resulting reduction in drug approval times and concerns expressed over potential regulatory or mission creep.).

¹³⁵ See Rebecca S. Eisenberg, *Biotech Patents: Looking Backward While Moving Forward*, 24 NATURE BIOTECHNOLOGY 317, 318 (2006).

¹³⁶ Rai & Eisenberg, *supra* note 103, at 290.

market failure theory¹³⁷ and the criticism that broad intellectual property rights have the potential to slow innovation in sectors such as biomedical research where discoveries are typically incremental rather than breakthrough in nature.¹³⁸ The main vector of this entrenchment appears to be the United States court system and PTO. Indeed, Jasanoff has asserted that “[w]ith the United States leading the world in many areas of genetic science and technology, the United States courts, as leaders in the nation’s legal policy development, have gained a potentially global policymaking status.”¹³⁹ As noted earlier, this should also include the United States PTO, which generally has followed *Chakrabarty* in issuing broadly conceived patents, out of “rational ignorance” or otherwise. The crux of this claim is that the court is in a sense the court of first global instance and, rather than legislatures, has the primary burden of grappling with the legal and ethical issues arising out of patented biomedical technologies. According to this view it was only after the courts grappled with these issues, particularly those arising out of molecular biology and genetic engineering, that state and federal legislatures began to undertake policy analysis of the issues involved. In this fashion, the courts’ broad interpretation of patent scope along with the stimulation of the race to the PTO by universities and research institutes through Bayh-Dole has led to a system where wealth maximization by university technology transfer offices, spin outs and private firms has become routine.

In addition to a broad scope of patent rights, courts have provided support for expansive patent licensing. Indeed, Congress was careful to ensure that Bayh-Dole allowed for exclusive licenses and that universities had the discretion to grant them. The United States Department of Justice has recently clarified its position on intellectual property licensing, stating that broad licensing strategies are “pro-competitive,” a position supported by relevant policy¹⁴⁰ and the long-standing recognition by the United States Supreme Court that the right to license is at the “core of the patent right.” Moreover, there appears little reason to think that preferential treatment will be accorded to biomedical patents in order to rectify inefficiencies in the patent system or that even if this were to occur that it would be a good thing.¹⁴¹ The current practice in most developed nations is that all potential patentees get the same

¹³⁷ See generally Bozeman & Sarewitz, *supra* note 3, Dosi et al., *supra* note 33.

¹³⁸ See Robert P. Merges & Richard R. Nelson, *On Limiting or Encouraging Rivalry in Technological Progress: The Effect of Patent Scope Decisions*, 25 J. ECON. BEHAV. ORG. 1 (1994); Bouchard 2007b, *supra* note 15.

¹³⁹ Jasanoff, *supra* note 82, at 893.

¹⁴⁰ U.S. DEPARTMENT OF JUSTICE & FEDERAL TRADE COMMISSION, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (1995), available at <http://www.usdoj.gov/atr/public/guidelines/ipguide.pdf>.

¹⁴¹ See JAFFE & LERNER, *supra* note 7, at 61 (“[T]here is a grave danger in trying to ‘fix’ the problems perceived to be associated with patents in particular areas by fooling with specific differential patent treatment for these technologies.”).

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treatment, with the caveat that patents are to some degree “technology specific”¹⁴² in part due to contextual expertise of persons having skill in the art.¹⁴³ Following ratification of TRIPS in most jurisdictions, market reform is more likely to occur in the regulatory regime, but not in the direction advocated by proponents of benefit sharing. A good example of this scenario is the successful lobbying by the pharmaceutical industry to abolish compulsory licensing in Canada and create linkage regulations in the United States (Hatch Waxman Act)¹⁴⁴ and Canada (Patented Medicines (Notice of Compliance) Regulations).¹⁴⁵ These programs provide the industry with strong patent and regulatory rights that did not exist prior to the relevant legislation coming into force¹⁴⁶. Abuses of patent and regulatory laws of this nature in both jurisdictions have been well documented,¹⁴⁷ and have undoubtedly given rise to considerable economic costs to both the public and government in terms of prolonging market exclusivity and monopoly pricing well after patents on the original new chemical entity have expired.¹⁴⁸

The importance of enabling provisions of large legal-regulatory regimes governing commercialization to the market success of for-profit entities cannot be understated. Teece¹⁴⁹ argued that profits from innovation depend critically

¹⁴² Dan L. Burk & Mark A. Lemley, *Biotechnology’s Uncertainty Principle*, 54 CASE WEST. RES. L. REV. 691 (2004).

¹⁴³ Bouchard 2007a and Bouchard 2007b, *supra* note 15.

¹⁴⁴ Drug Price Competition and Patent Restoration Act of 1984, 21 USC § 355 (2000) (commonly known as the Hatch-Waxman Act).

¹⁴⁵ Patented Medicines (Notice of Compliance) Regulations SOR/93-133 (Can).

¹⁴⁶ Prior to the NOC Regulations coming into force in 1993, the regulatory systems for drug approval and patenting in Canada were distinct and separate. *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 S.C.C. 49, 30985 [2006] S.C.J. No. 49 QUICKLAW (Nov. 3, 2006) at para. 12. In *AstraZeneca*, the Supreme Court of Canada noted (at para. 39) that it “is entirely understandable” that brand-name pharmaceutical firms avail themselves of NOC Regulations allowing evergreening by “adding bells and whistles to a pioneering product” after the original patent has expired.

¹⁴⁷ See Caffrey & Rotter, *supra* note 27, at 7 (discussing “questionable conduct relating to provisions of the Hatch-Waxman Act.”); Hore, *supra* note 26 (discussing evergreening in the context of the NOC Regulations); JAFFE & LERNER, *supra* note 7, at 61 (discussing a kind of “shenanigans” associated with attempts to get extended patent protection for patented drugs); Baker & Chatani *supra* note 105 (discussing dead weight losses and monopoly pricing relative to other subsidized industries); Bouchard 2007b, *supra* note 15 (discussing the effects of linkage regulations on innovation in the pharmaceutical and biotechnology industries).

¹⁴⁸ See Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 255-257 (2001) (discussing how operation of the linkage regime governing pharmaceutical products in the United States has been estimated to extend effective patent protection for biomedical inventions up 50% past the original patent term).

¹⁴⁹ See generally David J. Teece, *Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing and Public Policy*, 15 RES. POL’Y 285 (1986).

on the provisions of the existing appropriability regime available to support it. Appropriability apparently displays a threshold effect in that a minimum degree of intellectual property and regulatory rights are required to support innovation, following which further strengthening of rights does not stimulate further innovation.¹⁵⁰ The fact that there might be a non-linear relationship between the scope of intellectual property and regulatory rights and the scope of innovative research appears to be lost on many advocates of broad patent rights who often seem to assume that “more rights will equal more innovation.”

A more realistic scenario has been painted by Dosi et al.¹⁵¹, who posit that “social inefficiencies” develop when rights are added to the governing appropriability regime that exceed the threshold for stimulation of efficient innovation. These inefficiencies include increased rent seeking behaviours, dissipation of rents into litigation and reduced emphasis on truly innovative activity in favour of “me too” products and line extensions. The result is increased transaction costs through practices such as defensive patenting, increased emphasis on lobbying and regulatory capture efforts, and increased imitation costs. To this one might add a further increase in flow-through product costs as a result of patenting strategies owing to the fact that biomedical products represent a “complex” product industry compared to a “discrete” one (multiple patents per product)¹⁵² and an increased firm focus on marketing and government lobbying over research and development, concealed or distorted research findings, conflicts of interests in the FDA approval and NIH funding processes, undue influence over physician prescribing habits via pharmaceutical representatives, skewing the direction of research funding towards patentable findings and an increased emphasis on “me too” drugs and line extensions.¹⁵³ Finally, other inefficiencies may develop in jurisdictions such as the United States and Canada owing to operation of linkage regulations that allow evergreening of older patented products that would have otherwise come off patent protection. This would include enhanced litigation costs and increased deadweight loss due to undue prolongation of monopoly pricing.

E. Property Rights in Tissue Samples and Clinical Trial Data

In addition to fiscal, ethical and other forms of indirect support for biomedical research discussed above, the public also participates *directly* in the

¹⁵⁰ See Dosi et al., *supra* note 33.

¹⁵¹ *Id.* at 1111 (“appropriability is likely to display a threshold effect, meaning that a minimum degree of appropriability is necessary to motivate innovative effort, but above such a threshold further strengthening of appropriability conditions will not determine further increases of R&D investments and rates of innovation. Rather, social inefficiencies such as ‘anti-commons’ effects. . . , rent seeking behaviours, dissipation of quasi-rents into litigation etc. are much more likely to emerge.”).

¹⁵² *Id.* at 1115 (discussing the difference between complex and discrete products).

¹⁵³ Baker, *supra* note 59.

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production of scientific knowledge and the translation of this knowledge into clinical products and therapies.¹⁵⁴ Direct contributions include participation in Phase 1, Phase 2, and Phase 3 clinical trials, whether publicly disclosed or not, organ donation, and provision of tissue samples, including stem cells, bone marrow cells, blood, etc. used inter alia for genomic, proteomic and other “omic” studies. Together, these resources are used to inform therapeutic product development decisions made by firms and university researchers. In each case, individuals assume substantial risks to their health and well-being, including risks of permanent disablement or death, and legally consent to the use of their bodies or body parts by researchers or firms through the process of informed consent. In almost all, if not all, cases, the motives behind such choices are to advance human health for the common good.¹⁵⁵ This raises the question of whether the public is being equitably compensated for its efforts and risks, and the related question of whether the nature of informed consent has evolved along with the commercialization regime.

The first issue to be dealt with is what legal rights individuals have in data or tissues derived from their participation in publicly funded research. This is a legitimate question, as it is exactly data and tissue samples of this nature that are leveraged by university researchers and firms into shareholder profit. The answer to this question is, at least in the United States where the courts have grappled directly with the issue, none.¹⁵⁶ Indeed, Bovernberg has claimed there is a “double standard” governing the global commercialization of biomedical products:¹⁵⁷ that is, the members of the public provide valuable tissues and clinical trial data under conditions of risk to human health but then have no general legal rights in the resulting data, tissues or marketed products. This so-called double standard arises due to operation of relevant intellectual property laws which permit universities, their researchers and firms to commercialize contributions by the public yet deny the public the right to

¹⁵⁴ Translational research has been the topic of considerable funding interest from the federal government for years. For example, the Canadian Foundation for Innovation (“CFI”) issued RFPs for two major funding initiatives in the fall of 2005. In order to succeed in their applications, applicants were suggested to focus heavily on the twin pillars of translation of basic to applied research and commercialization of this research.

¹⁵⁵ Berg *supra* note 48; *see also* HUGO Statement on Benefit-Sharing, *supra* note 49; *see also* the statements by ICMJE and the WHO in the context of mandatory clinical trial registration. *See* Lemmens & Bouchard 2007b, *supra* note 96 and references in *supra* note 37 relating to mandatory clinical trial registration.

¹⁵⁶ It could be claimed that this is only true *ex post* in that individual participants and donors do own their tissues and may *ex ante* condition their participation in trials or donor scenarios based on the principle of equitable benefit sharing. This however is an untenable argument, which completely ignores both the power balance involved in informed consent (both from the perspective of patient-doctor and patient-industry sponsor) and the critical emotional state of participants in the context of participating in potentially life-saving therapies.

¹⁵⁷ Bovernberg, *supra* note 60, at 929 (discussing double standard).

compensation and, increasingly, reasonable access to affordable products.

In *Moore v. The Regents of the University of California*,¹⁵⁸ John Moore donated cells to a medical researcher who then used them to establish a cell line subsequently used for research and commercial development. Moore sued, asserting he should have a right to the products of his own body.¹⁵⁹ The California Supreme Court denied Moore a property right in his own tissues, thus preventing him from pursuing a claim for a share in profits made from his cells. The court denied Moore legal right (1) to his own genetic material (the DNA blueprint for his tissues) based on the fact that all humans share the genetic materials of the proteins involved, and (2) to the patented cell line because it was distinct (patentably novel) from Moore's ironically named "starter" cells. The court went further, stating that it did not want to impose a duty on researchers to obtain or investigate the pedigree of the cells used in their research, and finally that Moore's case for a property right was better off left to the legislature. However, as duly noted by Jasanoff,¹⁶⁰ the Federal Circuit and the United States Supreme Court have taken on these exact types of broad social issues when they felt it was necessary.

The United States District Court decision in *Greenberg v. Miami Children's Hospital Research Institute*¹⁶¹ upheld *Moore* in a much more broadly applicable legal precedent. Here, children, adults and non-profit institutions donated tissues for research into Canavan disease.¹⁶² As in *Moore*, the District Court held that the donors had no property interests in their own genetic information or tissues. However, given that patient support groups and researchers had invested significant time and money in their efforts to find a cure, grounds for unjust enrichment were found even though no guarantee of success could be had.¹⁶³

More recently, the United States Court of Appeals upheld the District Court of Missouri in *Washington v. Catalona*,¹⁶⁴ a case involving ownership of tissue samples provided by participants to university researchers. The court of appeals held the district court did not err in finding that Washington University was the proper owner of the biological samples provided to Dr. Catalona for

¹⁵⁸ *Moore v. The Regents of the University of California*, 793 P.2d 479, 490 (Cal. 1990).

¹⁵⁹ *Id.* at 480-483.

¹⁶⁰ Jasanoff, *supra* note 8, at 894.

¹⁶¹ *Greenberg v. Miami Children's Hospital Research Institute*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

¹⁶² A neurodegenerative disease of infancy in which the lack of the enzyme aspartoacylase results in the buildup of N-acetyl aspartate, leading to demyelination in the CNS, as well as increased brain volume and weight and spongy degeneration in the subcortical white matter of the brain (in which the white matter is replaced by microscopic fluid-filled spaces). Most children with Canavan disease die in the first decade of life. There is currently no cure or effective treatment for Canavan disease.

¹⁶³ See *Greenberg*, 264 F. Supp. 2d at 1072.

¹⁶⁴ *Washington University v. Catalona*, 437 F. Supp. 2d 985, 1002 (E.D. Mo. 2006), *aff'd*; No. 06-2286, slip op. (8th Cir. June 20, 2007) .

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research purposes when he was in the employ of that institution. The court further upheld the lower court to the effect that neither Dr. Catalona nor the donors had any ownership interest in the samples. The court also noted that the donors made informed and voluntary decisions to participate in genetic cancer research and donated their biological materials to the school as a valid *inter vivos* gift.

