

KSR v. TELEFLEX PART 2: IMPACT OF U.S SUPREME COURT PATENT LAW ON CANADIAN AND GLOBAL SYSTEMS-BASED INNOVATION ECOLOGIES

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I say unto you: one must still have chaos in oneself to be able to give birth to a dancing star. I say unto you: you still have chaos in yourselves.

Zarathustra

I. Introduction

In the companion article,¹ the impact of the decision by the Supreme Court of the United States (SCOTUS) in *KSR v. Teleflex (KSR)*² on the Canadian intellectual property and regulatory (IPR) rights landscape was discussed in relation to the current medical research enterprise.³ A number of claims were made as to why patent jurisprudence handed down by SCOTUS is important for scholars of Canadian health law and policy, including (1) economic and trade considerations for Canadian inventors and firms; (2) issues revolving around the importance of IPR rights to a system of state-sponsored public

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1 Ron A. Bouchard, "KSR v. Teleflex Part 1: Impact of U.S Supreme Court Patent Law on Canadian Intellectual Property and Regulatory Rights Landscape" (2008) 15 Health L. J. (221).

2 *KSR International v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) [*KSR*].

3 For a review of the author's work on topic see Ron A. Bouchard, "Balancing public and private interests in the commercialization of publicly funded medical research: Is there a role for compulsory government royalty fees?" (2007) 13(2) B.U.J. Sci. & Tech. L. 120; 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?" (2007) 6(1) C.J.L.T. 1; Ron A. Bouchard, "Living Separate and Apart is Never Easy: Inventive Capacity of the PHOSITA as the Tie that Binds Obviousness and Inventiveness" (2007) 4 University of Ottawa Law & Technology Journal 1.

health, including determination of the availability, price, and safety and efficacy of medical products, as well as the distribution of the tangible and non-tangible benefits of commercializing medical research among various public and private actors responsible for generating, capitalizing and marketing the products of that research; and (3) the importance of institutional structures underpinning IPR rights afforded to medical inventions from a global perspective. This article discusses a fourth set of reasons, namely that decisions by a global patent court of prominence such as SCOTUS have the potential to significantly affect the rate and direction of innovative activity of Canadian inventors and firms through the continually evolving nature of the relationship between large-scale IPR rights, national science and technology (S&T) policies meant to stimulate innovation, and the inherently spontaneous emergent characteristics of innovation⁴ and those responsible for it in IPR rights-intensive sectors.

Large scale S&T-based legal and regulatory regimes are crucial for inventors and firms working within innovation-intensive industries.⁵ This is particularly true in relation to domestic policies having as their objective enhancement of national competitiveness and productivity via commercialization of publicly funded research,⁶ which often single out biomedical and

4 As used here, the term “innovation” encompasses activities from the lead-up to invention, the moment of invention and all subsequent actions relating to product development and commercialization. Invention is subsumed within innovation, and constitutes only a small fraction of the risks and uncertainties encompassed by the latter. See Joseph A. Schumpeter, *Capitalism, Socialism, and Democracy*, 1st ed. (New York: Harper & Brothers, 1942) at 106; Edmund Kitch, “The nature and function of the patent system” (1977) 20 *J.L. & Econ.* 265 at 267-268. Nelson & Winter state: the act of invention creates a new product or process, whereas the broader act of innovation includes the work necessary to revise, develop, and bring that new product or process to commercial fruition. See Richard R. Nelson & Sidney G. Winter, *Evolutionary Theory of Economic Change* (Cambridge, Mass.: Belknap Press, 1982) at 262.

5 David J. Teece, “Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing and Public Policy” (1986) 15 *Research Policy* 285; 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” (2006) 35 *Research Policy* 1110.

6 Institute for Competitiveness & Prosperity, *Reinventing Innovation and Commercialization Policy in Ontario* (2004), online: <http://www.competeprosper.ca/images/uploads/release_071004.pdf>; Conference Board of Canada, *Six Quick*

life sciences sectors as fertile policy targets.⁷ Indeed, it has been suggested that commercialization-based S&T policies, legislation and initiatives provided both the foundation and fuel for the global biotechnology revolution.⁸ Therefore, to the extent that Canadian domestic IPR rights are out of line with IPR rights on a more global scale, they have the potential to harm local inventors and corporations seeking to market innovative products globally.⁹ As such, Canadian inventors do not operate within purely a local or narrow sphere, but rather are embedded within a complex global network of scientific, medical, legal, regulatory, economic, political and other social actors that – combined – act to produce, construct and use the products of scientific advances,¹⁰ including those within the medical sciences rubric.¹¹ It

Hits for Canadian Commercialization: Leaders' Roundtable on Commercialization by Brian Guthrie & Trefor Munn-Venn (Ottawa: Conference Board of Canada, 2005); Expert Panel on Commercialization, *People and Excellence: The Heart of Successful Commercialization*, vol 1 (Ottawa: Public works and Government Services, 2006) (Chair: Joseph L. Rotman); National Governors Association, *Innovation America: A Final Report* by Erika Fitzpatrick (Washington, D.C.: National Governors Association, 2002); Council on Competitiveness, *Innovate America: National Innovation Initiative Summit and Report* (Washington, D.C.: Council on Competitiveness, 2006); Council on Competitiveness, *Five for the Future* (Washington, D.C.: Council on Competitiveness, 2007).

7 E. Zerhouni, "The NIH Roadmap" (2003) 302(3) *Science* 63; Alan Bernstein, "Toward effective Canadian public-private partnerships in health research" (2003) 168(3) *Canadian Medical Association Journal* 288; U.S. Food and Drug Administration, *Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products* (Washington, D.C.: U.S. Department of Health and Human Services, 2004); Health Canada Health Products and Food Branch, *Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food* (Ottawa: Health Canada, 2006), online: <http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/hpfb-dgpsa/blueprint-plan_e.pdf>.

8 Bhavan N. Sampat, "Patenting and US Academic Research in the 20th Century: The World Before and After Bayh-Dole" (2006) 35 *Research Policy* 772 at 777; Bouchard "Balancing," *supra* note 3.

9 *Supra* note 1 at Sections III A, III B.

10 Bruno Latour, *Science in Action: How to Follow Scientists and Engineers Through Society* (Cambridge, Mass.: Harvard University Press, 1987); Sheila Jasanoff, ed., *States of Knowledge: The Co-Production of Science and Social Order* (London: Routledge, 2004).

11 Bouchard "Living," *supra* note 3.

is for this reason that creative acts underpinning innovation are increasingly being viewed as emanating from a complex “innovation ecology.”

As discussed in more detail below, the conceptual framework of an innovation ecology is encompassed and informed by the broader systems theory framework.¹² Wulf recently defined an innovation ecology as the various “interrelated institutions, laws, regulations and policies” necessary to underwrite successful commercialization of publicly funded research through an “infrastructure that entails education, research, tax policy, and intellectual property protection, among others.”¹³ As such, IPR rights form the linchpin between innovative medical research and the marketing and consumption of approved medical products. Casting the innovation landscape as a complex organic ecology rather than the historical linear model of basic-to-applied research is wholly consistent with newer conceptual and analytical models such as complex adaptive systems,¹⁴ network dynamics¹⁵ and systems dynamics,¹⁶ which view and model systems as a dynamic, adaptive and indeterminate network of nodes where the behavior of the system as a whole is governed by the ever-changing and non-linear nature of the con-

12 Ludwig von Bertalanffy, “An Outline of General System Theory” (1950) 1 *British Journal for the Philosophy of Science* 134; Ludwig von Bertalanffy, *General System Theory: Foundations, Development, Applications* (New York: George Braziller, 1968).