Moore, *Greenberg* and *Catalona* have been denounced based variously on principles of fairness, equity, and distributive justice. Together, along with several recent pharmaceutical controversies over the safety and efficacy of marketed drug products, these decisions have led to considerable mistrust of both private firms and the medical research enterprise generally.¹⁶⁵ The cases stand for the proposition that neither individuals nor patient groups have any property rights in tissues or other samples donated for medical research that subsequently get converted into commercial products. The unjust enrichment finding in *Greenberg* is unlikely to be widely applicable, as the patients and advocacy groups were heavily involved themselves in actually generating research data, going so far as to be significantly involved in the research and being named patentees on subsequent inventions. The same is also true of participants in clinical trials, as data from trials conducted by industry are generally owned by the sponsoring firms.

The common denominator in each of the cases noted above is that members of the public donating consensual use of their bodies for purposes of clinical science have no legal right in either their donated tissue or data obtained from the subsequent use of their bodies or body parts. The result is publicly funded commercial products and databases to which the public does not have free access and biomedical products for which the public must pay monopoly prices even when, as evidenced by the cases above, “but for” their participation there would be no product.

One example, albeit an extreme one, of this double standard is the fallout resulting from development of the anti-cancer drug Taxol, made from the Pacific Yew tree.¹⁶⁶ The public record is clear that the vast majority of the basic and clinical research was conducted at, and funded by, the NIH, including collection of the bark, all biological screening in cell cultures and animal-tumor systems, chemical purification, isolation and identification,

¹⁶⁵ See Lemmens & Bouchard 2007a, *supra* note 8; Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES MAG., Apr. 16, 2006, at 38; Bovenberg, *supra* note 60, at 930; GRAEME LAURIE, GENETIC PRIVACY: A CHALLENGE TO MEDICO-LEGAL NORMS (2002); Nelson, *supra* note 55; Argyres & Leibeskind, *supra* note 65, at 435–36; Lemmens, *supra* note 29; Kai-Lit Phua, *The Human Genome Project and Genetic Research: What Are The Implications for Ethics and Equity?*, 14 CRITICAL PUB. HEALTH 191 (2004); Rahul K. Dhandu, *Bioethics in Biotechnology: From Pain to Gain*, 63 DRUG DEV. RES. 93 (2005); Johns, Barnes, & Florencio, *supra* note 40.

¹⁶⁶ The author was counsel to the Canadian Generic Pharmaceutical Association in the Supreme Court of Canada’s leading decision on taxol: *Bristol-Meyers Squibb Co. v. Canada* [2005] 1 S.C.R. 533.

large-scale production, preclinical toxicology, filing of an Investigative New Drug Application with the FDA, along with all required documentation, and sponsorship of all clinical trials. Yet the government at the time¹⁶⁷ gave BMS exclusive rights to all clinical trial data and an exclusive license to commercialize the product. Given the one-sidedness of the Taxol example, it is not surprising that the pharmaceutical industry has been the target of much criticism in the context of recouping taxpayer return on investment. In one of the more self-explanatory examples of criticisms relating to the taxol case, Nader and Love noted:¹⁶⁸

The Federal Government will not get any royalties on Bristol-Myers Squibb's sales of Taxol. We get only the company's "best efforts" to commercialize Taxol.

Such a deal! The taxpayers pay for the invention of a promising treatment for cancer and then give a marketing monopoly to one company, complete with a free or nearly free supply of the primary ingredient. And the company's role is to agree to sell it back to us.

Based on the discussion thus far, it can be plausibly claimed that the ethical grounds on which voluntary participation and informed consent proceed have evolved along with privatization of medical research. Given the serious nature of the risks borne by the public in clinical trial participation and tissue and organ donation, one might further argue that for-profit entities have accrued a duty to compensate the public equitably for their efforts and risks, and that the public has a particularized expectation of an equitable share in the benefits of research embedded within the informed consent process.¹⁶⁹ Consequently, the ethics and altruism traditionally associated with medical research may indeed have evolved along side the privatization of medical research, and some form of benefit sharing can be legitimately contemplated as part of the informed consent process.

F. Access to Affordable Medical Products

The issue of reasonable access to affordable biomedical products and therapies is directly tied to the various inputs, risks and costs born by the public for these products and services. Indeed, public expenditures on pharmaceuticals and biotechnological products have risen considerably over the last several decades and represent a large portion of healthcare expenditures in Canada and the United States. In the United States, biomedical products, in particular prescription drugs, are used extensively and frequently by all segments of society. A recent survey¹⁷⁰ showed that just under 50% of

¹⁶⁷ The first Bush administration.

¹⁶⁸ Ralph Nader & James Love, *Looting the Medical Chest: How Bristol-Meyers Squibb Made Off with the Public's Cancer Research*, THE PROGRESSIVE, Feb. 1993, at 26.

¹⁶⁹ Simm, *supra* note 53.

¹⁷⁰ Greg Crister, *One Nation, Under Pills*, L.A. TIMES, Dec. 15, 2002, at M6.

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Americans use at least one prescription drug *daily* and carry, on average, eleven different prescriptions per year. In FY 2001 alone, Americans held 3.1 billion prescriptions worth an estimated \$132B. The projected costs of prescription drugs (not including biotechnological products, other patented OTC drugs or generic prescription and OTC drugs) is estimated to be approximately \$415B in FY 2014.¹⁷¹ In FY 2002, the profit rate for American pharmaceutical firms was 18.5% compared with a median rate for all Fortune 500 firms of 4.5%.¹⁷² The combined profits for ten pharmaceutical firms in the Fortune 500 index amounted to \$36B compared to that of the remaining 490 firms combined (\$34B).¹⁷³

In FY 2005, brand pharmaceuticals accounted for \$230B of sales and generics for \$22B, for a total of \$252B.¹⁷⁴ In FY 2004 the average price of a brand version of a drug was \$95.54 whereas the generic version was \$28.71.¹⁷⁵ Generics accounted for 56% of all prescriptions dispensed in FY 2005, yet only 13% of every dollar spent on prescriptions. The extent of potential drug savings to Americans in relation to generic medications over the next three years will depend strongly on the outcome of litigation under the Hatch-Waxman Act, which governs entry of generic pharmaceuticals in the United States. At stake are blockbuster drugs coming off patent during these years, valued at \$22B, \$27B and \$29B in FYs 2006, 2007, and 2008, respectively.¹⁷⁶

Similar data exist for Canada, where the fastest rising component of total healthcare spending is represented by prescription drugs. Total drug expenditures were \$4B, \$10B and \$18B in FYs 1985, 1995 and 2002, with an average annual growth rate of 9.7%. Per capital drug expenditures were \$150, \$350 and \$600 for the same FYs, with an annual growth rate of 8.5%. As noted by the Canadian Institute for Health Information, drugs represent one of the fastest growing costs of the Canadian health care system, with an average growth rate of 9.7% from FY 1985 to FY 2002 compared with 6.4% for the country's total health spending.¹⁷⁷ According to Statistics Canada, drug

¹⁷¹ GREG CRISTER, *GENERATION RX: HOW PRESCRIPTION DRUGS ARE ALTERING AMERICAN LIVES, MINDS AND BODIES 2* (Houghton Mifflin 2005).

¹⁷² Public Citizen, *supra* note 43; *The Fortune 500*, *infra* note 205; *see also* PUBLIC CITIZEN, 2002 DRUG INDUSTRY PROFITS: HEFTY PHARMACEUTICAL COMPANY MARGINS DWARF OTHER INDUSTRIES (2003), *available at* http://www.citizen.org/documents/Pharma_Report.pdf.

¹⁷³ Angell, *supra* note 25, at 11 (citing data from Fortune 500 lists in *Fortune* (April 7, 2003; April 5, 2004) and annual reports of pharmaceutical firms.).

¹⁷⁴ IMS HEALTH, 2005 ANNUAL REPORT (2006).

¹⁷⁵ NATIONAL ASSOCIATION OF CHAIN DRUG STORES REPORT (October 2005).

¹⁷⁶ Generic Pharmaceutical Association, <http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/Statistics.htm> (last visited Aug. 1, 2007) (citing Bain & Company Report).

¹⁷⁷ CANADIAN INSTITUTES OF HEALTH INFORMATION, DRUG EXPENDITURE IN CANADA 1985 TO 2005 (CIHI 2007), *available at* http://www.cihi.ca/cihiweb/dispPage.jsp?cw_page=AR_80_E [hereinafter DRUG

expenditures were \$14.6B in FY 2003, an increase of 11.5% and 14.5% over FYs 2002 and 2000 values, respectively. Total drug expenditures were \$16B between June 2004 and June 2005 for a total of 378 million prescriptions.¹⁷⁸ Expenditures on pharmaceutical products alone represented 16% of total healthcare expenditures in Canada and are increasing faster than all other expenses within the healthcare umbrella. According to OECD data,¹⁷⁹ per capita drug expenditures grew from 9.5% to 16.4% of total health expenditures in Canada during FYs 1985 and 2003. By 2003, Canada ranked third in the world in per capita drug expenditures, behind only the United States and France.¹⁸⁰

Generic pharmaceutical sales accounted for 16.8% of the total Canadian market, totalling nearly \$2.7B of drugstore and hospital sales. The average cost per prescription for brand drugs was \$60 and \$43 per prescription in FYs 1998 and 2004 whereas that for comparable generics was \$19.48 and 22.33 for the same years. The average cost for a brand version of a drug increased by about 35% over the last 5 years, while that for generic versions rose 16%. The generic share of retail prescriptions in FY 2004 was 42.7%, or 161 of a total of 216 million prescriptions. Growth of generic prescriptions was 13.3% compared to the previous 12-month period. While generic drugs fill about 40% of all prescriptions in Canada, they account for approximately 16% of the \$16B Canadians spend annually on prescription drugs in FY 2004.

As illustrated by the above data, competition between brand and generic pharmaceutical firms is and will continue to be intense in the upcoming years. A recent 2001 report by Datamonitor estimated that a certain basket of drugs with combined global revenues of \$100B in FY 1999 would lose patent protection by FY 2005 and that 75% of these products would be subject to intense generic competition.¹⁸¹ As intense litigation under legislation governing brand-generic competition in the United States and Canada would suggest, these values appear to be at least reasonably in the right ballpark. This competition is not, however, limited to the conventional pharmaceutical industry. It has recently been estimated that biotechnology products with

EXPENDITURE IN CANADA 1985 TO 2005].

¹⁷⁸ INDUSTRY CANADA, LIFE SCIENCES BRANCH, CANADIAN PHARMACEUTICAL INDUSTRY PROFILE (2003), available at [http://strategis.ic.gc.ca/epic/internet/inlsg-pdsv.nsf/vwapj/pharmaprofile.pdf/\\$FILE/pharmaprofile.pdf](http://strategis.ic.gc.ca/epic/internet/inlsg-pdsv.nsf/vwapj/pharmaprofile.pdf/$FILE/pharmaprofile.pdf); DRUG EXPENDITURE IN CANADA 1985 TO 2005, *supra* note 177; IMS HEALTH, COMPUSCRIPT DATA 2004: CANADIAN DRUG STORES AND HOSPITALS PURCHASE AUDIT (2004); GOVERNMENT OF CANADA PATENTED MEDICINES PRICES REVIEW BOARD, PMPRB 2004 ANNUAL REPORT (2005), available at <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=436>.

¹⁷⁹ ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, OECD HEALTH DATA 2004 REPORT (2004).

¹⁸⁰ DRUG EXPENDITURE IN CANADA 1985 TO 2005, *supra* note 177.

¹⁸¹ DATAMONITOR, THE GENERICS INDUSTRY IN 2005: A NEW THREAT TO PHARMA (July 2001).

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approximately \$10B in sales will come off patent in FYs 2004-2009.¹⁸² As both state and federal dockets in the United States have clearly shown, strong players in the biotechnology industry are as litigious as their brand pharmaceutical siblings.¹⁸³ Thus, the issue of genericization of patented biomedical inventions is set to mushroom considerably in the upcoming years for biotechnology players as well as pharmaceutical players.

An important caveat regarding the figures presented above is that data on revenues and expenditures relating to biomedical products from truly independent sources are few and far between and difficult to locate. Ultimately, one would need data for expenditures by government and individuals as well as industry sales and revenue data for brand and generic pharmaceuticals broken down into prescription and OTC use, as well as similar data relating to biotechnology products, therapies and screening tools. Nevertheless, based on the data above combined with those presented in SECTION III.A. *supra*, it is reasonable to speculate that the total market for all categories of biomedical products would amount to somewhere in the neighbourhood of \$300B in the United States and \$100B in Canada for FY 2005 alone. These are not insubstantial figures, particularly given the pharmaceutical and biotechnology industries were nascent only a hundred years ago.

This data provides evidence that prescription drugs have become a fact of life in North America. It further demonstrates that the public, employers and governments spend enormous sums of money on biomedical products via out-of-pocket expenditures, insurance reimbursement plans and subsidized drug formularies. Given that the same data sources demonstrate that drug and related health expenditures are predicted to grow at the same or higher rate as over the last decade, it is relevant to ask whether the public have reasonable access to the products of publicly funded medical research. The question has particular resonance in light of profits made by universities and their industrial partners and the scope of public inputs to product development.

The answer to the question posed above appears to be, again, no. As noted by Reich,¹⁸⁴ there is a global drug gap of one third of the world's population, or equal to about two billion people. While it is true that the hardest hit are those in developing countries, there is ample evidence that there is a substantial number of people in jurisdictions with high GDP per capita ratios such as United States and Canada who do not have access to affordable medication.¹⁸⁵

¹⁸² Carole S. Ben-Maimon & Rob Garnick, *Biogenerics at the Crossroads*, 24 NATURE BIOTECHNOLOGY 268, 268-69 (2006).

¹⁸³ A review of Lexis and QL databases (March 14th, 2006) indicated that there were 116 decisions released by US federal (108) and state (8) courts in relation to just two biotechnology companies (Amgen and Biogen). This ignores ongoing and pending litigation in which no decisions have yet been released.

¹⁸⁴ Reich, *supra* note 46.

¹⁸⁵ Bozemand & Sarewitz, *supra* note 3, at 1-2 and references therein.

For example, data from the 2006 United States Census Bureau¹⁸⁶ demonstrate that approximately 40% and 60% of adults with and without insurance go without at least one drug per year because of price considerations. The data also show that of the population surveyed 46M (16%) had no health insurance at all.¹⁸⁷ A similar situation exists in Canada, where the Canada Health Act¹⁸⁸ does not generally cover prescription medication, and there is a well documented link between household income and poor health outcomes.¹⁸⁹

As implicated above, problems relating to access in developed nations have been brought about, in part, by the intellectual property-regulatory regime governing the acquisition and enforcement of rights pertaining to commercialized biomedical products. Economic costs of the regime that are ultimately borne not only by the costs incurred by institutions and firms relating to patenting and licensing, but also those associated with litigation under patent legislation and linkage regulations such as Hatch Waxman and the NOC Regulations,¹⁹⁰ which operate to keep cheaper generic alternatives off market for a substantial length of time.¹⁹¹ The result is maintained monopoly prices and reduced access to affordable drugs, even in relatively prosperous nations. This scenario has led (given Canada's public health care system, ironically in the United States but not in Canada) to a series of public hearings on undue profitability in light of the publicly funded nature of the product development cycle,¹⁹² and legislation¹⁹³ amending linkage regulations to facilitate access to affordable medications to those in need.

G. Prosperity Resulting from Commercialization

The issue of access to affordable medical treatment is intimately connected with that of household income and GDP per capita as indices of consumer

¹⁸⁶ Defined as \$36,800 or below for a family of four.

¹⁸⁷ U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2005 (2006).

¹⁸⁸ R.S.C. 1985, ch. C-6 (2002).

¹⁸⁹ CANADIAN COUNCIL ON SOCIAL DEVELOPMENT, EQUALITY, INCLUSION AND THE HEALTH OF CANADIANS SUBMISSION TO THE COMMISSION ON THE FUTURE OF HEALTH CARE IN CANADA 6-10 (November 15, 2001).

¹⁹⁰ Caffery & Rotter, *supra* note 26; Eisenberg (2003), *supra* note 1; Rebecca S. Eisenberg, *The Shifting Functional Balance of Patents and Drug Regulation*, 20 HEALTH AFFAIRS 119, 121-24 (2001) [hereinafter Eisenberg (2001)].

¹⁹¹ Glasgow, *supra* note 148; Bouchard 2007a and 2007b, *supra* note 15.

¹⁹² Argyres & Leibeskind, *supra* note 65, at 435, 440; FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>; Caffrey & Rotter, *supra* note 26.

¹⁹³ S. 54, 108th Cong. (2003) (known as the Schumer-McCain Bill of 2002); S. 1225, 108th Cong. (2003) (known as the Gregg-Schumer Amendment of 2003). Senators Stabenow and Lott proposed the *Lower Priced Drugs Act*, introduced Feb. 15, 2006 in the Senate. S. 2300, 109th Cong. (2006).

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purchasing power.¹⁹⁴ The fiscal nature of the input-output relationship is underscored given that one of the largest and growing “benefits” of privatized medical research is the profitability of the endeavour for universities and their industrial partners. Over the past century, numerous economic and policy analyses have been undertaken with the goal of supporting a role for publicly-funded research and S&T policy in creating national economic benefits. In OECD countries, it is federal governments who have historically provided the largest contribution of funding for total biomedical research and development activities based on S&T policies in which technology transfer and commercialization play a central role.

Keith Pavitt has argued that economic justification for innovation-based S&T policies is grounded in the assumption that the useful output of basic research is codified information, which has the property of being a public good.¹⁹⁵ Conversion of this public good into patentable private goods is dependent on intellectual property rights, thus highlighting the importance to innovation policy and economic analyses of the prevalent intellectual property-regulatory regime.¹⁹⁶ As noted at the end of the discussion on intellectual property rights in Section III.D, *supra*, the importance of large domestic and international intellectual-regulatory regimes in developing innovation-based S&T policies and programs cannot be underestimated, as they determine the costs, efficiencies, inefficiencies and risks of commercialization for for-profit and public actors alike. While there is some disenchantment with the market failure models of S&T policy assessment,¹⁹⁷ it is nevertheless the accepted dogma for analyzing the successes and failures of the existing regime. Indeed the literature is replete with authoritative declarations of the public good supposedly flowing from innovation, including improved health due to creation of new products, creation of new firms, increases in employment in regional economies and making “people see and smile”¹⁹⁸ that are lacking in strong empirical supporting evidence.

Nevertheless, Pavitt argued that national economic spillovers from publicly funded research (let alone expenditures that are health-related *per se*) have been very difficult to identify let alone carefully measure. Under his gaze,

¹⁹⁴ Bozeman & Sarewitz, *supra* note 3, at 2 (“The most resilient justification for publicly funded science has been job creation and increased standards of living Yet GDP (gross domestic product) *per capita* is the coarsest possible proxy for quality of life; indeed the affluent-world experience of the past 30 shows that science- and technology-based economic growth is accompanied by increasing inequality in distribution of economic benefits, including increasing unemployment or underemployment, decreasing real wages, increasing wage inequality, and increasing wealth concentration within nations and between nations . . .”).

¹⁹⁵ Pavitt, *supra* note 57, at 12694.

¹⁹⁶ Dosi et al., *supra* note 33, at 1112.

¹⁹⁷ See generally Bozeman & Sarewitz, *supra* note 3; Dosi et al., *supra* note 33.

¹⁹⁸ Michael J. Remington, *The Bayh-Dole Act at Twenty-Five Years: Looking Back, Taking Stock, Acting for the Future*, 17 J. ASS'N U. TECH. MANAGERS 15, 17 (2005).

countries with the best records and strongest policies underpinning the importance of basic research (e.g., the United States and United Kingdom) have historically performed much less well economically and technologically than competitors conducting less basic research (e.g., Japan and Germany). Moreover, the economic benefits from basic research that can be identified are poorly distributed across sectors, even amongst research and development-heavy sectors. Implicit in this conclusion is another: when research does make the successful transition from bench to bedside, the resulting economic gains are closely held within firms and sectors and thus not widely disseminated. Mazzoleni and Nelson have sounded a similar note of caution relating to the scope of empirical data supporting national S&T policies aimed at commercialization:

The range of arguments about the positive social value of patents is obviously much wider than the area of strong empirical studies explored to date. An analyst, citing earlier studies that appear to show limited value, obviously is vulnerable to the argument that those studies do not provide evidence on some of the possibly most important functions patents serve.

We cannot present here an empirically supported and intellectually persuasive argument on this broad question. The important empirical research that needs to be done in order to map out the basic facts simply has not been done yet¹⁹⁹

Thus, while it is not possible to say with any authority that a S&T policy emphasis on technology transfer and commercialization does not lead to direct benefits to the public that can be realized within a public health context, it does seem reasonable to conclude that there is as yet an absence of clear and convincing empirical evidence for the opposite proposition.

In the absence of strong supporting data, world and domestic economic statistics may be useful when trying to understand how an S&T focus on economic prosperity and national productivity relates to the nature of public benefits arising from commercialization. While some segments of the population in developed countries have insurance and some don't, and some have public medical coverage and some don't, one inescapable conclusion is that someone must pay for biomedical products once they are on the market, irrespective of government/insurance subsidies. This is particularly true of pharmaceuticals and biotechnological products as opposed to hospital stays which may be subject to more jurisdictional variation in the fraction of the cost picked up directly by individual members of the public (e.g. Canada and the United States). So if one assumes that pharmacies charge the same price for biomedical products to varying people in a given developing country irrespective of whether those people pay themselves directly or indirectly

¹⁹⁹ Roberto Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RES. POL'Y 273, 280 (1998).

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through insurance, do all people have the same ability to pay? A related question is whether or not the percentage of people who do not have the ability to pay has changed during the term where universities and firms have experienced escalating profits subsequent to relevant S&T policies and programs?

The answer according, inter alia, to the UN Human Development Report series, is once again no. Importantly, this is true even in developed countries with relatively high GDPs per capita and growth rate values as shown by the data summarized in Table 1 below:²⁰⁰

Table 1: World Economic Data Relating to Prosperity Gap in Developed Nations

Country	GDP (trillion)	GDP per capita (thousand)	Real Growth Rate (percent)
US	11.75	40.1	4.4
Canada	1.023	31.5	2.4
Netherlands	0.481	29.5	1.2
Germany	2.36	28.7	1.7
	Gini Index²⁰¹	Lowest 20%	Highest 20%
US	41	5.2	46.5
Canada	31.5	7.5	40
Netherlands	32.6	7.3	40
Germany	30	8.2	38.5

The top portion of the table provides data relating to the national and per capita gross domestic product (GDP) of the United States and Canada and comparator nations while the bottom shows Gini Index values, including for the lowest and highest quintiles, for these jurisdictions. The data illustrate that in countries with the highest GDP per capita, even those with high growth rates such as the United States, there is considerable income disparity between the wealthiest and poorest quintiles of the population. The data demonstrate that the wealthiest quintile experience near perfect equality in the United States, Canada and other comparator nations while the poorest quintile are much farther towards perfect inequality. Moreover, even in the most prosperous nations, the Gini Index has been slowly increasing over time, reflecting an increased income gap. For example, the index values in the United States were 0.394, 0.403, 0.428, 0.462 and 0.469 in 1970, 1980, 1990, 2000 and 2005, respectively. This represents a 20% increase in income inequality since Bayh-Dole was debated and implemented, during which time income for the top

²⁰⁰ CENTRAL INTELLIGENCE AGENCY, THE WORLD FACTBOOK 2005 100–02, 575–77 (2005); THE WORLD BANK, WORLD DEVELOPMENT INDEX, GAP BETWEEN RICH AND POOR: WORLD INCOME INEQUALITY (2002).

²⁰¹ WORLD BANK, WORLD DEVELOPMENT INDICATORS (2002). The “Gini Index” (or coefficient) refers to the measure of income inequality within a country. A country’s Gini rating is between 0–100, with 0 representing perfect equality and 100 perfect inequality.

quintile increased substantially (cf. Figure 1).

There is little doubt that this income disparity significantly affects access to healthcare. The 2005 UN Human Development Report is a case in point. The data in Table 1 clearly show the United States to be a leader in almost all of the economic indicators given, yet social inequalities have given rise to significant inequalities in healthcare provision, including access to biomedical products²⁰². These inequalities can be traced, in part, to family incomes, insurance availability, ethnicity, education, and, most importantly, access to care. According to the report, almost 20% of non-elderly Americans lacked access to care, resulting in a litany of related health outcomes including outpatient care, number of services while in hospital, access to drugs and other therapies, and mortality rates both in and out of hospital.

Advocates of broad patent rights and innovation often argue that commercialization results in increased regional job creation and wages, thus facilitating income equity and access to monopoly-priced products. However, data indicate a substantial trend to the contrary.²⁰³ In particular, the average pay for chief executive officers increased 27% in FY 2005 to \$11.3M. By contrast, the average employee took home \$43.5K in FY 2004. Employee pay also failed to keep pace with inflation whereas this was clearly not true of CEOs and other senior management. The average salary for senior executives was more than 170x the average worker's earnings in FY 2004, up from a multiple of 68 in 1940. Similar data exist for Canada, where income share of the bottom 20% families in 2000 was 2.8% compared to 45.1% among top 20% (16:1 ratio or 16,000%).²⁰⁴ Of the executives surveyed in the United States, approximately 50% will collect substantial pensions, with at least 20% expecting \$1M in annual benefits. By contrast, 86% of total American households did not expect to receive any inheritance whatsoever in FY 2006 and beyond. For those who did, the total value of all inheritances quadrupled from years 1965 to 2005 from a little over \$50B to just under \$200B. That the value of median inheritances fell per individual reflected the fact that bequeathed wealth became more concentrated in a small portion of the population, with the top 10% of estates worth \$244,600 or more.

Figure 1 illustrates the temporal relationship between United States household income and the timing of large scale commercialization-based S&T policy changes and escalating revenues by firms and universities from technology transfer and commercialization. The income data in the graph are

²⁰² Bozeman & Sarawitz, *supra* note 3, at 2.

²⁰³ Eric Dash, *CEO Pay Keeps Rising, and Bigger Rises Faster*, N.Y. TIMES, Apr. 9, 2006, at C5; Eric Dash, *Off to the Races Again, Leaving Many Behind*, N.Y. TIMES, Apr. 9, 2006, at C1; Eduardo Porter, *Inherit the Wind; There's Little Else Left*, N.Y. TIMES, Mar. 26, 2006, at D1.

²⁰⁴ CANADIAN COUNCIL ON SOCIAL DEVELOPMENT, EQUALITY, INCLUSION AND THE HEALTH OF CANADIANS: SUBMISSION TO THE COMMISSION ON THE FUTURE OF HEALTH CARE IN CANADA 5 (2001).

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from the 2003 United States Census report.²⁰⁵ The red box represents the timing of the changes to United States S&T policy, including the coming into force of Bayh-Dole, the *Diamond v. Chakrabarty* decision, consolidation of patent appeals into the Federal Circuit and the restructuring of the United States PTO as a fee for service organization. The blue box represents the timing of these changes relative to escalation of profits by firms and universities over the same period. From the data one can reasonably posit that income distribution for all income percentiles below the 50 percent data have remained largely unaffected by the growth in university technology transfer and commercialization and during the time which profits for large pharmaceutical (and increasingly biotechnology) firms have risen to the top of the Fortune 500 index. This was accompanied by record profitability in the pharmaceutical industry, which reaped a 300-500% increase in revenues beyond those for median Fortune 500 firms from 1980 to 2000. Indeed, in 2002 profits by the top 10 drug firms exceeded that for the remaining 490 firms combined. Earnings have been realized in the context of reduced tax burdens compared to other industries²⁰⁶ and a decrease in drug approval times, and hence cumulative transaction costs, over the same time period.²⁰⁷ There is no question that the return on investment of commercialization-based S&T policy has been substantial, for firms and universities. What is not so clear is how such returns have filtered down to the majority of the population. The data are consistent with the claim²⁰⁸ that S&T-based economic growth over the last 30 years in developed nations has been “accompanied by increasing inequality in distribution of economic benefits, including increasing unemployment or underemployment, decreasing real wages, increasing wage inequality, and increasing wealth concentration within nations and between nations.”