13 William Wulf, “Changes in Innovation Ecology” (2007) 316 *Science* 1253.

14 Per Bak & Ken Chen, “Self-Organized Criticality” *Scientific American* (January 1991) 46; Nicolis Gregoire & Ilya Prigogine, *Exploring Complexity* (New York: W.H. Freeman, 1990); M. Mitchell Waldrop, *Complexity: The Emerging Science At The Edge Of Order And Chaos* (New York: Simon and Schuster, 1992); Stuart Kauffman, *At Home In The Universe: The Search For The Laws Of Self-Organization And Complexity* (New York: Oxford University Press, 1995); Steven Johnson, *Emergence: The Connected Lives of Ants, Brains, Cities and Software* (New York: Simon & Shuster, 2003).

15 Albert-Laszlo Barabasi, *Linked* (New York: Penguin, 2002).

16 Jay W. Forrester, “Learning Through Systems Dynamics as Preparation for the 21st Century” (Keynote Address, Systems Thinking and Dynamics Modeling Conference, Concord Academy, Concord Me., 27-29 June 1994), online: <http://www.clexchange.org/ftp/documents/shyk12sd/Y_1994-075DAsPrepFor21stCen.pdf>; John D. Sterman, *Business Dynamics: Systems Thinking and Modeling for a Complex World* (Homewood, Ill.: Irwin/ McGraw-Hill, 2000); Jack B. Homer & Gary B. Hirsch, “Systems dynamics modeling for public health: Background and opportunities” (2006) 96(3) *American Journal of Public Health* 452.

nections between actors and institutions rather than as a predictable sum of a set of linear deterministic nodes.¹⁷

One implication of the systems view discussed above is that smaller domestic innovation ecologies are collapsing globally due, among other things, to the global reach of decisions like *KSR*, harmonization of regulatory standards,¹⁸ adoption of international intellectual property instruments such as the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and convergence of national S&T policies in order to reproduce the success of university technology transfer and commercialization in the United States.¹⁹ In this light, domestic patent legislation and appellate jurisprudence that diverges from that of other nations seeking to capitalize on their S&T bases may harm the global patenting strategies and marketing efforts not only of multinationals engaged in local biomedical product development, but also of domestic firms and inventors seeking to capitalize on publicly funded medical research globally. IPR rights of this nature also carry significant weight in determining what type of healthcare products, devices and screening procedures become available to the public, when and on what scope they become available, how much they cost, and the reach of innovative domestic products, firms and clinical research into the global market. A more subtle, but potentially more important, consideration is that reduced domestic standards for patentability and product regulation may – paradoxically – inhibit truly creative activity in a complex innovation system, either by privileging less innovative forms of activity protected by IPR rights or via national S&T policies that have as their object the “fencing in” or controlling of otherwise open and creative innovative activity as part of prevailing economic models of science-based domestic productivity. The ironic result of this scenario is that innovation might be stifled by the very policies meant to stimulate it.

17 For a general discussion of the application of systems theories to law, see Lynn LoPucki, “The systems approach to law” (1996) 82 Cornell L. Rev. 479; J.B. Ruhl, “The fitness of law: Using complexity theory to describe the evolution of law and society and its practical meaning for democracy” (1996) 49 Vand. L. Rev. 1407; J.B. Ruhl, “Regulation by adaptive management: Is it possible?” (2005) 7(1) Minnesota Journal of Law, Science and Technology 21 (and references therein).

18 Health Canada Health Products and Food Branch, *supra* note 7.

19 Sheila Jasanoff, “The Life Sciences and the Rule of Law” (2002) 319 Journal of Molecular Biology 891.

II. Implications for Canadian and Global Innovation Ecology

A. Innovation as Example of General Systems Ecology

We have seen that, to the degree that Canadian patent jurisprudence is out of line with that of the United States, or on a more global scale, it has the potential to harm Canadian inventors and corporations seeking to market innovative products globally.²⁰ All this is fairly obvious. Less obvious however, is how the push-pull between the relatively narrow concepts of inventiveness and obviousness in relation to patent law may impact the general pattern, frequency and scope of innovative activity by persons skilled in the art of medical research, and, paradoxically, how a *lower* bar for patentability of medical inventions might actually inhibit innovative activity, not just locally but globally. As discussed elsewhere,²¹ the role of large and complex legal and regulatory systems in setting the tone for domestic and global patterns of innovation and appropriability cannot be overestimated.

The term “ecology” was conceived in the late 19th century by the German zoologist Ernst Haeckel,²² and in its present day usage refers to a branch of science concerned with the existence and nature of the interrelationship of organisms with their environment as well as the totality of relations among them. With an eye to complexity theory, cast either as a science-based complex adaptive system or an actor-network theory grounded in the social sciences, we might recast the latter as a dynamic network of interrelated nodes with adaptive self-organizing properties, where the behaviour of the whole is greater than the sum of its linear parts. All three usages are relevant to the present discussion, and indeed all three are collapsed into that of “systems ecology” which encompasses the multitude of interactions and transactions within and between biological and ecological systems.

Systems ecology is primarily concerned with the manner in which the behaviour of ecosystems on a macro level can be understood, influenced and possibly controlled, at least in part, by human intervention. For the

20 Bouchard, *supra* note 1 at Sections III B, III C.

21 *Supra* note 5.

22 For a general discussion of Haeckel and ecology, see Wikipedia, “Ernst Haeckel,” online: Wikipedia <http://en.wikipedia.org/wiki/Ernst_Haeckel>; Wikipedia, “Portal: Ecology,” online: Wikipedia <<http://en.wikipedia.org/wiki/Portal:Ecology>>.

present purpose, this would include large legal and regulatory systems impacting innovation such as national and international IPR rights and S&T-based policies, but also, on a more human scale, the inherent creativity and inventive nature of people skilled in the art of technologies comprising the larger innovative system. Importantly, a systems approach to innovation encompasses and extends concepts and methodologies from what were once considered disparate and unrelated disciplines. This includes the leveraging of new technologies such as complex computer networks and high performance computing (HPC) technology in order to develop mathematical models of systems historically viewed as being too complex to quantify.²³ A parallel framework has been applied in the context of biological and medical research, referred to as systems biology. A systems approach to innovation differs greatly from earlier models of “basic” and “applied” research, where science was seen to be either in pursuit of fundamental knowledge or as reduction to practice, and where ideas were linearly translated from one discrete category to the next, following which they were transformed into marketed products.

Important to the present discussion is that systems models differ substantially and substantively from conventional S&T models focusing on discrete individuals, structures and policy vehicles separated from the whole. This has profound implications for the legal and regulatory institutions that underpin innovation. Rather than focusing on discrete network nodes, systems models recognize and indeed privilege the *interrelationships* and *interdependence* between nodes, such as those between individuals, groups and institutions, accepting expressly that it is the sum of the interaction between these elements that characterizes an organization’s function. For this reason, systems theories have been very useful in managing corporations.²⁴ As noted elegantly by Stokes,²⁵ the shift in analytical focus from discrete parts

23 C. F. Kurtz & D. J. Snowden, “The new dynamics of strategy: Sense-making in a complex and complicated world” (2003) 42 IBM Systems Journal 462; Robert A. Este, “The Necessity of Conceptual Skill Enhancement to Address Philosophical Challenges of New Science: Background and Implications” (Paper presented at the International Conference on Complex Systems, New England Complex Systems Institute, Boston, October 2007) [unpublished].

24 Peter M. Senge, *The Fifth Discipline: The Art and Practice of the Learning Organization* (New York: Doubleday, 1990).