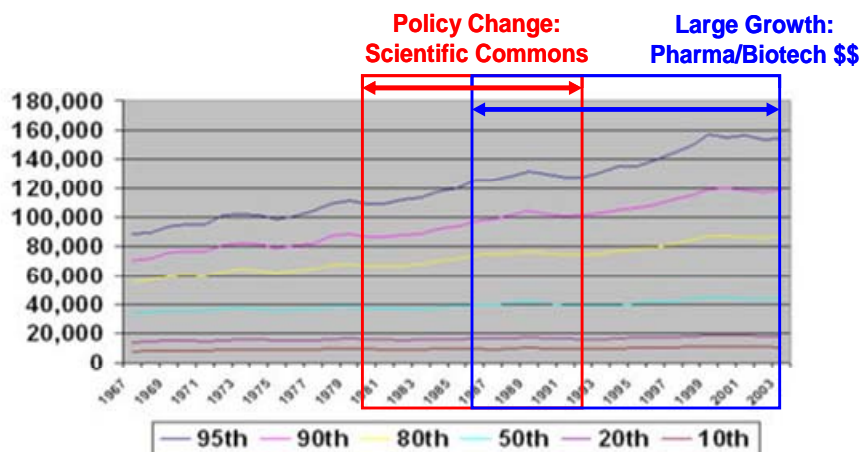
Figure1: Relationship between Commercialization-focused Changes in Science

²⁰⁵ CARMEN DENAVAS-WALT, BERNADETTE D. PROCTOR, & ROBERT J. MILLS, U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2003 (2004).

²⁰⁶ PUBLIC CITIZEN, *supra* note 116; *The Fortune 500*, FORTUNE, April 15, 2002, at F26; PUBLIC CITIZEN, DRUG INDUSTRY PROFITS: HEFTY PHARMACEUTICAL COMPANY MARGINS DWARF OTHER INDUSTRIES (June 2003).

²⁰⁷ European Generic Medicines Association, *A Bitter Pill to Swallow: Myths and Realities of the Pharmaceutical Industry* (2003) (on file with the author) (discussing reduction in research and development times required for drug development and approval from 109 to 71 months from FY 1986 to FY 2000).

²⁰⁸ Bozeman & Sarewitz, *supra* note 3, at 2.

and Technology Policy and Firm and University Profits and Income Distribution

In addition to *general* notions such as national economic spillovers, wage gaps, etc., the issue also arises of whether benefits from more *specific* or direct public participation in the product development lifecycle of biomedical firms are equitably distributed. A narrower version of the national economic spillover scenario is provided by case studies where members of the public have contributed biological tissues and other clinical data to universities or firms for use in specific, and sometimes very narrow, medical uses. Have they received tangible or intangible benefits from these contributions? Indeed, what evidence there is suggests that direct benefits to tissue donors and clinical trial subjects are too “diffuse” to be meaningful, if not completely inaccessible.²⁰⁹ As illustrated by the discussion of *Moore, Greenberg and Catalona* above,²¹⁰ this is a particularly onerous problem for individuals who donate tissue samples and other genetic or proteomic information to federally funded genetic research programs only to be shut out, not only of profits reaped by federally-funded researchers and firms, but of the therapeutic advantages of research on such tissues due to monopolistic pricing by researchers, universities and firms responsible for successful commercialization.

H. Ethical Considerations

A typical claim of bioethics in the context of benefit-sharing is that it is “intuitively straightforward that a nation, company or person should not make money on somebody else’s resources without paying for them.”²¹¹ In this light, wealth maximizing behaviour in the absence of equitable public benefits may be viewed as exploitation. This is particularly true of commercialization of publicly funded biomedical technology, as the public pays for university and

²⁰⁹ Bovenberg, *supra* note 60, at 930.

²¹⁰ See *supra* Section VI.B.

²¹¹ Berg, *supra* note 48, at 240.

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firm product development activities both directly (e.g., clinical trials, donation of tissue and other data samples, risks thereof) and indirectly (e.g., taxpayer and charitable funding of research, transaction costs of inefficient patent and regulatory system). Where substantial profits are made from tangible and public intangible contributions, it would be necessary to ensure equitable sharing in such profits in order to avoid the charge of exploitation.

This issue was dealt with by Justice Moreno in *Greenberg v. Miami Children's Hospital*.²¹² He found that Greenberg et al. advanced sufficient grounds to make out a claim for unjust enrichment based on "fundamental principles of justice, equity and good conscience."²¹³ Justice Moreno also held that the defendants could not rely on the freedom to operate under patent law, since licensing privileges attaching to a patent do not preclude a patentee from being unjustly enriched.²¹⁴ A potential restriction on the general application of the court's unjust enrichment finding is that the plaintiffs only had to make out a threshold case in order to avoid summary dismissal with regard to the facts underpinning the unjust enrichment count, which the plaintiffs succeeded in doing. A broad application of this principle would work towards a position of equitable benefit-sharing.

As noted briefly above, one might also make the claim that by participating in clinical trials as well as providing organ and tissue samples, donations and genetic information under conditions of substantial risk, the public are extending their moral rights in personhood and property on altruistic grounds for the common good. Indeed, this is the very ground on which the medical community argued recently for mandatory clinical trial registration.²¹⁵ From this, one might extend an equitable claim for fiscal rights to the effect that in liberal democracies such as those in the United States and Canada, societal balancing is grounded in broad considerations of distributive justice. This type of distributive argument may be particularly strong in jurisdictions with some type of publicly funded health care or welfare systems aimed at the common good and where the research, commercialization, licensure and marketing of biomedical products is heavily regulated. Based on arguments such as these, one might then speculate that because (a) firms receive many tangible and intangible resources for free from patient volunteers under conditions of risk, (b), these resources are provided for the common good and with the expectation of access to affordable medical care and (c) pharmaceutical and biotechnology firms have become among the most profitable in the world since commercialization efforts by universities and their researchers have escalated following the implementation of Bayh-Dole and other commercialization-

²¹² 264 F. Supp. 2d 1064 (2003).

²¹³ *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1072 (S.D. Fla. 2003).

²¹⁴ *Id.* at 1072; *see also* *Chou v. Univ. of Chicago*, 254 F.3d 1347, 1363 (Fed. Cir. 2001).

²¹⁵ *See generally* ICMJE, WHO, and other statements relating to mandatory clinical trial registration, *supra* note 37.

based S&T policies, it follows that the ethics and altruism traditionally associated with medical research have changed with the commercialization regime to the extent that the public now expect to receive an equitable share of the benefits of publicly funded research.

According to Pullman and Latus, ethical justifications for benefit-sharing, particularly in the context of genetic research, can be divided into two forms.²¹⁶ Principled justifications arise out of the unique moral status of human tissues (or data obtained from the use of human bodies for clinical trials) encompassing notions of personhood, property and the common good. Extending the analogy to genetic information proposed by HUGO in its statement on benefit-sharing (see below), data and other information obtained from the consensual use of human bodies for commercial purposes should in turn benefit the public in a particularized manner. In other words when individuals allow themselves to be used by researchers involved in health research for largely (though not necessarily exclusively) altruistic reasons, the resulting profits should be shared equitably by the public via the public health system. This particularized balancing of public and private interests is grounded by considerations of distributive justice by way of conferring maximum value to all legitimate stakeholders, particularly those in need. Practical justifications for benefit-sharing arise from the facts that donations of tissue samples or participation in clinical trials often occur geographically or temporally remote from where and when actual commercialization may occur, with the result that there is no reasonable expectation of direct benefit-sharing by individual research participants.²¹⁷ Similarly, tissues or data may be banked or otherwise used for purposes other than those for which they were offered, leaving participants without novel therapeutic interventions until such time as they become more profitable or widely available. That benefit-sharing is a moral obligation under these and other conditions has been endorsed by HUGO, the WHO and others.²¹⁸ Again, arguments of this nature are relatively stronger in jurisdictions with wholly or partially publicly funded health care systems.²¹⁹

An extension of the above argument is that no other industry enjoys such powerful and direct contributions to its product life cycle as those of the pharmaceutical and biotechnology sectors. As already noted, public contributions to the bio-pharmaceutical sector include a wealth of direct and indirect contributions, which together for a cumulative “subsidy” that is at

²¹⁶ Pullman & Latus, *supra* note 49, at 242.

²¹⁷ *Id.*; see also Bovenberg, *supra* note 60, at 929–30.

²¹⁸ HUGO Statement on Benefit-Sharing, *supra* note 49; Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries, *Fair Benefits for Research in Developing Countries*, 298 SCIENCE 2133 (2002); WORLD HEALTH ORGANIZATION, REPORT OF A WHO MEETING ON COLLABORATION IN MEDICAL GENETICS 12 (2002), available at http://whqlibdoc.who.int/hq/2002/WHO_HGN_WG_02.2.pdf.

²¹⁹ Pullman & Latus, *supra* note 49, at 243.

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once analogous to and extends well beyond tariffs, duties and other tangible and non-tangible subsidies received by other industries. Baker recently demonstrated that the deadweight loss associated with biomedical monopolies is considerably larger than that calculated for other heavily subsidized industries.²²⁰ The loss to society was estimated to be equivalent to the amount spent by firms on product research and development, even assuming the widely criticized \$800M to \$1.5B in research and development costs per drug proposed by DiMasi²²¹ is correct. For example, the average increase in price for pharmaceuticals resulting from patent protection beyond marginal cost was calculated to be ~400% of marginal cost, with the gap in many cases exceeding 1000%.²²² This can be compared with a gap of 30% associated with the largest comparable tariffs, in this case the steel industry. To give a broader context, the magnitude of the deadweight loss owing to patent monopolies on biomedical products ranged from 0.1-0.5% of GDP, depending on market elasticity. More specifically, deadweight loss was \$11B, \$23B and \$41B with elasticity values of 15, 30 and 50% (reasonably assuming that all drugs experience some type of mark up over marginal costs). According to Baker, losses of this nature are minimally an order of magnitude larger than efficiency losses typically addressed with economic policies.²²³

I. Public Contribution to “Scientific Progress”

It may also be noted that scientists and other medical researchers are not the only members of the public contributing to the relevant intellectual commons. This issue extends well beyond the tissue donation scenarios of *Moore*, *Greenberg* and *Catalona*. Notwithstanding its presumed “quantitative” and “objective” nature, the process of scientific discovery is widely seen to be inherently unpredictable, emanating from many sources of public discourse (science, medicine, philosophy, art, architecture, engineering, policy analysis, economics). As noted by Nelson in the context of innovation theory, both incremental and breakthrough technological advances occur as part of a collective, cultural and evolutionary process.²²⁴ This is especially true within

²²⁰ DEAN BAKER, CENTER FOR ECONOMIC AND POLICY RESEARCH, FINANCING DRUG RESEARCH: WHAT ARE THE ISSUES? (2004).

²²¹ Joseph A. DiMasi, *New Drug Innovation and Pharmaceutical Industry Structure: Trends In The Output Of Pharmaceutical Firms*, 34 DRUG INFO. J. 1169 (2000) [hereinafter DiMasi, *New Drug Innovation and Pharmaceutical Industry Structure*]; Joseph A. DiMasi, *Risks in New Development: Approval Success Rates for Investigational Drugs*, 69 CLINICAL PHARMACOLOGY & THERAPEUTICS 297 (2001); Joseph A. DiMasi, Ronald W. Hansen, & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003).

²²² BAKER, *supra* note 219, at 9.

²²³ *Id.*

²²⁴ Nelson, *supra* note 55, at 1695; *see also*, BARBER, *supra* note 114, at 4–5; KUHN, *supra* note 114, at 1–2; HAGSTROM, *supra* note 114, at 292–93; MERTON, *supra* note 114, at

the rubric of biomedical inventions, where a wide range of scientific, regulatory and economic actors are responsible for the construction of scientific truths and ultimate markets for products based on those truths.²²⁵ In this manner, the public, through various discourses and interdisciplinary nodes of interconnectivity between disciplines are significantly, if indirectly, responsible for scientific advances and innovation. As is obvious to any historian of science, this is hardly the first time that fertile sources of basic and practical knowledge have combined to produce substantial shifts in the role of science in society, as a similar confluence of ideas and practical uses thereof occurred during the Enlightenment when Newton, Descartes and their contemporaries were working against the backdrop of parallel developments in philosophy, alchemy, architecture and art.²²⁶ Therefore, members of the public contribute critically to the production and construction of scientific progress,²²⁷ independently of whether or not individuals contribute directly to specific research and development efforts.

The current S&T policy environment linking basic research to innovation and product development is tied to the notion, advocated some time ago by Schumpeter, that science is and has always been more or less an applied activity.²²⁸ As noted above, this stands somewhat in opposition to the notion that basic research can be kept distinct from applied research, which became widely held (rightly or wrongly) following publication by Vannevar Bush of his policy and political stance on the post-war national science program.²²⁹ As discussed in detail by Stokes,²³⁰ science has existed as a combined knowledge-based and applied activity for hundreds of years, particularly following the development of more quantitative measurement devices and the need for immediate considerations of use, e.g. that which both followed and inspired the cellular understanding of microbial infection. Given that science can legitimately be characterized historically as “output-oriented,” it is fair to say that contributions of public discourse to the construction and production of scientific knowledge in turn contributes significantly to innovation and product

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²²⁵ Bouchard 2007b, *supra* note 15 (discussing the application of actor-network theory to pharmaceutical inventions and the impact thereof on the standard for obviousness).

²²⁶ See LEONARD SHLAIN, ART & PHYSICS: PARALLEL VISIONS IN SPACE, TIME, AND LIGHT (1991); F. DAVID PEAT, SYNCHRONICITY: THE BRIDGE BETWEEN MATTER AND MIND (1987).

²²⁷ Jasanoff, *supra*, note 8, at 891; Jasanoff, *supra* note 28, at 19–20.

²²⁸ JOSPEH SCHUMPETER, CAPITALISM, SOCIALISM AND DEMOCRACY (Harper and Row 1942); See also Nelson, *supra* note 65, at 1694-1695 (discussing the “widespread belief that modern fields of technology are, in effect, applied science, in the sense that practice is directly drawn from scientific understanding, and that advancing technology is essentially a task of applying scientific knowledge to achieve better products and processes Indeed, . . . Schumpeter (1942) argued that by the mid twentieth century that was largely the case. . . .”).

²²⁹ VANNEVAR BUSH, SCIENCE: THE ENDLESS FRONTIER (1945).

²³⁰ See STOKES, *supra* note 21.

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development, e.g. via identification of important public health problems at which new technological solutions are aimed.²³¹ This type of generalized yet integral contribution of the public to the evolution of the commons argues strongly in favour of a direct interest by the public in profits realized from the commercialization process.

J. Democracy Matters

The discussion thus far must be interpreted in light of the distributive metric for access to essential medication and therapies²³² and the vital norm in liberal democracies that needed goods such as biomedical products are not, indeed should not, be freely tradable commodities when deemed to be a socially recognized need.²³³ The latter point is particularly relevant to the issue of public health given that clinical research, patenting, licensing and marketing of biomedical products is strongly regulated in most developed nations and because biomedical products are generally derived from publicly funded research aimed at the global common good. Indeed, all liberal democracies recognize that the state has some role to play in promoting equitable access to needed social goods. According to Walzer,²³⁴ egalitarian justice in a system of complex equality requires that goods be distributed contextually, according to their practicable social meanings, and that no good be allowed to dominate distribution of goods in other spheres of society. While conflict between spheres is inevitable, an important limitation on the free commercialization of goods is that the market is merely one zone of democratic society, not the whole of it. In this model, market forces can be legitimately submitted to

²³¹ As noted by Gerald Holton, research of this type “locates the centre of research in an area of basic scientific ignorance that lies at the heart of a social problem.” Gerald Holton, as quoted by Donald Stokes in Donald Stokes, *Completing the Bush Model: Pasteur’s Quadrant, in Science the Endless Frontier 1945–95: Learning from the Past, Designing for the Future*, December 9, 1994, <http://www.cspo.org/products/conferences/> (follow “Highlights from Conference and Entire Transcript” link, then click on the “text” icon adjacent to the article’s name (quoting Gerald Holton)). Donald Stokes has referred to this type of research as lying within “Pasteur’s Quadrant,” the quadrant in a matrix whereby research is inspired by both a quest for fundamental understanding and considerations of use. *See id.* at 7–8.

²³² UN International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200 (XXI), U.N. GAOR, 21st Sess., Supp. No. 16, U.N. Doc. A/6316 (Dec. 16, 1966); Universal Declaration on the Human Genome and Human Rights, UNESCO Gen.Conf. Res. 29 C/Res.16, reprinted in Records of the General Conference, UNESCO, 29th Sess., 29 C/Resolution 19, at 41 (Nov. 11, 1997) (adopted by the UN General Assembly, G.A. Res. 152, U.N. GAOR, 53rd Sess., U.N. Doc. A/RES/53/152 (Mar. 10, 1999)); HUGO Statement on Benefit Sharing, *supra* note 49.

²³³ MICHAEL WALZER, SPHERES OF JUSTICE: A DEFENSE OF PLURALISM AND EQUALITY 78-122, 318-19 (Basic Books 1983).

²³⁴ *Id.*

restrictions in order to promote the equitable distribution of needed goods.²³⁵

The discussion above has critical ramifications for the privatization of medical research, particularly with regard to equitable access by the public to monopoly-priced products. At varying points in the twentieth century, governments in most liberal democratic states accepted the principle that biomedical products and health care in general are needed goods and that under certain conditions (old age, disability, poverty, etc.) market forces can and should be preempted by the needs of the welfare state.²³⁶ In particular, the state frowns on exchanges of desperation whereby people are forced to bargain without adequate resources for the very means of life. However, as noted above this is precisely the condition in which great swaths of the public in developed as well as developing nations find themselves. Furthermore, various international and domestic human rights legislation and instruments recognize either directly or indirectly through the right to life, the right to health or the right to physical integrity that access to health care is a human right, providing further basis for the claim that health care products ought not to be distributed solely on the basis of market criteria alone.²³⁷ Thus, particularly in jurisdictions that have embraced some degree of public healthcare, distributive reallocation of asymmetric benefits can be justified on political grounds.

Distributive reallocation would go some way to alleviate concerns, expressed both outside and inside government, over mission creep.²³⁸ As government officials in their capacity as agents of the public consult with the private sector over an increasingly large number of issues relevant to research, commercialization, licensure and marketing of biomedical products, it will be imperative to maintain not only the integrity of government-industry relations, but also to be seen to be doing so publicly. Indeed, Gagnon²³⁹ has claimed that the failure of standard economic models to account for dramatic structural and economic transformations in the global pharmaceutical industry over the last two decades compared with other leading sectors lends itself to the conclusion

²³⁵ In addition to grounds for equitable reallocation discussed already, this argument provides further answer to the claim advanced by firms and universities that producers of essential medical goods only have the duty to respond to the demand of consumers for new products.

²³⁶ WALZER, *supra* note 233.

²³⁷ Virginia Leary, *The Right to Health in International Human Rights Law*, 1 HEALTH & HUMAN RIGHTS 24 (1994); Eleanor D. Kinney, *The International Human Right to Health: What Does This Mean for Our Nation and World?*, 34 IND. L. REV. 1457 (2001).

²³⁸ Lemmens & Bouchard 2007a, *supra* note 75.

²³⁹ Marc-André Gagnon, *Finance And Differential Accumulation In The Global Pharmaceutical Industry* (Conference Presentation, Dec. 2006), available at http://www.er.uqam.ca/nobel/ieim/IMG/pdf/NoteD_2006-12-07-Gagnon.pdf; Marc-André Gagnon, *Capital, Knowledge and Power in the Global Pharmaceutical Business: Structural Competition for Differential Accumulation* (Conference Presentation, Dec. 2006), available at http://www.er.uqam.ca/nobel/ieim/IMG/pdf/NoteC_2006-12-07-Gagnon.pdf.

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that proactive industries are gaining ground on competitors by transforming socio-economic institutions and actors to increase strategic control over industry, government and the public. This is a particular concern in Canada given that the deregulation agenda is moving forward under the banner of Smart Regulations and other biomedical product-specific policy directives.²⁴⁰ From this, one might conclude that distributive reallocation of benefits based on political grounds takes on certain exigency in proportion to the degree that public-private partnerships and other forms of government-industry partnering enhance, or are seen by the public to enhance, the political influence and market power of firms over competing spheres to the detriment of the public.

K. Difficulties with a Direct Flow-Through Benefit to the Public

Despite the outrage over *Moore*, *Greenberg* and *Catalona*, it has nevertheless been suggested that direct revenue sharing by individual members of the public has practical difficulties. Berg has claimed that there is a lack of what he refers to as “specific” ethical grounds for direct benefit sharing.²⁴¹ The first difficulty is *who* exactly should participate in such fiscal benefits, as it would be pragmatically difficult to keep track of every individual participating in tissue donation schemes and clinical trials. The second difficulty is created by the temporal lag between such participation and actual commercialization. Berg also argues against payment based on a lack of available funds, particularly from participating universities, because such remuneration would result in universities conducting fewer trials.²⁴² To the extent such studies were co-funded or had significant pharmaceutical partners, however, some of these concerns may be deemed economically efficient from the perspective of lowering commercialization transaction costs. Additionally, keeping track of study participants should not present too much of a challenge because of today’s information technology and computer processing capabilities. A more legitimate roadblock is Berg’s ethical concern that human beings have not performed any “particular acts of competence” to create their own DNA or tissues.²⁴³ Indeed, given the chance most if not all patients would rather not grapple with onerous and life-threatening symptoms of disease.

Commercializing participation in clinical trials and tissue donations will only exacerbate powerful ethical concerns over the participation of individuals in traditionally disadvantaged groups, the extent of which the public is only now realizing.²⁴⁴ In its Statement on Benefit-Sharing, HUGO has specifically advocated against financial inducements for participation in biomedical

²⁴⁰ Bouchard & Lemmens, *supra* note 19, at 5, 11 (discussing the potential impact of mission creep on funding decisions, drug approval and public mistrust over same.).

²⁴¹ Berg, *supra* note 48, at 242; Bovenberg, *supra* note 60, at 931–32.

²⁴² Berg, *supra* note 48, at 241–42.

²⁴³ *Id.* at 242.

²⁴⁴ Lemmens, *supra* note 29, at 645.

research, particularly research involving genetics.²⁴⁵ Financial inducements would tend to commoditize bodies and contribute to an anticommons by enabling members of the public to negotiate benefits for use of their tissue and clinical trial participation.²⁴⁶ In addition, human health would not directly benefit from such commoditization; ensuring that stipends for such participation would be put back into the donor's health concerns, or indeed into donor's hands at all, would be nearly impossible. Restricting benefit-sharing only to those members of the public who participate in research would also create divisiveness between so-called distinct groups or communities within society, and would be inconsistent with the notion of solidarity and the public good.²⁴⁷

IV. COMPULSORY GOVERNMENT ROYALTY AS A DISTRIBUTIVE TOOL

A. Introduction

Up to now, my analysis has been focused on assessing whether public and private interests in the commercialization process are in reasonable balance. Put another way, is the public receiving an equitable share of the benefits of publicly funded research in light of the variety of its contributions to, or "subsidies" of, medical product development? I conclude that the balance significantly tilts against the public interest in favour of the private interest. In particular, several grounds have been offered to support both a general and a direct public interest in profits realized from commercialization of publicly funded biomedical research. These include (but are not limited to: (1) the wide array of public and government contributions to the commercial pipeline; (2) the erosion and/or inversion of the intellectual commons and the detriment to the public of this; (3) the lack of property or other legal interests in clinical trial data and tissue samples; (4) the lack of access of the public to affordable biomedical therapies; (5) the asymmetric distribution of the financial benefits arising from commercialization; and (6) various ethical and political considerations supporting benefit-sharing. As noted above, however, the ethical grounds are thin for a direct flow-through pecuniary interest back to individual members of the public. Here, I advance the proposition that government is better and more legitimately placed to receive and leverage a direct pecuniary interest, specifically in the healthcare arena. This pecuniary interest will be referred to henceforth as a compulsory government royalty (CGR). Theoretically, CGR payments would flow back to government following successful commercialization of technologies funded by the public purse.

Royalty revenue from the proposed CGR mechanism could be used

²⁴⁵ HUGO Statement on Benefit-Sharing, *supra* note 49.

²⁴⁶ Bovenberg, *supra* note 60, at 931.

²⁴⁷ Berg, *supra* note 48, at 242.

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primarily to ensure equality of access to essential medications and health care, with surplus funds used to address public health concerns, facilitate clinical trials and other innovative commercialization efforts for traditional small or niche markets where few firms currently operate. It could also provide an important additional source of funding for clinical research. The terms and conditions of a CGR could easily parallel those in traditional license agreements between universities and firms and be either standard or negotiated. Negotiated terms may have the advantage of stimulating early adoption of innovative technologies (particularly if coupled with cascading tax credits), thus facilitating economic efficiency in the innovation process. Importantly, the proposed model is aligned with and works to mitigate the tension in the mandates of major public health agencies to protect public health while simultaneously stimulating the economy through medical research. As such, it operates to balance public and private interests in the privatization of innovative research and thus ensures taxpayers' interests in securing an appropriate return on federally funded research are protected.²⁴⁸

As discussed below however, this is not the first time that some form of distributive reallocation has been proposed in the context of the existing commercialization regime. However, a significant period of time has passed since the Bayh-Dole Act was passed. This has allowed for the development of a certain equilibrium of the system, rendering its function and the the interaction of its various elements more amenable to observation. Moreover, a good deal of the discussion of the social value of medical research as it relates to commercialization has been initiated by the scientific community, university administrators and the funding branch of government rather than arm's length health policy scholars. Therefore, the time seems right to reassess the legitimacy of opposition to the notion of benefit reallocation.

B. Previous Discussions of Recoupment

A "recoupment" provision was contained in the original Bayh-Dole legislation only to be removed just prior to being signed into law.²⁴⁹ Concerns were expressed by academic and industry lobbying groups over the administering agency, form, and costs to firms of royalty payments. The provision was grounded in the assertion, most famously made by Senator Harley Kilgore (D-W.Va.) that unfettered commercialization amounted to a giveaway of the fruits of publicly funded research to firms, which in turn reinforced asymmetric distributions of economic and market power within society.²⁵⁰ The specific grounds of contention included uncertainties regarding (a) whether funds recouped would be returned to the original funding agencies

²⁴⁸ NATIONAL INSTITUTES OF HEALTH, NIH RESPONSE TO CONFERENCE REPORT REQUEST FOR PLAN TO ENSURE TAXPAYER'S INTERESTS ARE PROTECTED (July, 2001) [hereinafter NIH RESPONSE].

²⁴⁹ Sampat, *supra* note 21.

²⁵⁰ *Id.*, at 12; Dosi et al., *supra* note 33, at 1110.

or to general revenues, (b) how collections and auditing would be conducted and (c) whether the costs of administering the program would exceed funds collected.²⁵¹ Recoupment would have seen the federal government receive 15% of gross income over \$70,000 and an additional 5% on income in excess of \$1M- up to the amount government contributions under the funding agreement(s). Not dissimilar to most existing university-industry agreements, the object was to recoup institutional investment in product development. However, where the original Bayh-Dole provision was intended to do solely this, university technology transfer agreements invariably go two steps further in that they typically include further royalty fees on marketed products through various benchmarking provisions as well as assuming an equity stake as part of spinout exit strategies (IPOs, share/asset purchase, etc.) or outright acquisition.²⁵² In short, it is reasonable to say that all three of the concerns expressed by the academic community over the original recoupment provision are mitigated if not obviated by three decades of successful university-firm contracting and technology transfer and commercialization efforts, though more will be said about this below. Moreover, as demonstrated by the \$206B settlement between United States Attorneys General and Big Tobacco in 1998,²⁵³ public agencies have not shied away from recovering public health costs from firms when they see fit, and have proved adept at successfully administering and reinvesting these funds to finance public health research, primary health care initiatives and other public health programs.

The NIH re-examined the issue of recoupment in 2001 in response to concerns expressed by the public over whether “taxpayer interests” were being adequately protected in light of the large fiscal and other contributions to private drug development.²⁵⁴ Reasons given by the NIH for rejecting recoupment in this round of discussions were that (a) it would undermine the medical research enterprise, (b) reduce funds for academic development, (c) discourage faculty members from engaging in technology transfer, and finally, (d) destroy industry agreements with academic institutions. Opposition to recoupment was, not surprisingly, supported primarily by university lobbying groups and research scientists,²⁵⁵ who opined that the public benefits enough from products arising out of medical research and the economic activity spurred by those products.

This was not the last time a provision designed to yield an equitable

²⁵¹ Sampat, *supra* note 21; NIH RESPONSE, *supra* note 248.

²⁵² Mark Edwards, Fiona Murray & Robert Yu, *Value Creation And Sharing Among Universities, Biotechnology and Pharma*, 21 NATURE BIOTECHNOLOGY 618 (2003).

²⁵³ See JOY JOHNSON WILSON, SUMMARY OF THE ATTORNEYS GENERAL MASTER TOBACCO SETTLEMENT AGREEMENT (March 1999), <http://academic.udayton.edu/health/syllabi/tobacco/summary.htm>.