25 Donald E. Stokes, *Pasteur’s Quadrant: Basic Science and Technological Innovation* (Washington, D.C.: Brookings, 1997).

to the functioning of the organization as a whole has the effect of unpacking and explicating conceptual models as well as their historical successes and failures. Taking a broader view of the functioning of the system as a whole led Stokes to question linear models of innovation, to underscore the importance of bidirectional flows of knowledge synthesis and translation within and between nodes and to criticize overly simplistic models of innovation which viewed research as either "basic" or "applied" and where knowledge moved only unidirectionally from the basic to the applied stage.

Systems theory generally, and any derivation thereof that would apply to an innovation ecology rooted in S&T policy, sees these interactions not as a static closed system, but rather as a continually evolving dynamic and open process. The acceptance of conceptual models privileging open systems with dynamic interactions within the system and between the system and its environment has occurred only recently²⁶ and involves a fundamental shift from absolute universal principles, methods and models of knowledge synthesis to epistemological models that are relative, contingent, and general in nature.

B. Ramifications of Strong IPR Rights for a Systems Approach to Innovation

That open systems represent dynamically evolving processes that continually exchange both tangible and non-tangible resources (creative ideas, energy, people, capital, information, etc.) with their environment has obvious implications for an innovation ecology rooted in constrained, bounded or otherwise "fenced in" IPRs, yet which is contingent upon the inventive capacity of persons skilled in the art of innovation in a given field. In an important sense the closed nature of strong IPR rights regimes underpinning innovation contrasts significantly with the largely unconstrainable spontaneous, creative, adaptive and emergent properties of its constituent elements, particularly individuals, but also the entirety of the innovation ecology.

The importance of innovation and the translation of new ideas to firms on open systems of knowledge creation and translation has been recognized by prominent patent scholars and economists, among them Keith Pavitt, Richard Nelson and Giovanni Dosi.²⁷ This refers largely to the creation and

26 K.D. Bailey, *Sociology and the New Systems Theory: Toward a Theoretical Synthesis* (New York: State of New York Press, 1994); *supra* note 15; Paul W. Glimcher, *Decisions, Uncertainty and the Brain* (Cambridge, Mass.: M.I.T. Press, 2003).

27 Keith Pavitt, "National Policies for Technological Change: Where are the In-

disclosure of new knowledge to the public for use by other researchers working in that and other fields and for uptake by firms in the context of their product development activities. In addition to providing stimuli for further knowledge-driven research, an open system of innovation also encompasses what Stokes called practical “considerations of use.”²⁸ The latter term refers to the creation of new knowledge in response to a socially recognized need, such as new medical or information technology products. Consequently, the bidirectional flow of tacit and focal knowledge via the vector of public disclosure is necessary for innovation to occur in an open system. In the context of the current medical research enterprise, this would include both publicly-funded university researchers working to advance medical and scientific knowledge, as well as persons skilled in the art of medical product development in firms. Implicit is that neither publicly funded research nor firm employees are privileged from a general systems theory perspective. This is because both groups of innovators are needed in the long run to develop true breakthrough products that benefit society from a broad structural and functional perspective due in no small measure to the substantial costs and risks of medical product development.

Owing to their constrained nature, opposing the concept of an open system of innovation is the argument,²⁹ applied broadly to commercializa-

creasing Returns to Economic Research?” (1996) 93 Proceedings of the National Academy of Science 12693 at 12695; Richard R. Nelson, “The Advance of Technology and the Scientific Commons” (2003) 361 Philosophical Transactions of the Royal Society of London 1691 at 1692, 1697; Roberto Mazzoleni & Richard R. Nelson, “The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate” (1998) 27 Research Policy 273 at 280; Dosi, Marengo & Pasquali, *supra* note 5; Mariana Mazzucato & Giovanni Dosi, eds., *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech* (Cambridge: Cambridge University Press, 2006); Luigi Orsenigo, Giovanni Dosi & Mariana Mazzucato, “The pharma-biotech sector: Policy issues” in Mariana Mazzucato & Giovanni Dosi, eds., *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech* (Cambridge: Cambridge University Press, 2006) 402.

28 *Supra* note 25; see also Donald Stokes, “Completing the Bush Model: Pasteur’s Quadrant” (Paper presented at the Science the Endless Frontier 1945-95: Learning from the Past, Designing for the Future Conference, Center for Science, Policy and Outcomes, Columbia University, 9 December 1994), online: <<http://www.cspo.org/products/conferences/>> at 3, 6, 8-9 and 12.

29 Kenneth J. Arrow, “Functions of a theory of behavior under uncertainty” (1959) 11 *Metroeconomica* 12; Kenneth J. Arrow, “The Economic Implications of

tion-based S&T policies, that broad and inclusive IPR rights are not just sufficient but necessary to motivate innovation. Economic arguments of this nature permeate contemporary policy and political discussions of innovation,³⁰ in no greater form than those relating to national productivity and prosperity agendas in the context of globalization.³¹ It is often claimed in this context that IPR rights are particularly important for the life sciences owing to the sensitivity of medical inventions to patent and regulatory protection.³² If we accept this assumption, then it becomes important to ask: what are the implications of an open systems ecology framework for constrained IPR rights (including large legal and regulatory systems and national S&T-based policies underpinning them) in light of the spontaneous, emergent, adaptive and continually changing nature of a systems-based innovation ecology?

One of the important elements of a successful innovation ecology is the presence of persons skilled in the art of medical research who are inherently creative and inventive.³³ Given that the majority of breakthrough medical discoveries are highly serendipitous, the development and synthesis of new forms of knowledge (particularly under circumstances where the conceptual models for analyzing that knowledge are themselves highly creative and inventive in nature) cannot be fully mandated or controlled from a systems

Learning by Doing" (1962) 29 *Review of Economic Studies* 155; Kenneth J. Arrow, "Economic welfare and the allocation of resources for inventions" in R.R. Nelson, ed., *The Rate and Direction of Innovative Activity: Economic and Social Factors* (Princeton: Princeton University Press, 1962); Richard R. Nelson, "The simple economics of basic economic research" (1959) 67 *Journal of Political Economy* 297; Richard R. Nelson & Sidney G. Winter, *An Evolutionary Theory of Economic Change* (Cambridge, Mass: Harvard University Press, 1982).

30 See for example, Dosi, Marengo & Pasquali, *supra* note 5 and Barry Bozeman, "Public Value Failure: When Efficient Markets May Not Do" (2002) 62 *Public Administration Review* 145; Barry Bozeman & Daniel Sarewitz, "Public Value and Public Failure in United States Science Policy" (2005) 32 *Science & Public Policy* 119.

31 *Supra* note 6.