²⁵⁴ NIH RESPONSE, *supra* note 248.

²⁵⁵ Jocelyn Kaiser, *NIH Report Knocks Tax on Blockbusters*, 293 SCIENCE 1575 (2001); Donald Kennedy, *Drug Prices: Real Problem, Wrong Solution*, 292 SCIENCE 1797 (2001).

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distribution of the benefits of medical research was rejected by federal funding agencies. The NIH refused to exercise “march-in” rights²⁵⁶ for products developed using publicly-sponsored research in 1997²⁵⁷ and again in 2003²⁵⁸ even though concerns were expressed in numerous quarters, including by Congress, over whether taxpayers were getting an adequate return on investment in light of monopoly prices that far exceeded those in other jurisdictions and given the scope and variety of fiscal and other contributions to medical research.²⁵⁹ The NIH also rejected public overtures, including submissions to Congress and the Senate to support inclusion of a reasonable price clause²⁶⁰ in the Bayh-Dole framework, due to strong opposition, again from industry and the university community.

About the same time as the debate over march-in rights and the reasonable pricing clause were taking place, Donald Evans, then Secretary of Commerce, advocated for a recoupment provision as part of proposed reforms to the Advanced Technology Program (ATP).²⁶¹ The proposal required grant recipients to pay annual royalties amounting to 5% of gross revenues to the

²⁵⁶ § 203 of the Bayh-Dole Act provides for the funding agency with jurisdiction to ignore patent rights and grant additional licenses to other reasonable applicants. The right is limited and can only be exercised provided that that one of four criteria is met: (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in its field of use; (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees; (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or (4) action is necessary because the agreement required by § 204 (Preference for US Industry) has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement.

²⁵⁷ Regarding inventions made by Johns Hopkins University and licensed to Baxter Health Care Corporation relating to stem cell technology. NATIONAL INSTITUTES OF HEALTH, IN THE CASE OF THE PETITION OF CELLPRO INC (Aug. 1, 1997).

²⁵⁸ Congress and public actors petitioned the NIH over the cost of the AIDS medication ritonavir, marketed as NORVIR by Abbott Labs: NATIONAL INSTITUTES OF HEALTH, IN THE CASE OF NORVIR, July, 29, 2004, available at <http://www.ott.nih.gov/policy/March-in-norvir.pdf>.

²⁵⁹ Eliot Marshall, *NIH Nixes Appeal to Bypass Patent Law*, 277 SCIENCE 759 (1997); David Malakoff, *NIH Weighs Demand to Force Sharing of AIDS Drug Patents*, 304 SCIENCE 1427(2004); David Malakoff, *NIH Declines to March in on Pricing AIDS Drugs*, 305 SCIENCE 926 (2004).

²⁶⁰ In response to concerns expressed by Congress, the NIH’s proposed policy in 1989 to the effect there should be a “reasonable relationship between the pricing of a licensed product, the public investment in that product and the health needs of the public” included in all exclusive licenses to inventions made under NIH Collaborative Research and Development Agreements, or CRDADS. NIH Response, *supra* note 248, at 7.

²⁶¹ U.S. DEPT. OF COMMERCE, THE ADVANCED TECHNOLOGY PROGRAM: REFORM WITH A PURPOSE (Feb. 2002).

federal government. The royalty was seen to enhance stability of the program, increase equity in the distribution of benefits of publicly funded research, and facilitate the efficiency of the ATP. Not surprisingly, as with opposition to recoupment, the ATP proposal died on the floor following now familiar industry and academic consultations.²⁶²

The latest touchstone for the debate over recoupment occurred in spring 2007 over proposed legislation to create the Advanced Research Projects Agency-Energy. A recoupment provision was brought up for analogous reasons to those offered during the original Bayh-Dole debates and those over the reasonable pricing clause and march-in rights discussed above. As previously, following consultations with academic and industry lobbying groups, the House Science and Technology Committee dropped the provision.²⁶³

Based on the above, it is reasonable to conclude that is unlikely that neither universities nor their industry lobbying counterparts, researchers themselves, nor those standing in on their behalf (including the NIH and CIHR) will stray too far from their central claim that taken together, patenting, technology transfer and commercialization are critical to the success of the so-called medical research enterprise or that any intrusion into the legislative fence surrounding profits by firms and their university partners is contrary to the “spirit” of Bayh-Dole.

There are a variety of responses to criticisms of distributive reallocation of the benefits of medical research of the sort reviewed above, including a CGR. First, as to whether funds recouped would be returned to the original funding agencies directly or via their oversight agencies or to general revenues, there is no reason, from a public health policy perspective, it couldn't be both. Funds could be returned in whole or part to federal agencies such as the Department of Health and Human Services and Health Canada in the United States and Canada respectively, under which both research funding (NIH, CIHR, NRCs) and drug regulatory/approval (FDA, TPD) agencies operate. As noted earlier, state settlements ensuing from big tobacco litigation initiated by a number of state Attorneys General provide a good starting point for an economically and administratively efficient working model regarding health-related recoupment and targeted expenditures.

Second, there is no good reason to assume a CGR would either undermine

²⁶² Charles Wessner, *Advanced Technology Program Survives Challenge*, ISSUES IN SCI. & TECH., Fall 2002, available at http://findarticles.com/p/articles/mi_qa3622/is_200210/ai_n9099691; Neil MacDonald, *ATP, MEP to be Phased Out*, FED. TECH. WATCH, Feb 10, 2003, at 3-4, available at <http://www.compete.org/docs/pdf/FTW03feb10.pdf>.

²⁶³ Association of American Universities, Letter to House Science and Technology Committee, May 18, 2007, http://www.aau.edu/research/AAU-NASULGC-ARPA-E_5-18-07.pdf; Association of American Universities, Press Release: University Associations Thank House S&T Leaders for Removing Damaging Provision from ARPA-E Legislation, May 23, 2007, <http://www.aau.edu/members/Update07.43.pdf> (registration required).

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the medical research enterprise or reduce research funds. Indeed there was speculation of this nature regarding the distribution of firm profits when university royalties were incorporated via Bayh-Dole, and as successive AUTM and Fortune 500 reports reveal clearly, royalty payments to universities have done nothing to mitigate firm profitability and university profits have gone from a baseline approaching nil in 1980 to well in excess of \$1.5B by 2007. Moreover, most universities already recognize and accept the principle of recoupment as part of their technology transfer activities,²⁶⁴ as recoupment of funds invested by university technology transfer offices in patenting and licensing is built into most licenses between university researchers and their licensors. In addition, recoupment provisions are becoming increasingly accepted as part of cause-specific research funding agencies (Cancer, Alzheimer's, Heart & Stroke, Diabetes, etc.). Thus to the extent that a CGR bolsters consumer purchasing power and research funding coffers, it should have the opposite effect over time to that worried over by academic researchers by stimulating both market push and pull mechanisms.

Third, recoupment was seen by critics as producing instability in the university funding environment. However, in the context of the ATP debate, the stability of funding and industrial partnering was seen by the Department of Commerce to be enhanced by a CGR mechanism²⁶⁵ owing to the fact that royalties would help sustain ATP coffers, and thus strengthen going concerns and other co-funded commercial ventures. This argument was supported by a 2001 National Research Council report to the effect that grant instability was particularly hard on small and medium-sized enterprises (SMEs). To this one might add that a CGR could conceivably stabilize the market for medical product development by facilitating a positive feedback cycle entailing more funding for research (push) and a solid base of consumers for the resulting products (pull). Equity concerns of the type discussed in Section III.H. *supra* were viewed by the Department of Commerce to be satisfied by a recoupment mechanism because the fiscal gains resulting from commercialization of publicly funded technologies were seen to far outweigh impingements of firm bottom lines. This owes to enhanced efficiencies and reduced transaction costs not only for individual firms commercializing particular technologies, but also in terms of the cost savings and economic spillovers for related industries and,

²⁶⁴ Litan, *supra* note 52, at 4 (discussing that technology transfer offices have been charged with maximizing revenues from university-owned intellectual property rather than the volume innovations in the market); Sampat, *supra* note 21, at 786 (discussing under Bayh-Dole that universities have "complete latitude in making decisions about what to patent and how to license" and "typically make patenting and licensing decisions based on their own self-interest rather than public interest"). He further notes that "a recent survey of 76 major university technology transfer offices, licensing incomes the most important criterion by which technology transfer offices measure their own success." *Id.* (citing Richard Jensen & Marie Thursby, *Proofs and Prototypes for Sale: The Licensing of University Inventions*, 91 AMER. ECON. REV. 240, (2001)).

²⁶⁵ U.S. DEPT. OF COMMERCE, *supra* note 261.

one presumes, municipal and regional technology clusters.

Fourth, is the academic community's criticism that a CGR mechanism would mitigate and "destroy" industry agreements between firms and universities researchers. However, this criticism does not map well onto the explosion in university-based medical research and its wide of range of clinical applications combined with the well documented push by most governments in the developed world for enhanced productivity and competitiveness through innovation and the well described drying up of traditional pharmaceutical pipelines means. Consequently, in the presence or absence of a short nadir in university-industry agreements following institution of a CGR supported by strong leadership, it is more than likely that the patenting, technology transfer, licensing and commercialization efforts by universities, and the in-licensing and outright purchasing of publicly funded biomedical technologies by multinational pharmaceutical and biotechnology firms, will continue apace well into the future. As discussed previously,²⁶⁶ to the extent that linkage regulations²⁶⁷ in North America continue to allow for evergreening of older product lines, pharmaceutical companies are poorly incented to engage in truly innovative activity in favour of adding "bells and whistles" to existing products on which older new chemical entity patents have since expired, thus allowing for continued monopoly pricing.²⁶⁸

Fifth, as recognized earlier,²⁶⁹ one thing in common to each of these debates is that the most strenuous opposition to recoupment and other forms of social redistribution or reallocation of commercialization benefits has come historically from the academic community, industry and, increasingly, the NIH. Unfortunately, none of these actors are the right locus for arm's length debate over the social value of distributive reallocation of benefits due to the numerous layers of conflicts involved, which are largely monetary in nature (both in terms of profitability of commercialization as well as grant funding). Moreover, none of these groups have a role in determining the social impact of intellectual property and regulatory regimes that influence market monopolies, drug pricing or reimbursement.²⁷⁰ While the conflict between public and private objectives is obvious for private firm actors, it is less so for quasi- or, increasingly, pseudo- public actors such as scientists, universities and research

²⁶⁶ Bouchard 2007a and 2007b, *supra* note 15.

²⁶⁷ Eisenberg (2003) and Eisenberg (2001), *supra* notes 1 and 190.

²⁶⁸ *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 S.C.C. 49, 30985 [2006] S.C.J. No. 49 QUICKLAW (Nov. 3, 2006)

²⁶⁹ See for example Bozeman; Bozeman & Sarewitz; Sampat; Dosi et al., *supra* notes 33, 3, 21 and 33, respectively.

²⁷⁰ Of the 6 groups consulted by the NIH for its Response to the Committee Report for FY 2001 DHHS Appropriation regarding the Committee's request for a plan to ensure taxpayers' interests in publicly-funded medical research were protected (NIH RESPONSE, *supra* note 248), 4 were university lobbying groups and two were industry lobbying groups. Notably, there were no organizations representing actual taxpayers.

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institutes and their funding agencies. This is underscored by comments made by scientists²⁷¹ during the 2003 NIH recoupment debate to the effect that recoupment was both “unfair” and “inappropriate” from the perspective of academic institutions and that the only relevant social return from NIH-sponsored research is the ensuing product development and dissemination of research results. Sentiments such as these have been echoed by academic lobbying groups as far back as the original Bayh-Dole recoupment debates all the way to the Atomic Energy debates of 2007, and are indicative of the fact that scientists who commercialize their publicly funded inventions whether acting alone or through their funding agencies are, and should be, conflicted out of high level policy negotiations on ethical grounds due to self-interest.

Indeed, the recent quaternary anniversary of Bayh-Dole spawned numerous retrospectives and reviews of the scientific and economic impact of the legislation, primarily by scientists, university administrators, their industrial partners and those supporting them. Many of these articles take the position that privatization of medical research has positioned universities and their industrial partners to achieve advances in medical product development that could not have been achieved by purely public or purely private efforts. While the economic returns on investment in medical research have been substantial for firms and universities, it is also true that very few of these authors are in a position to comment with the necessary training, expertise and experience on the social impact of a growing emphasis on university-industry collaboration or indeed how, or even why, a high return on the public investment in research necessarily equates with enhanced or adequate levels of health from a public policy perspective. This has more to do with who is authoring the papers rather than their interest in seeing the right thing done or the policy, economic opinions and data on which they were commenting. As noted by Ziman:²⁷²

In the last 20 years the whole field of science studies has been transformed by the realization that science can only be understood if it is treated as a *social institution*, both within its own sphere of activity and in its relationship with the world at large [italics in original].

This statement, regarding twenty years of progress in understanding the necessity of taking a broader view when assessing the social implications of science (and S&T policy) by Ziman, was made not in 2004, but 1984. The simplification of the so-called “inherent” social benefits of technology transfer and commercialization by the academic community that led up to and runs throughout the Bayh-Dole retrospectives is reminiscent of the same type of

²⁷¹ Kaiser, *supra* note 255; Kennedy, *supra* note 255; David Korn & Stephen Henig, *Recoupment Efforts Threaten Federal Research: Encouraged by Congress to Patent Inventions, Academic Researchers Now Face a Drive by Government to Recover Royalty Income*, ISSUES IN SCI. & TECH., Summer, 2004, available at http://www.issues.org/20.4/p_korn.html.

²⁷² JOHN ZIMAN, AN INTRODUCTION TO SCIENCE STUDIES: THE PHILOSOPHICAL AND SOCIAL ASPECTS OF SCIENCE AND TECHNOLOGY 3 (Cambridge University Press 1984).

simplification by scientists and university administrators in the post Vannevar Bush years in order to entrench scientific independence and self-policing in the context of the post-war funding machine.²⁷³

As discussed in detail by Bozeman and Sarewitz,²⁷⁴ while scientists do have the training to assess the technical quality of research they and others conduct, they do not have the skill level, knowledge base, legitimacy or even value system required to adequately assess the broad social value of scientific research let alone the vast social, economic, public health and political implications of technology commercialization. An easy example of this paradox is that while many PhDs have decades of tacit and focal knowledge of various aspects of medicine and medical techniques, they are not the ones people turn to for serious medical interventions. There is a difference between scientists being able to self-police and prioritize funding given to them by domestic governments and the ability to police the social impact of their work. One is reasonable, the other far from it.