32 Mazzucato & Dosi, *supra* note 27.

33 Rebecca Eisenberg, "Obvious to whom? Evaluating inventions from the perspective of the PHOSITA" (2004) 19 *Berkley Tech. L.J.* 885; Arti K. Rai, "Regulating scientific research: Intellectual property rights and the norms of science" (1999) 94(1) *Nw. U.L. Rev.* 77; Bouchard "Should," "Living," *supra* note 3. The inherent creativity of the PHOSITA was explicitly recognized by SCOTUS in *KSR* (at 4, 14 and 17).

perspective. On the contrary, new forms of knowledge arise spontaneously in an emergent manner that is continually and dynamically adaptive to their surroundings, no matter how many “interested parties” are invested in the construction, production and use of that knowledge.³⁴

The more rules one attempts to force on the system, particularly those geared to control behaviour at the bottom level of organizational hierarchies (i.e., the people primarily responsible for producing new knowledge and synthesizing it into new products), the more the creative character of the system may be pulled into inefficient forms from the perspective of maximizing the system’s fitness.³⁵ In other words, the more overbearing the legal and regulatory systems used to “harness,” “facilitate,” “leverage” or otherwise control invention and/or innovation, the less actual invention and/or innovation may ensue. One potential consequence of this may be that attempts to over-regulate an inherently uncertain system may result in inefficient behaviour of the system that contradicts its stated objective. Inefficiency need not rise to the level of policy failure;³⁶ rather it could simply constitute highly inefficient operation of the system in view of the desired policy goal. One means by which inefficiencies of this nature may occur is where a controlled system allows (usually by ignorance or under-sight) for “escape” of energy within the system away from the desired goal towards less innovative, less resource heavy yet more constrained pathways that benefit discrete actors and institutions rather than the overall system. It would not matter whether escape occurs as a result of a lack of true innovative creativity or of a responsive and targeted corporate intellectual property strategy. Rather, the focus is on the impact of top-heavy regulation and the notion that escape occurs as a

34 *Supra* note 10. Even Brian Arthur in his effort towards a cohesive theory of invention (W. Brian Arthur, “The Structure of Invention” (2007) 36(2) Research Policy 274, at 284) acknowledges that for a highly incremental and recursive process of invention, invention is nevertheless “subject to the vagaries and timing of the discovery of new phenomenon, of the appearance of new needs, and of the individuals who respond to these.”

35 As discussed *infra*, it is not possible to optimize the functioning of a complex adaptive system. “Maximizing fitness” as a point of mechanical efficiency is distinguished from optimization, since complex systems do not typically optimize the function of the entire system in the context of “brittle” problems. This can be compared, for example, to robust adaptation to a changing environment in a state of criticality, i.e., one balanced on the so-called edge of order and chaos.

36 Bozeman & Sarewitz, *supra* note 30.

direct result of imposition of order at increasing levels of detail that favour inefficiency, such as that induced by a highly constraining IPR rights regime that skews the benefits of a system towards discrete actors.

Indeed, it is plausible that just such an escape has occurred in the pharmaceutical industry over the last two decades. It has been widely acknowledged that the creative efforts of this industry have been directed (or misdirected) towards development of so-called “me too” drugs and line extensions, primarily formulation changes, rather than true innovative breakthrough products.³⁷ The Supreme Court of Canada acknowledged in *AstraZeneca v. Canada*³⁸ that it is entirely understandable that pharmaceutical firms would avail themselves of large scale legal and regulatory provisions allowing evergreening³⁹ of older products by “adding bells and whistles” after the original patent has expired. One might argue that senior executives leading these corporations have just this duty to their respective shareholders under most enabling local and domestic corporate/commercial statutes. Given the economic efficiencies involved in this approach compared to risk-intensive innovative product development activity, it is hardly surprising that the vast majority of drugs approved in Canada, the United States and other jurisdictions provide moderate, little or no improvement over existing approved products.⁴⁰ Under this view, it is *not* merely the capital and risk-intensive

37 Bouchard “Living,” *supra* note 3.

38 *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49 at 12, [2006] 2 S.C.R. 560.

39 Evergreening refers to undue extension of the statutory monopoly attached to a drug product by means of listing numerous patents on a register with obvious or uninventive modifications. Under such circumstances, the patentee prolongs its monopoly beyond what the public has agreed to pay: *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067 at para. 37, 194 D.L.R. (4th) 193; *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26 at 66, [2005] 1 S.C.R. 533; *Astra Feneca Ibid.* at 39. According to the Romanow Report: Evergreening is “A particular concern with current pharmaceutical industry practice” and “delays the ability of generic manufacturers to develop cheaper products for the marketplace and it is a questionable outcome of Canada’s patent law.” Health Canada, *Building on Values: The Future of Healthcare In Canada* (Ottawa: Health Canada, 2002) at 208-209, 253 (Chair: Roy Romanow).

40 According to reports published by the French La Revue Prescrire and Canadian Patented Medicines Prices Review Board (PMPRB), less than 5% of all new patented medical products in France and Canada are for truly novel products for which there are no existing competitors: La Revue Prescrire, “Drugs

nature of product development that opposes breakthrough commercial innovations, as is often claimed (though of course, this may be true to some extent), but rather a non-systems based legal-regulatory regime that allows for and indeed privileges incremental product development activities rather than true creative inventiveness.

So where does this leave breakthrough invention and innovation in the medical sciences? One possible answer lies in the labs of publicly funded researchers and the progressively diminishing sector of the biotechnology industry occupied by SMEs. Under circumstances where truly innovative pharmaceutical research and development are reduced, or where firms privilege an “invention by investment” strategy analogous to portfolio financing,⁴¹ publicly funded researchers and SMEs are left to carry the lion’s share of the financial risk of medical product development. This will be particularly true of SMEs, as they face the greatest exposure to extinction in the venture capital “valley of death.” The vulnerability of SMEs in the medical sciences has been exacerbated in recent years by the tendency of the pharmaceutical industry to obtain licenses to or acquire biotechnology products later and later in the product development cycle (i.e., following Phase 1 or 2 clinical trials rather than following animal model validation or other pre-model validation benchmark testing) and that of larger multinational biotechnology firms to collapse their legal, regulatory and policy interests with those of their pharmaceutical siblings.⁴² While, by virtue of its lower risk profile, firms will tend in the ag-

in 2001: A number of ruses unveiled” (2002) 11 *Prescrire International* 58; Patented Medicine Prices Review Board, *Annual Report 2000* (Ottawa: Patented Medicine Prices Review Board, 2001). For a discussion of both reports, see Joel Lexchin, “Intellectual Property Rights and the Canadian Pharmaceutical Marketplace: Where Do We Go from Here?” (2005) 35 *International Journal of Health Services* 237. The U.S. FDA indicated that only 15% of new medications marketed by brand-name pharmaceutical firms between 1989-2000 were true innovative drugs: Tim Hubbard & James Love, “A New Trade Framework for Global Healthcare R&D” (2004) 2 *PLoS Biology* 147; Song Hee Hong *et al.*, “Product-line extensions and pricing strategies of brand-name drugs facing patent expiration” (2005) 11 *Journal of Managed Care Pharmacy* 746.

41 William Kingston, “Intellectual Property’s Problems: How Far is the U.S. Constitution to Blame?” (2002) 4 *Intellectual Property Quarterly* 315.

42 Andrew Marshall, “Who speaks for small biotech? The biotech industry’s trade organizations need to better represent the concerns of their rank and file” (2007) 25 *Nature Biotechnology* 693.

gregate to favour some form of invention by investment strategy, it nevertheless runs contrary to the *quid pro quo* nature of the traditional patent bargain and constitutes an increasingly inefficient result of innovation-based policy and legislation when a portfolio pushes out or otherwise dominates all other forms of innovation. As noted above, a shift in the risk of product development away from multinational firms towards publicly funded researchers and SMEs is somewhat ironic given that the former possess the larger research and development budgets (and thus the greater capacity for risk) while the latter represent the two populations most frequently targeted by current productivity and commercialization-based S&T policy (with non-existent or the least capacity for risk).⁴³

The impact of an escape of creative energy in a system of innovation away from inventive activities towards those which harvest the benefits of a skewed IPR regime is not only felt by inventors and firms. It is also experienced by society, both in concrete financial terms and in a more tangential manner through the loss of innovative responses to practical considerations of use. While the latter is straightforward, the former arises due to social inefficiencies which develop when the scope and depth of intellectual property and regulatory protection to firms extend well beyond that required for efficient stimulation of innovation.⁴⁴ Inefficiencies of this nature are substantial from a public health law and policy perspective, the most obvious being diminished access by the public to cheaper generic versions of essential medications due to prolonged monopoly pricing by brand-name drug companies. Related to this is the subsequent "chilling" of competition by the generic pharmaceutical industry due to the litigation costs of over-reaching

43 Conference Board of Canada and Expert Panel on Commercialization, *supra* note 6. See also Bernstein, *supra* note 7; Mark Ratner, "Looking for Solid Ground Along the Critical Path" (2006) 24 *Nature Biotechnology* 885; 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" (2007) 81 *Clinical Pharmacology & Therapeutics* 141.

44 Dosi, Marengo & Pasquali, *supra* note 5; Bouchard "Balancing," *supra* note 3. See also Dean Baker & Noriko Chatani, *Promoting Good Ideas on Drugs: Are Patents the Best Way? The Relative Efficiency of Patent and Public Support for Bio-Medical Research* (Washington, D.C.: Center For Economic and Policy Research, 2002); Dean Baker, "The Reform of Intellectual Property," online: (2005) 32 *Post-Autistic Economics Review* 1 <<http://www.paecon.net/PAERreview/wholeissues/issue32.htm>>.

IPR rights.⁴⁵ This is a particular concern in North America⁴⁶ due to operation of “linkage regulations” tying patent protection to food and drugs approval and regulation.⁴⁷

Other types of social inefficiencies resulting from escape include practices such as defensive patenting, increased emphasis on lobbying and regulatory capture efforts, increased imitation costs, increased flow-through costs due to concealed or distorted research findings, conflicts of interests in the drug approval and medical research funding processes, undue influence over physician prescribing habits via pharmaceutical representatives, and skewing the direction of research funding towards patentable products.⁴⁸ Together, inefficiencies of this nature can be predicted to result in increased rent seeking behaviour by firms (particularly those which undertake an “invention by investment” approach to IPR strategy), dissipation of rents into litigation by both private and public actors alike, and reduced emphasis on truly innovative activity in favour of “me too” products and line extensions.

Perhaps the largest social cost of an over-reaching IPR rights regime from a systems perspective is the deadweight loss to society from extended patent monopolies due to evergreening of older product lines. The deadweight loss is a critical consideration for publicly funded health care as it represents the excess burden on the public when equilibrium for a needed good is not optimal, in the sense that allocation of a good to one person makes that person better off while making another person worse off. Put another way, either individuals with more marginal benefit than marginal cost are not buying the good or those with more marginal cost than marginal benefit are doing so. In any event, both sets of circumstances are indicia of consumer supply and demand driven by price considerations, which in turn depend powerfully on the basket of IPR rights attached to a given product. For example, the average increase in price for pharmaceuticals due to patent

45 Bouchard “Should,” “Living,” *supra* note 3.

46 Edward Hore, “A Comparison of US and Canadian Laws as They Affect Generic Pharmaceutical Drug Entry” (1992) 55 Food & Drug L.J. 373; Andrew A. Caffrey & Jonathan M. Rotter, “Consumer Protection, Patents and Procedure: Generic Drug Market Entry and the Need to Reform the Hatch-Waxman Act” (2003) 9 Va. J.L. & Tech. 1; Valerie Junod, “Drug Marketing Exclusivity Under United States and European Union Law” (2004) 59 Food & Drug L.J. 479 .

47 Eisenberg, *supra* note 33.

48 Baker, Baker & Chatani, *supra* note 44; Dosi, Marengo & Pasquali, *supra* note 5; Bozeman, Bozeman & Sarewitz, *supra* note 30.

protection beyond marginal cost in the United States was calculated recently to be about 400% (with the gap in many cases exceeding 1000%), compared with 30% for the largest comparable tariffs in other industries.⁴⁹ These losses are an order of magnitude larger than efficiency losses typically addressed with economic policies to date.⁵⁰ If supported by further empirical research, these figures represent a potentially staggering loss of taxpayer return on investment under any view of the social costs of innovation.

C. Innovation as a Complex Adaptive System

In addition to general systems theory applications, there are several features of “complex adaptive systems”⁵¹ as analyzed in an array of natural, biological and technological networks⁵² that are highly relevant to correctly observing, understanding, explicating and, to the degree possible, successfully managing a complex innovation ecology.

The first of these is that complex systems, when operating effectively and efficiently, are governed not exclusively by local rules but by broad generic properties that determine the “robustness” of the system, defined as

49 Baker, *supra* note 44 at 9.

50 *Ibid.*

51 Referred to herein as “complex systems” or “complexity” for short, but *not* to be confused with “per se” complex systems. See *infra* discussion around footnote 74. An important caveat for the use of systems theories and complex adaptive systems is that no claim is being made to the universality of these models or their inevitable applicability to human behavior. Rather, the claim is that (1) they may offer a new and useful “way of seeing” the levels of complexity and interdependencies involved in the regulation of medical research and product development and therefore (2) may have potential value in a democratic context for policy- and decision-making purposes.

52 As with the genesis of the period of “scientific enlightenment,” often credited to Newton and Galileo, there are numerous claims and timelines for the genesis of systems theory and complex adaptive systems. See generally John H. Holland, *Adaptation in Natural and Artificial Systems* (Ann Arbor: University of Michigan Press, 1975); John H. Holland, *Hidden Order: How adaptation builds complexity* (New York: Basic Books, 1995); James Gleick, *Chaos: Making a New Science* (New York: Penguin, 1987); Christopher G. Langton, *Artificial Life: the proceedings of an interdisciplinary Workshop on the Synthesis and Simulation of Living Systems, held September, 1987 in Los Alamos, New Mexico* (Redwood City, Cal.: Addison-Wesley, 1989); Brian W. Arthur, “Positive Feedbacks in the Economy” *Scientific American* (February 1990) 92; *supra* note 14; *supra* note 24.

the ability of a system to learn and adapt dynamically to conditions that are constantly changing.⁵³ A related and critical issue for the purpose of policy development is that complex systems encompass a level of inherent uncertainty alien to almost all previous models of human behaviour rooted in modernity. Complex systems are spontaneous, dynamic, uncertain and hard to control; even so, they are highly responsive systems owing to their ability to learn, adapt and rearrange their building blocks through experience.⁵⁴ As such, a complex system is decentralized rather than centralized in its operation.⁵⁵ Complex systems are emergent in that the adaptive and hierarchical reshuffling of agents and building blocks occurs at progressively higher levels of complexity.⁵⁶ That complex systems are characterized by “perpetual novelty”⁵⁷ suggests they are inherently creative, implying complexity-based models may be particularly useful in crafting and overseeing national innovation policy.

Second, and important for drafting policy and legislation to support innovation, it is not possible to completely “optimize” the functioning of a complex system.⁵⁸ One must therefore let go the notion that a single policy stone can be cast into the pond that will maximally “leverage” available S&T resources in order to “facilitate” innovation. The nature of innovation is more akin on several levels to a bucking bronco than a fuel-efficient car. Indeed, many, if not the majority, of the most valued discoveries in science have been serendipitous in nature rather than predictable outcomes of targeted IPR rights-intensive commercialization programs. Recognition of the inherently uncertain and emergent nature of innovation, owing to the spontaneous serendipitous nature of acts of invention themselves, may be one of the most profoundly valuable insights of the complex adaptive systems framework for the construction and operation of national S&T-based policy

53 Waldrop, *supra* note 14 at 145, 334; Kauffman, *supra* note 14 at 19; Johnson, *supra* note 14 at 181; *supra* note 15 at 220-238. The words “not exclusively” are used purposively here, as many complex adaptive systems do have explicit local rules which can in turn generate emergent global rules in a robust system.