Conflicts of interest of this nature are a particularly important consideration if one accepts the notion that public policy represents a purposive course of action by governing bodies designed to solve discrete problems,²⁷⁵ in this case the whether the benefits of publicly funded medical research are equitably distributed, and that the benefits and costs of science affect different segments of the public in different ways and to different degrees.²⁷⁶ An argument favouring minimization, or at least proportional representation, of scientists in public health policy debates (perhaps akin to the composition of Research Ethics Boards) would be consistent with the fact that universities and scientists involved in technology transfer and commercialization make decisions based on their own self-interest rather than the public interest²⁷⁷ and tend to avoid discussions of public values or social returns of medical research, which slow the momentum of the science funding machine.²⁷⁸

C. Further Grounds for a Compulsory Government Royalty

In addition to those advanced above, there are numerous other grounds favouring CGR as a tool for distributive reallocation. First, a CGR has the advantage of a clear and direct structural (legal), functional (economic) and

²⁷³ STOKES, *supra* note 20, at 20.

²⁷⁴ Bozeman & Sarewitz, *supra* note 3, at 6-7.

²⁷⁵ WILLIAM I. JENKINS, *POLICY ANALYSIS: A POLITICAL AND ORGANIZATIONAL PERSPECTIVE* (1978); MICHAEL HOWLETT & M. RAMESH, *STUDYING PUBLIC POLICY: POLICY CYCLES AND POLICY SUBSYSTEMS* (OXFORD 1995); JAMES ANDERSON, *PUBLIC POLICY MAKING: AN INTRODUCTION* (Houghton Mifflin 1996).

²⁷⁶ Bozeman & Sarewitz, *supra* note 3, at 1-2.

²⁷⁷ Sampat, *supra* note 21, at 32; Jerry G. Thursby, Richard Jensen, & Marie C. Thursby, *Objectives, Characteristics and Outcomes of University Licensing: A Survey of Major U.S. Universities*, 26 J. TECH. TRANSFER 59 (2001).

²⁷⁸ Bozemand & Serewitz, *supra* note 3, at 7.

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institutional (administrative) nexus between the scope of public input to product development and the scope of benefits derived from this input. Unlike a tax, which levies past, present and future innovation, the proposed CGR yields a royalty stream only on (a) past innovative activity, that is (b) undertaken by publicly funded researchers or their agents and (c) assumed by firms (d) only relative to the commercialized product at issue. As such, it offsets the effective “excise tax” levied by firms on products arising from strong patent protection and resulting monopoly pricing²⁷⁹ as well as the associated deadweight loss on national economies.²⁸⁰ The latter issue is particularly relevant to a royalty mechanism grounded in distributive concerns, as the dead weight loss associated with biomedical monopolies is considerably larger than that calculated for other “subsidized” industries. As already discussed above, the deadweight loss on pharmaceutical products which are the subject of patent protection is estimated to be equivalent to the amount spent by firms on product research and development,²⁸¹ even assuming the widely criticized \$800M to \$1.5B in research and development costs per drug proposed by DiMasi²⁸² and colleagues is correct. For example, Baker calculated that the average increase in price for pharmaceuticals resulting from patent protection beyond marginal cost is ~400%, with the gap in many cases exceeding 1000% marginal cost. This can be compared with a gap of 30% associated with the largest comparable steel tariffs.

A CGR would also satisfy various legal grounds said to underpin equitable benefit sharing in the case law and international instruments:²⁸³ the ground of compensatory justice is satisfied in that the public receives compensation in proportion to its direct contributions to product development; the requirement of procedural justice is satisfied in that administrative procedures for gathering and distributing royalties would under law be required to be fair, impartial and inclusive; and the requirement of distributive justice would be satisfied through an equitable allocation of benefits. As noted in *Greenberg*,²⁸⁴ to cut the public out of profits subsidized by them is equivalent to unjust enrichment based on the principles of justice, equity and good conscience. The proposed CGR would also comport with the “global public good” model whereby efficient health funding is aimed at promoting truly public health issues.²⁸⁵ Members of the public contributing resources to product development do so largely for

²⁷⁹ BAKER & CHATANI, *supra* note 116.

²⁸⁰ BAKER, *supra* note 220, at 5-7.

²⁸¹ *Id.*

²⁸² DiMasi, *New Drug Innovation and Pharmaceutical Industry Structure*, *supra* note 220; DiMasi, Hansen, & Grabowski, *supra* note 220.

²⁸³ HUGO Statement on Benefit Sharing, *supra* note 49.

²⁸⁴ *Greenberg v. Miami Children’s Hospital Research Institute*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

²⁸⁵ PUBLIC-PRIVATE PARTNERSHIPS FOR PUBLIC HEALTH (Michael Reich ed., Harvard University Press 2002).

reasons of solidarity and the common good by extending the moral rights in personhood and property to firms.²⁸⁶

Returning a direct royalty stream to the government rather than to individual members of the public could avoid many of the ethical dilemmas noted in Section III.K. *supra*. For example, the discrepancy between payment for contributing samples in cases where research conducted on the samples is profitable and when it is not profitable, or not profitable for many years down the line, is avoided. Also, the direct royalty stream to the government avoids the issue of donors not actually having performed any specific act of competence to create their own DNA. In addition, returning the royalty stream to the government would mitigate, or sidestep altogether, concerns that individuals in disadvantaged circumstances would share proportionally more samples, or, that individuals would be less likely to share samples for altruistic reasons if samples had economic value. Removing such concerns would place more emphasis on the moral duty associated with either solidarity for one's own genetic group, in the case of a significant but less prevalent disease, or the public as a whole, in the case of general public health.²⁸⁷ Returning a revenue stream to the government also avoids the power imbalances, conflicts of interest, and transaction costs involved in negotiating both individual contracts for benefits and contracts between patient advocacy groups and trial sponsors.

A major S&T policy argument in favour of a flow-through royalty stream to government is that government is the party traditionally responsible for the administration of public health. Government administration of the CGR makes good policy and administrative sense, as agencies such as the Department of Human Health Services and Health Canada have accumulated substantial expertise in administering public health matters under their jurisdiction and, thus, would be in an excellent position to receive and re-invest revenues from a CGR mechanism. CGR payments could be implemented in a similar manner to how several U.S. states have put large damage awards from tobacco litigation directly back into health-related research and infrastructure (see *infra*). Relevant government agencies could place similar restrictions on revenues accrued through the CGR stream. Dominant public health agencies, such as the DHHS and Health Canada would likely be in the best position to undertake administer CGRs owing to administrative competency. Statutes or contracts could create the required formal right or interest in commercialized biomedical products, similar to those utilized by technology transfer offices. The U.K. Wellcome Trust is one possible precedent for how contractual rights relating to revenue- and equity-sharing might be accrued in the funded-research context. The Trust is one of the largest charitable sources of funding for biomedical research in the world and has institutionalized the acquisition and exploitation of intellectual property rights arising from the research it funds. Further, it obliges all researchers receiving funds to sign contracts

²⁸⁶ Pullman & Latus, *supra* note 49.

²⁸⁷ Berg, *supra* note 48.

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relating to equity- and revenue-sharing when trust-funded technologies are successfully commercialized.²⁸⁸

Another argument in favour of the CGR model is that governments themselves have placed significant emphasis on the “new innovation economy.” As noted in Section III.B., *supra* the mandates of both the CIHR and NIH clearly demonstrate this emphasis. These mandates, along with those of their parent agencies, represent a fundamental economic driver for health research and public health concerns. Based on the public nature of these mandates, the following assumptions are reasonable: the public now has a legitimate and particularized expectation of “enhanced economic development” arising from health research; that this economic improvement will be specifically directed to “improving the health” of the public, taking into consideration “ethical issues;” and “a transparent approach that facilitates accountability” will characterize such policies and procedures.²⁸⁹ To cut the public out of profits from research it directly and indirectly subsidizes, amounts to unjust enrichment of the private sector according to fundamental principles of justice, equity and good conscience.²⁹⁰ The proposed CGR mechanism would relieve the tension between public and private interests inherent in the founding documents of the NIH and CIHR, and would further operate to alleviate public concerns over mission or monopoly creep as well as those over the potential influence the industry could wield industry in terms of an increased emphasis on public-private partnerships and co-funding requirements for certain research grants.²⁹¹

A particularized public fiscal interest such as a CGR is also grounded in the substantial contributions of public funds towards blockbuster medications. As noted by MIT in its 1995 study of the fourteen drugs identified by pharmaceutical firms as the most medically significant in the last quarter century, eleven, or about 80%, were significantly supported by government

²⁸⁸ See Wellcome Trust-Funded Intellectual Property: Exploitation Consent and Standard Equity/Revenue-Sharing Agreement, § 3, available at <http://www.wellcome.ac.uk/node2310.html> (follow “Wellcome Trust-Funded Intellectual Property” hyperlink) (last visited Dec. 1, 2006).

²⁸⁹ Section III.B.

²⁹⁰ *Greenberg*, 264 F. Supp. 2d, at 1072–73; *Canada v. Farbwerke Hoechst*, S.C.R. 49, 56 [1964] (holding that the Commissioner should scrutinize pharmaceutical patents carefully to determine if they merit the grant of a monopoly privilege specifically because the public interest at stake).

²⁹¹ See Mike Tyers et al., *Problems with Co-Funding in Canada*, 308 SCIENCE 1867-1868 (2005); Wayne Kondro, *Scientists Say Genome Canada’s Co-Funding Rules Stymie Good Ideas*, 309 SCIENCE 232 (2005); Graeme Laver et al., *How Commercialization Puts a Blight on Research*, 412 NATURE 7665 (2001); ROYAL SOCIETY WORKING GROUP ON INTELLECTUAL PROPERTY, KEEPING SCIENCE OPEN: THE EFFECTS OF INTELLECTUAL PROPERTY POLICY ON THE CONDUCT OF SCIENCE (2003), available at <http://www.royalsoc.ac.uk/displaypagedoc.asp?id=11403>.

funding.²⁹² Similarly, the NIH has reported that the public pays for approximately 85% of pharmaceutical research and development efforts.²⁹³ By contrast, approximately half of all monies attributed by pharmaceutical firms to “drug development activities” is spent on marketing. Therefore, based on the scope and depth of such direct and indirect public and government contributions to the large pharmaceutical and biotechnology pipeline, governments have legal, policy, and ethical obligations to ensure in-kind benefit-sharing to the public. This is underscored by the fact that co-funding of public health research represents at least 25% of Canada’s research budget in the biomedical sciences.²⁹⁴ Responsible for collection and administering CGRs, governments would fulfill their end of the moral bargain by constraining overuse of resources in the scientific commons and ensure equitable sharing of benefits between participating users. This would limit deleterious effects of the current biomedical commercialization process on those with the least power and/or ability to adapt. Clearly, the government must also ensure that pharmaceutical and biotechnology firms do not simply raise prices to offset CGRs, thus avoiding a zero-sum outcome for members of the public.

There is some international precedent for the concept of direct revenue-sharing by government via public participation in the commercialization process. The Human Genome Organization (HUGO) has recommended that firms dedicate a percentage of profits from genomic research to maintain local, national or international healthcare infrastructure; or for vaccines, tests, drugs, and other therapeutic treatments as follows:

In the case of profit-making endeavours, the general distribution of benefits should be the donation of a percentage of the net profits (after taxes) to the health care infrastructure or for vaccines, tests, drugs, and treatments, or, to local, national and international humanitarian efforts.

. . . that profit-making entities dedicate a percentage (e.g. 1% - 3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts.²⁹⁵

Although HUGO’s mandate applies in the context of genomic research, and may be read to relate largely to international scenarios, it could be legitimately

²⁹² Gerth & Stolberg, *supra* note 116.

²⁹³ CONTRIBUTIONS TO PHARMACEUTICAL DEVELOPMENT – CASE STUDY ANALYSIS OF THE TOP SELLING DRUGS, NAT’L INST. HEALTH REPORT (2000).

²⁹⁴ Carty, *supra* note 23, at 874.

²⁹⁵ HUGO Statement on Benefit-Sharing, *supra* note 49. A somewhat analogous provision for economic reallocation exists in the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (2002), Articles 49 and 50 of which states that the mechanisms for benefit-sharing may vary depending upon the type of benefits, the specific conditions in the country and the stakeholders involved and may include licences with preferential terms.

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applied to domestic healthcare policy and regulation as well as extended from genetic research to public health research per se. The CGR model is also consistent with HUGO's assertion that justice should underpin a public benefit-sharing interest. First, it fulfils the requirement of compensatory justice, as the public would receive direct recompense in return for its contribution towards biomedical product development. Second, it fulfils the requirement of procedural justice in that the administrative procedures governing the manner in which a CGR is collected and distributed would under law be required to be both impartial and inclusive. Third, it fulfils the requirement of distributive justice via the equitable allocation of benefits arising from commercialization of biomedical inventions, including access to affordable resources and goods. At present, there is significant inequality between the wealthiest and poorest nations in the direction and priorities of research and in the distribution and access to the benefits thereof. Given the vast difference in power between those carrying out research and those participating in it, coupled with the possibility of substantial profit, considerations of justice support the desirability of equitable distribution of profits to respond to public health care needs. As demonstrated by data in Table 1 and Figure 1 above, this applies equally well to large swaths of the public in developed nations.

Another fundamental aspect of the CGR model is that proposed royalty fees could be targeted to improving public health in a manner consistent with the legislation and policy underpinning major funding agencies. Thus, royalty profits ensuing from commercialization of publicly funded biomedical research could be used to fund, and perhaps subsidize, government expenditures relating to the very problems which the products were meant to solve. There is precedent for this type of sector-specific revenue expenditure in North America. In 1998, the United States Attorney General settled out of court with the five largest tobacco manufacturers on all antitrust, consumer protection, common law negligence, statutory, common law, and equitable claims for monetary, restitutionary, equitable, and injunctive relief alleged by several states.²⁹⁶ The settlement amount of \$206B, was to be distributed over 25 years. According to a survey by the National Conference of State Legislatures, most of the money from the settlement was allocated specifically for healthcare expenditures.²⁹⁷ At that time, 41 states spent or were considering spending the money, which was seen to represent recovery of *public* health costs of treating tobacco-related illnesses arising from smoking, to finance public health

²⁹⁶ JOY JOHNSON WILSON, SUMMARY OF THE ATTORNEYS GENERAL MASTER TOBACCO SETTLEMENT AGREEMENT (1999), *available at* <http://academic.udayton.edu/health/syllabi/tobacco/summary.htm>.