54 Waldrop, *ibid.* at 145-146; Kauffman, *ibid.* at 24, 321; Langton, *supra* note 52 at 228; Holland *Adaptation*, *supra* note 52 at 169; Johnson, *ibid.* at 19.

55 Waldrop, *ibid.* at 145.

56 Holland *Adaptation*, *supra* note 52 at 169.

57 Waldrop, *supra* note 14 at 147.

58 *Ibid.* at 146-147, 167; Johnson, *supra* note 14 at 186; Kauffman, *supra* note 14 at 14.

and programs, and follows logically from the dynamic, indeterminate and emergent nature of complex systems. Rather than optimizing the function of the system, in a refrain familiar to many policy scholars,⁵⁹ the goal of complex adaptive systems is to enhance the robustness of the system⁶⁰ by creating conditions for efficient, responsive learning and adaptation to changing conditions over time.

In this light, for a systems-based innovation ecology supported by S&T policies where innovation is driven both by and for a variety of public and private actors within a democratic context, a reasonable policy goal would be maximizing social efficiencies and minimizing social inefficiencies. To the extent the system is skewed too far to public or private interests, it will move away from a robust position between order and chaos and thus away from the desired state of criticality. As discussed further below, the term “efficiency,” in so far as it is interpreted here to apply to an innovation ecology, is not relegated solely to the realm of measurable administrative inputs and

59 For an excellent historical survey and analysis of efficiency in public policy, see generally Janice Gross Stein. *The Cult of Efficiency* (Toronto: Anansi, 2001).

60 When a complex system is near or at a phase transition or critical state between chaos and order, the sum of the interactions between actors can be said to be working at maximum efficiency as measured by expenditure of energy used to yield the largest number of useful options in the shortest period of time. However, even though maximum efficiency can be reached after a phase transition to a state of criticality, the system still may not have achieved a truly “optimal” state whereby *any* improvement in efficiency, or robustness, is impossible. In other words, the location of that particular phase transition in state space (local space embedded within a larger space containing all possible places the complex system could exist – one mountain among many peaks and valleys) may not be “optimal,” compared to the optimal maximum among all local maxima in that state space. Efficiency in complex system can thus be understood as system which is no longer “wandering” over all possible state spaces in search of a threshold level of robustness, but has restricted itself to a smaller range of spaces. The concept of “efficiency” should be understood from a public policy perspective in terms of an active search for access within state space for behaviors that address particular challenges faced by the system and which allow it to be robust. Another reason why a system cannot be “optimized” is that optimization pertains to a time-gated particular set of circumstances which will always exist only in the past, whereas maximizing a system’s efficiency/fitness refers to the fact that the “goal” of a robust system is to adjust rapidly to changing circumstances to do “well enough.”

outputs,⁶¹ but rather is informed by the rights and values of society in the prevailing legal-democratic state from which policy emanates and within which creative acts underpinning innovation occur. In most prevailing democracies, this would encompass distributive considerations such as justice, equity and equality. Therefore, it is legitimate to ask *efficient at what?* and *efficient for whom?* when analyzing and constructing a forward-looking systems-based innovation policy.⁶² An advantage of employing a systems approach to innovation is that maximizing the “distributive fitness” of the entire innovation ecology, as opposed to the relative fitness of discrete modules, may mitigate the vulnerability of front-loaded policy-regulatory systems grounded in rationality, predictability and determinism to the use of considerations of efficiency as an end in and of itself⁶³ or as a cloak for economic agendas legitimated by the notion of the rational self-maximizing actor.⁶⁴

As suggested within the context of environmental law, which is also heavily contingent on so-called basic and applied science, a policy vehicle that would be best positioned to support robust innovation would be one that was open, flexible, responsive and governed by strong leadership comfortable with the idea of continual change in the context of uncertainty.⁶⁵ Indeed, a responsive and adaptive policy would well serve the emergent properties of complex systems, whereby actors at one level serve as building blocks for those at higher levels through continual learning and adaptation, and where at each succeeding level of complexity entirely new properties appear entailing new generalizations and conceptualizations.⁶⁶ Learning and adaptation occur, *inter alia*, by actors and institutions through trial and error in successive generations⁶⁷ or through random yet emergent self-organizing

61 Stein, *supra* note 59 at 21-51.

62 *Ibid.* at 1-20, 68-69. One might slightly recast these questions for the present purposes as *robust at what?* and *robust for whom?*

63 Joseph Heath, *The Efficient Society: Why Canada Is As Close To Utopia As It Gets* (Toronto: Penguin/Viking, 2001). See also, Neil Harrison, “Complex Systems and the Practice of World Politics” in Neil Harrison, ed., *Complexity in World Politics* (Albany, NY: SUNY Press, 1997) 183 at 183 (discussing how rationality-based decision making in politics renders maximization of self-interest the normatively acceptable standard of behavior).

64 Stein, *supra* note 59 at 45-74.

65 See generally Ruhl “Fitness,” “Regulation,” *supra* note 17.

66 Waldrop, *supra* note 14 at 82, 86, 145.

67 Johnson, *supra* note 14 at 168; *ibid.* at 168.

encounters between agents leading to growth.⁶⁸ The latter process is likely familiar to anyone making a decision in relation to a problem before them (going for coffee, reacting to a difficult interpersonal situation) the answer to which is simultaneously grounded in historical memory and cognitive associations, yet which only seems “rational” and “good” in retrospect. A lack of learning or adaptation by agents, or maladaptive actions by delinquent agents who ignore the rules and skew the functioning of a system in their own favour, can prevent a system from working efficiently and can, under certain circumstances, lead to extinction of the system or its subcomponents.⁶⁹

Complexity can offer a somewhat paradoxical view of human relations in that collective behavior is inherently complex (rather than merely complicated), spontaneous, unpredictable and indeterminate while still obeying, in a reasonably stringent fashion, general laws. This tension between order and disorder reflects the notion, often expressed in the complexity literature,⁷⁰ that robust order is that which exists at the so-called “edge of chaos”. Tension between these elements however need not rise to the level of paradox. An alternative view might simply be that a robust system represents a dynamic fine-tuned balance of spontaneous inventive behaviors by agents and institutions with more slowly changing broad generic laws governing the space within which these spontaneous behaviors take place. Given the relatively purposive nature of public policy,⁷¹ it is reasonable to assume that

68 Kauffman, *supra* note 14 at 25; Johnson, *supra* note 14 at 75-79.

69 Johnson, *ibid.* at 137, 181, 187; Langton, *supra* note 52 at 320, 137 (citing tornadoes, traffic jams, stock market failures, etc.).

70 Although this phrase was popularized by Stuart Kauffman in the context of medical research (e.g., Kauffman, *supra* note 14 at 19) it was coined by Chris Langton in the context of computational work involving cellular automata (Christopher G. Langton. “Computation at the edge of chaos: Phase transitions and emergent computation” (1990) 42 *Physica D* 12). While the term has been taken up widely among social science scholars as well as scientists, its use in both settings has not been without serious criticism. See, for example, Melenie Mitchell, Peter Hrabar and James Crutchfield. “Revisiting the edge of chaos; Evolving cellular automata to perform computations” (1993) 7 *Complex Systems* 89). See also: Roman Frigg. “Self-organized criticality – What it is and what it isn’t” (2003) 34 *Studies in the History of the Philosophy of Science*. 613.

71 William I. Jenkins, *Policy Analysis: A Political and Organizational Perspective* (Lon-

innovation policy contributes in a substantial way to the initial starting conditions of the system and thus determines (or helps to, along with relevant law and regulation) the character of the space that both allows and constrains inventive and innovative behaviors by system actors.

Indeed, one of the main advantages of taking a complex systems approach to patent and innovation policy in the first place is to acknowledge the centrality of uncertainties involved in the processes of invention and innovation. This lends itself to a range of novel vistas in understanding the delicate nature of the balance between certainty and predictability and lack of both when thinking about how to best construct and utilize national S&T policy to bolster a robust innovation ecology and to do so in a manner that allows us to derive as much long term social utility as possible out of the recursive processes of invention and innovation rather than settling for “default outcomes”.⁷² The point here is not to put building blocks together to build a good system, but rather to identify and use building blocks that can be used by individuals and institutions to build many good systems in an emergent, adaptive manner.⁷³ To put it another way, enhancing the utility and functionality of the building blocks at the level of the operational system where relevant actors and institutions are in greatest contact with one another within a system, or those in parallel systems, makes that system more responsive and adaptive to change and positions it most efficiently to learn from experience.

Third, while broad generic rules govern the behaviour of the system, order in a complex *adaptive* system resides primarily at the “edge of chaos.”⁷⁴

don: M. Robertson, 1978); M. Howlett & M. Ramesh, *Studying Public Policy: Policy Cycles and Policy Subsystems* (Toronto: Oxford University Press, 1995); James Anderson, *Public Policy Making: An Introduction* (New York: Houghton Mifflin, 1996).

72 Este, *supra* note 23 at 5 (referring to default outcomes of scientific advance as “fine technically-focused accomplishment coupled with the error of mistaking such accomplishment for philosophical clarity”). See also Arthur, *supra* note 34 (at 277) for a discussion of the recursive and incremental nature of technological innovation (“recursive” referring to the notion that “a technology consists of building blocks that are technologies, that consist of further building blocks that are technologies, repeats down to the fundamental level of individual components”).

73 Waldrop, *supra* note 14 at 147. See also Arthur, *supra* note 34.

74 According to popular articulation of complexity theory (Kauffman, *supra* note

True chaos does not exist in a complex adaptive system; otherwise the system would not be adaptive. Rather, it acts as a “close enough” stimulus for growth and adaptation from afar (but not too far so as to obviate the tacit need for adaptation). In this sense, chaos and complex adaptive systems are separated by a sharp, if hard to define, dividing line. There have been differing opinions over the years on exactly what constitutes “order” and “chaos,” and it has apparently been the role of complexity theory to demonstrate that in fact the two can coexist within one system, though separate and apart. For example, work over a century ago by Poincaré led to the notion that chaos is simply extremely complicated information (deterministic order) rather than an absence of order.⁷⁵ In this model, because chaos ultimately is deterministic, it is therefore possible to predict the outcome of a chaotic system provided one has perfect knowledge of the initial conditions and context. This can be contrasted with work by Prigogine,⁷⁶ who stated that complexity is non-deterministic and thus cannot be used to predict the fu-

14 at 15; *ibid.* at 330; Johnson, *supra* note 14 at 189), adaptive behavior occurs at the “edge” of chaos rather than “in” the chaotic realm. That is not to say there is no chance or uncertainty at the edge of chaos or indeed in highly ordered systems. Nevertheless, chaos and uncertainty are not equivalent terms, although they can produce similar effects. Unlike uncertainty, true chaos is outside adaptive capacity. Complex adaptive systems cannot learn and adapt under truly chaotic conditions. Chaos can, however, be present in complex systems that are not adaptive and can yield novel inventions. These are, by nature, entirely chance occurrences and go, for the most part, unnoticed and/or undeveloped. A system that is “over the edge of chaos” as opposed to “at the edge of chaos” lacks the adaptive systems required to efficiently and effectively recognize and push the inventive discovery through the tunnel of innovation and into the marketplace. Within a realm of chaos, a chance discovery is more likely to give rise to a further series of chaotic events, unless by chance it escaped its own chaotic system. A complex system that accepts a certain, even significant, element of uncertainty as part of its adaptive innovation process thus differs substantially from one that accepts even a small amount of true unbounded chaos. The former can be effectively harnessed with forward looking policy aimed at learning and adapting to changing conditions, while no policy can effectively harness the latter.

75 N.K. Hayles, *Chaos Bound : Orderly Disorder in Contemporary Literature and Science* (Ithaca, N.Y.: Cornell University Press, 1991).

76 I. Prigogine, *The End of Certainty* (New York: The Free Press, 1997). But see criticism of this position by Casti, *infra* note 78.

ture. The distinction between chaotic systems and complex systems is their dependence on antecedent events and their relation to equilibrium states.⁷⁷ Chaotic systems, by virtue of their disordered nature, do not rely on their history as complex ones do. On the one hand, chaotic behaviour pushes a system in equilibrium out of order. On the other, complex systems evolve far from equilibrium at the edge of chaos and evolve at a critical state that is dependent on a history of irreversible and unexpected events, e.g., a non-chaotic state.

This has potentially interesting ramifications for an innovation ecology grounded in domestic and global purpose-driven S&T policy and IPR rights for two reasons: first, because complex adaptive systems can exist in a “critical state” between the two poles of static order and random disorder; and second, because these systems can be perturbed by external events to become either highly ordered or highly disordered, i.e., static or chaotic.⁷⁸ Well drafted policy may therefore act as a stabilizing factor⁷⁹ in the face of a tendency by some complex systems to evidence “surprises” when moving towards a chaotic state.⁸⁰ By contrast, poorly drafted policy can act as a

77 M. Buchanan, *Ubiquity : Why catastrophes happen* (New York: Three Rivers Press, 2000).

78 See generally Bak & Chen, *supra* note 14; Waldrop, *supra* note 14; Ruhl “Fitness,” *supra* note 17; John L. Casti, *Complexification: Explaining the Paradoxical World Through the Science of Surprises* (New York: HarperCollins, 1994).

79 Ruhl, *ibid.* at 1410.

80 See generally Casti, *supra* note 78. For discussion of Casti’s “science of surprises” in the context of environmental regulation, see *ibid.* at 1438-1442, describing, *inter alia*, the failure of reductionist theories to fulfill the promise of “producing predictive certainty when faced with dynamical systems,” due in part to the combination of uncertainty, emergence and catastrophe features of complex adaptive systems. The latter refers to a sudden change in a dynamic system brought about by an arbitrarily small and incremental change in a system variable, and encompasses the concept of “strange attractors” with respect to chaos theory (e.g., butterflies flapping their wings in one continent inducing dramatic events in another part of the world). Such attractors “represent the behaviors that flow from the forces of order and disorder that might exist within a system, and which thus regulate the surprise generators of chaos, emergence and catastrophe.” This coheres with the implications for law and policy development of Casti’s earlier work on the limits of mathematical and logical systems in the context of Gödel and Turning (John L. Casti, *Searching for Certainty: What Scientists Can Know About the Future* (New York: Morrow, 1990), which would suggest

destabilizing factor by, for example, being over-reaching and undefined or overly narrow and controlling.