²⁹⁷ Maureen Cosgrove, *States Favor Healthcare In Spending Tobacco Settlement*, March 22, 2000, <http://www.stateline.org/live/ViewPage.action?siteNodeId=136&languageId=1&contentId=13967>.

research, primary care, community health centers, reimbursing hospitals for treating the uninsured, expansions of Medicaid and Children's Health Insurance Programs, the federal-state partnership to insure poor children not covered by Medicaid, and other health-related programs.²⁹⁸

A CGR mechanism is also consistent with the "global public good" model,²⁹⁹ which posits that efficient public health funding by federal governments is aimed at promoting truly public health issues, particularly those which satisfy concomitantly domestic and global health concerns. That is, the public should share directly in benefits gained from their fiscal participation in developing innovator knowledge bases (tacit, codified) and resulting commercial product lines. Indeed, Pullman and Latkus have supported direct benefit-sharing based on ethical considerations flowing from consensual use of human bodies for commercial research, and because such use is typically grounded in reasons of altruism, solidarity and the public good.³⁰⁰ Suggested schemes include fees or in-kind benefits such as employment or shared use of facilities by publicly funded researchers. The authors correctly point out, however, that such benefits should be directed to the improvement of public health, whether in the form of improved access or contribution to infrastructure costs.

A direct pecuniary interest to government for specific allocation to healthcare infrastructure and expenditures would also help to alleviate the substantial degree of public mistrust which has evolved during the last decades over large profits made by multinational firms and the degree of malfeasance by such firms in pursuing the largest bottom line possible notwithstanding the risks entailed to human health.³⁰¹ In another context, Jasanoff noted that a major limiting trend in supporting the public interest in commercialization is that courts have tended to favour economic agents over those forwarding ethical claims.³⁰² The results in *Moore*, *Greenberg* and *Catalona* are exemplary of this limitation. These decisions have placed serious practical restrictions on ethical claims made to commercialization of biomedical technologies to the extent these precedents are followed in the United States and other jurisdictions. The corollary of this however is that the public has a better claim to a direct pecuniary interest in relation to the CGR model.

Finally, a CGR may have indirect effects to mitigate concerns over erosion

²⁹⁸ Maureen Cosgrove, *States Favor Healthcare in Spending Tobacco Settlement*, STATELINE.ORG, Mar. 22, 2000, available at <http://www.stateline.org/live/ViewPage.action?siteNodeId=136&languageId=1&contentId=13967>.

²⁹⁹ Bovenberg, *supra* note 60, at 932; *see also supra* Section III.H.

³⁰⁰ Pullman & Latus, *supra* note 49, at 243.

³⁰¹ *See generally* GRAEME LAURIE, *GENETIC PRIVACY: A CHALLENGE TO MEDICO-LEGAL NORMS* (Cambridge University Press 2002); Lemmens, *supra* note 29, at 645-48; Lemmens & Bouchard 2007a, *supra* note 75, at 334-341.

³⁰² Jasanoff, *supra* note 8, at 897.

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of the scientific commons. At worst, the model should be neutral regarding erosion and/or inversion of the commons. A closer look however, suggests that a guaranteed royalty stream may indeed have positive effects on the commons due to the effects on the bottom lines of all patentees, including those at universities and firms, and the desire of such players to avoid such costs where economically efficient. In particular, firms and universities would be incented to patent more efficiently, which would in turn (a) decrease numbers of both upstream and downstream patents, (b) reduce the transaction costs to firms and the public flowing from commercial innovation, and (c) increase the proportion of tacit and, particularly, codified knowledge in the public domain, which would in turn be freely accessible and appropriable for both public use and further innovative efforts on behalf of firms. As noted by Pressman et al. in their recent study of university licensing practices, the significant reduction of issued patents containing claims to DNA sequences since 2001 reflects an understanding by those responsible for technology transfer that hefty patent costs will not always be recouped when too many technologies are patented.³⁰³ In turn this has led to greater selectivity and reduced transaction costs. Thus, CGRs may limit erosion of the commons and/or restrict development of an anticcommons.

D. Limited Impact of Compulsory Government Royalty on Firms

While the concept of a CGR may at first glance seem an attack on firm³⁰⁴ bottom lines, there would likely be less cause for worry than first meets the eye. In addition to the very low percentage of patents that are actually valuable, one of the most pragmatic ceilings on the fiscal impact of the CGR model is the claim that the majority of true firm innovations arise not from publicly funded research but rather from in-house research and development activities.³⁰⁵

According to Pavitt, despite policies in the majority of developed countries encouraging publicly funded research, the majority of evidence for true growth and productivity is not in the basic-to-applied direction (university to firm) but rather the other way around.³⁰⁶ Rather, most evidence points to causal guidance by firms, through publication of knowledge and disclosure of products, to universities in order to signal important areas where innovation is needed and products required by the public. Thus, the main resource allocation from universities to firms is tacit, rather than codified, knowledge, though both are likely to be important in certain industries such as

³⁰³ Lori Pressman et al., *The Licensing of DNA Patents by U.S. Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECHNOLOGY 31, 39 (2006).

³⁰⁴ All arguments in this section apply to any for-profit entity, including firms, university technology transfer offices, researchers and university spin out firms.

³⁰⁵ See Pavitt, *supra* note 57, at 12698.

³⁰⁶ *Id.* at 12694.

biotechnology.³⁰⁷ Indeed, as underscored by both Pavitt and Nelson, national economic spillovers from publicly funded research have been very difficult to identify. This is in line with data from a recent survey of 414 biomedical researchers in the United States showing that despite apparently large licensing revenues generated by universities (\$1B in FY 2002)³⁰⁸ industry funding to universities represents only 4% of their total research budget,³⁰⁹ and the \$1B figure noted above represents under 0.5% of the total revenue and grant income of approximately \$230B.³¹⁰ Moreover, very few institutions have in fact shared in the \$1B revenue basket (\$1.4 in 2004). In FY 2000 for example, five of hundreds of universities with technology transfer offices accounted for \$570M of the \$1.26B in licensing revenues.³¹¹ As noted by Pavitt, this understanding of the relationship between public and private firms in the evolution of technological progress has existed for some time. Both de Tocqueville and Marx understood that technological advances in the early 19th and 20th centuries formed the essential driver for basic research knowledge, as well as resources, techniques, and data for its execution.³¹²

The reach of CGRs for firms could also be limited by tying royalties to product patents as opposed to process patents,³¹³ or those on upstream technologies.³¹⁴ These solutions would have the reciprocal effect of enhancing the commons while increasing network externalities due to reinvigorated upstream spillovers and therefore the overall efficiency of the innovation-product life cycle. Indeed, to the extent that entrenched patent rights lead to weaker incentives for holders of broad patent portfolios,³¹⁵ a renewed focus on truly novel product patents would presumably reduce sub-optimal social outcomes. It would also increase economic efficiencies by providing increased incentives not only for “would-be entrants” but also for relatively entrenched firms by shifting innovative emphasis away from “line” extensions towards truly innovative products. Similarly, by limiting patent scope narrowly to the invention disclosed (and away from upstream patents directed more to research tools, techniques, or principals; in other words, content historically rooted in the scientific commons), the PTO and the courts may significantly curtail fiscal outlay by firms on CGRs. Guidance from the PTO and the courts would

³⁰⁷ Wolfe et al., *supra* note 86.

³⁰⁸ Triggles, *supra* note 25, at 142.

³⁰⁹ Walsh, Cho, & Cohen, *supra* note 24, at 2.

³¹⁰ Triggles, *supra* note 25, at 142.

³¹¹ ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, AUTM LICENSING SURVEY: FY 2000 (2001), <http://www.autm.net/about/dsp.pubDetail2.cfm?pid=19>.

³¹² Pavitt, *supra* note 57, at 12694.

³¹³ See Merges & Nelson, *supra* note 138, at 14.

³¹⁴ See Heller & Eisenberg, *supra* note 53, at 699.

³¹⁵ See Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention* in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS, 609, 619 (National Bureau of Economic Research ed., 1962).

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impact not only on the transaction costs of patents held by firms but also those licensed from universities. In theory, this would almost certainly result in increased economic efficiency of the innovation-product system due to greatly decreased transaction costs and mitigated risk allocation to competitors on both weak and overly broad patents. Under these conditions, royalties could be viewed as an efficient investment and incentive towards truly innovative product development activities.

The closing argument offered in favour of limiting the impact of CGRs on for-profit entities is that most patents are widely understood to have little value. This phenomenon is not an inefficiency of the patent system, but rather inherent to the innovation process itself.³¹⁶ This is because the impact of a new idea or discovery cannot be known with reasonable certainty until well after it has been devised and because commercial significance depends strongly on subsequent technological and economic input. The difference between the continual flow of patent applications from would-be inventors and those that are actually profitable is due to at least two types of inherent attribution bias that increase the transaction costs of innovation. The first bias arises because people generally tend to over-estimate the likelihood that low probability events will in fact occur.³¹⁷ As noted by Heller and Eisenberg, potential patentees with more of a deterministic perspective rather than those with a more probabilistic one (as would be true of at least a majority of scientists working today) would be more likely to make this error.³¹⁸ The second bias is that people generally tend to overvalue their assets while concomitantly undervaluing those of competitors, resulting in an increased tendency to patent inventions that have little hope of achieving commercial success.³¹⁹

V. SUMMARY & CONCLUSIONS

There is little question that substantial benefits accrue to society from biomedical research. It is questionable, however, whether these benefits are distributed equitably between the parties responsible for generating, capitalizing and consuming the products of such research. I submit that the benefits from publicly funded research are not equitably distributed amongst public and private interests, and that there are several reasonable grounds on which to base a claim for a direct economic interest in profits realized from commercialization of publicly funded biomedical research. Included are the substantial breadth of fiscal and other contributions by the public and government to the commercial biomedical pipeline, erosion, and/or inversion

³¹⁶ See JAFFE & LERNER, *supra* note 7, at 33.

³¹⁷ See Amos Tversky & Daniel Kahneman, *Advances in Prospect Theory: Cumulative Representation of Uncertainty*, 5 J. RISK & UNCERTAINTY 297, 316 (1992).

³¹⁸ See Heller & Eisenberg, *supra* note 53, at 701.

³¹⁹ Cf. Darrin R. Lehman et al., *The Effects of Graduate Training on Reasoning: Formal Discipline and Thinking About Everyday-Life Events*, 43 AM. PSYCHOLOGIST 431 (1988).

of the intellectual commons that otherwise works to the benefit of the public, the lack of property or other legal interest in clinical trial data and donated tissues and the uses to which these are put, the lack of access to affordable biomedical therapies, disequilibrium of fiscal benefits arising from commercialization to public and private parties, ethical and political grounds and obligations supporting benefit-sharing, and the fact that changes to legislation or regulatory provisions facilitating operation of the current commercialization regime are unlikely. The outcome of this analysis is that the public assumes a majority share of the risks and economic inefficiencies of the current commercialization regime, and that patentee firms and universities retain the lion's share of the fiscal rewards and economic efficiencies of commercialization.

It was argued that given public and private interests in the scientific commons are in opposition to one another by operation of relevant intellectual property law that there is tension between these interests to the extent that technologies underwritten by the public are successfully commercialized and the benefits are not equitably distributed amongst public and private actors responsible for commercialization. This apparent tension extends to governments who attempt to fulfill their traditional gatekeeper function at the same time as facilitating industrial commercialization and to universities who continue to maintain their newly gained fiscal and intellectual property interests in the commercialization arena while at the same time espousing their traditional public interest function and norms. It is therefore necessary for the public to both recognize that it has a legitimate and particularized economic interest in commercialization and take active steps in order to ensure this interest is respected. Given difficulties in locating practical and principal grounds in the notion of direct benefit-sharing by individual members of the public, it was posited that the more legitimate route to safeguard a public interest would be that direct fiscal benefits be returned to government on successful commercialization of publicly funded biomedical technologies, and that the appropriate vehicle would be a CGR, or compulsory government royalty.

The CGR model has several additional advantages in that it avoids ethical dilemmas inherent in commoditizing research participation, is consistent with the stewardship and constitutional obligation of national governments to administer public health and fulfill the mandates of their primary funding agencies to ensure the public's now administratively, if not legislatively, particularized expectation of direct economic gains and improved public health in the context of publicly funded biomedical research. The proposed CGR is also consistent with a global public good model in that a portion of profits realized from publicly funded biomedical research are returned directly to promote public health. Finally, the CGR model may work to mitigate the significant level of public mistrust that has developed in recent years in relation to firms and, increasingly, their university patent-holding counterparts.

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It is unlikely that the tide of privatization of medical research will abate any time soon. The degree to which governments participate in the process however will depend on answers to a series of deeply existential questions for the public health branch of national governments, beginning with- is the primary function of the agency to protect the public? Is it to stimulate the economy through health research commercialization? And, if both, where does the balance lie on the scale of public to private concerns? The answer to this third question will dictate the direction of future privatization efforts, whether and how benefits from privatized research should be equitably distributed, as well as the degree of risk assumed by the public should governments vacate their traditional consumer protection role in favour of economic development. It will also determine the degree to which agencies become dependent on industry for the development and implementation of regulatory policy. This may be a poignant concern for governments such as those of Canada, the United Kingdom, France and other jurisdictions which lack the cultural, fiscal and human resources necessary to underpin a more arm's length litigious relationship between government and industry such as that in the United States.³²⁰ Given the scope of frustrations expressed over perceived inequities in benefit sharing, it is becoming increasingly possible that the current commercialization regime constitutes policy failure from a truly public health perspective.

Consequently, whether there is a new social contract regarding the scientific commons or the nascent nature of the old contract has simply been revealed for what it is by recent developments in domestic and international patent law and S&T policy, it has become obvious that all interested parties must adjust to the new commercialization landscape. This includes governments as well as the publics' own perception of its pecuniary and legal rights and interests in commercialization of biomedical technologies. If governments fail to so adjust, and to do so in a manner that fails to respect the various forms of public input and risk assumption *viz* the commercialization process, it is reasonable to assume that they should be held accountable for their actions.

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³²⁰ Mary E. Wiktorowicz, *Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain and France*, 28 J. HEALTH POL. POL'Y & LAW 615 (2003).

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