It has been claimed⁸¹ that order typical of the critical state in which many (but not all) complex systems exist applies equally well to both large political and economic macro-systems and smaller cellular or technological micro-systems. Whether or not this turns out to be true in the long run, there is some work to suggest that the more complicated the complex system, the more autonomous its agents and the less control is possible over them.⁸² As suggested in the context of pharmaceutical innovation, policy vehicles that do not respect the complex nature of the system they seek to regulate or those that in fact over-regulate an inherently indeterminate system have the potential to harm the innovative character and outputs of the system, either by allowing escape of resources into the hands of discrete actors and institutions or through loss of innovative capacity relative to practical considerations of use. Order in a complex system exists as a delicate yet resilient expression of the balance between competition and cooperativity of system elements. The relevance of this to innovation can be seen in the balance amongst various public and private interests in medical product development and regulation.⁸³ A related issue is that complex systems can be near or in a "phase transition" from one major state to the next, and that a system can be pushed into a phase transition as a result of agents' choices and actions. Movement toward a phase transition is completely inclusive: due to the interconnectedness of actors and institutions, nothing is excluded from the effects of a phase transition.⁸⁴

There are several reasons why the notion of a phase transition has a certain attraction not only for Canada, but also for other nations seeking to capitalize on their S&T bases in the medical sciences. In order of narrow to broad relevance, these include the well documented fact that Canada is currently: (a) moving from a system of medical research focused on accrual of new knowledge by university-based researchers to one which underscores the importance of translating knowledge into marketable products through public-private partnerships; (b) seeking to emulate the successes of the Unit-

that it is not possible, using the law as a tool, to discover *all* truths about law, due in part to the inherent uncertainties involved in complex systems.

81 Arthur, *supra* note 52 at 325; Waldrop, *supra* note 14 at 330.

82 Johnson, *supra* note 14 at 186.

83 Bouchard "Balancing," *supra* note 3.

84 *Supra* note 15 at 18.

ed States in commercializing university-based medical research by leveraging national and international IPR rights; (c) one of the first jurisdictions in the world to transition from a regime of drug approval and regulation based on the precautionary principle (do no harm) to a corporate-based risk management style regime; (d) moving from a traditional political “gatekeeper” role in supporting medical research and drug regulation, where the government’s primary responsibility was to protect the public, to a hybrid position where government is equally responsible for public health protection and ensuring a high return on investment in medical research; and (e) doing this in such a fashion so as to succeed not only domestically but globally in order to enhance national productivity and prosperity. These signs suggest that Canada may indeed be entering into, or swiftly nearing, a significant transition in its system of public health and innovation in the medical sciences. This transition will likely involve a shift in the values and priorities of various public and private actors, as well as in the means and policy levers by which rationally self-interested actors will seek to achieve their goals.

Fourth, what order exists in a complex system can either help or hinder the functioning of the system. It has been observed, for example, in a range of natural and biological systems, that imposition of too much order can yield a system that is inflexible, and that this inflexibility moves the system away from its maximal fitness level.⁸⁵ An example of the effects of over-ordering was touched on above in the context of innovation in the traditional pharmaceutical sciences, where imposition of too much and too narrow a regulatory vehicle had negative rather than positive effects on the system’s fitness of purpose, i.e., to produce new breakthrough essential medications. It is presumably near (rather than over) the edge of chaos where a system appears best able to coordinate complex activities and evolve efficiently. As claimed by Kauffman,⁸⁶ in systems that are highly ordered, poor compromises are easily made; in chaotic systems, no compromise can be made; and in a phase transition, compromise can be made but not quickly. If too little or too much control or autonomy is exerted by a set of actors or institutions within a complex system, the system can deteriorate or collapse.⁸⁷ Recognizable by anyone who has worked in a stifling organizational bureaucracy, once all major patterns and institutions have been explored in a highly controlled

85 Kauffman, *supra* note 14 at 26.

86 *Ibid.* at 28.

87 Johnson, *supra* note 14 at 187; Ruhl “Fitness,” *supra* note 17 at 1440-1442.

complex system, it moves into “detail mode” where later invention and innovation is limited to modest improvements on increasingly optimized designs.⁸⁸ For examples of how detail mode can be facilitated by an inefficient IPR rights regime and stagnate innovation, one need look no further than the impact on the rate and direction of innovative activity of “weak patents,” linkage regulations, or line extensions and “me too” products that currently monopolize the pharmaceutical marketplace.

Not surprisingly, given the uncertainties inherent in complex systems, the goal of maximizing the fitness of a complex system typically entails a balance of competition and cooperation and accommodation between agents.⁸⁹ A balance of competition and cooperation works to achieve as much stability as the system will allow. Even so, order of this critical nature is said to exist only on the edge of chaos rather than as a metaphorical centrist position. Independent of where order exists on some metaphorical spectrum, an important implication of a mental model of complexities for our purposes here is that a “fit” system is neither too flexible nor too ordered, but balanced between the two. This is relevant because it underscores the importance of correctly observing, understanding, and explicating the characteristics of a complex system prior to setting one in motion. Deciding on the right amount of order to impose on a system has a particular resonance under conditions where a nation voluntarily enters a potentially costly phase transition involving serious public health considerations. In this sense, timing is everything, as politics is the outcome of the system, not *vice versa*.⁹⁰ Johnson⁹¹ has suggested that new complex systems are more labile and volatile, and hence more “aggressive and confrontational” than older more established systems. If applicable to large political and legal systems this may serve to highlight the need for foresight in assessing when the impact of a new system might be dangerous to human health. The notion that the more learning experience one has with complex systems, the greater predictive value they may have,⁹² suggests the use of HPC technology-based systems models of complex behaviour may be valuable for political actors setting in motion a phase transition of the magnitude and degree of invasiveness currently be-

88 Kauffman, *supra* note 14 at 14.

89 Waldrop, *supra* note 14 at 145; *ibid.* at 19; Johnson, *supra* note 14 at 187.

90 Waldrop, *ibid.* at 332.

91 Johnson, *supra* note 14 at 81.

92 *Ibid.* at 168.

ing contemplated in Canada. HPC technologies cannot, however be used to explicitly predict future outcomes. Rather they can be used ideally to build policy that is robust across a range of future scenarios.

While too much or too little order can harm a system, some tension between dominant elements or modules in a system can have the opposite effect; that is, to help maximize fitness.⁹³ As noted above, in between total order and total chaos is a space in which sustainable system behaviour is possible for a length of time, and it has been suggested this space be positioned close to the edge of chaos in order to remain robust and thus to maximize system fitness.⁹⁴ Therefore, tensions in the current medical research enterprise can, when managed properly, be productive forces in commercializing publicly funded research. This applies to the various public and private interests in generating, capitalizing and using the products of medical research, administrative tensions within enabling legislation and regulations that explicitly seek to balance public health protection with economic interests, the prioritizing by federal funding agencies of certain areas of research over others, and the role of private firms in commercializing the results of that research. From a systems-based perspective, public and private interests in commercialization are not inherently and irretrievably in conflict;⁹⁵ rather they meaningfully conflict only to the degree that the benefits of the regime are hoarded by one of the enterprise partners.⁹⁶ Productive tension of this nature has been discussed in the context of a self-organizing model of the economy, where events perceived as negative had the potential to stimulate growth and system optimization via feedback learning.⁹⁷

Fifth, in order to enhance fitness, it is appropriate in a complex system for human actors participating in the system to be as aware as possible of their roles and actively participate in the evolution of the system. Growth of a system towards fitness occurs via numerous lines of intelligent feedback among actors and groups in the system. Feedback is particularly

93 Waldrop, *supra* note 14 at 90,172.

94 Stuart Kauffman, *Origins of Order: Self Organization and Selection in Evolution* (Oxford: Oxford University Press, 1993) at 31; see also Ruhl "Fitness," *supra* note 17 at 1442 (for a discussion of this tension within the context of environmental adaptation).

95 Bouchard "Balancing," *supra* note 3.

96 Bozeman & Serawitz, *supra* note 30.

97 Paul Krugman, *The Self Organizing Economy* (Cambridge: Blackwell Publishers, 1996).

important in a distributed, decentralized, complex and open system, as it governs learning, growth and self-regulation.⁹⁸ Critically for a complex innovation ecology contingent on a wide range of collaborative arrangements (e.g., municipal, regional, domestic and global technology clusters, to name just one type), feedback both depends on and arises from the interconnections between system elements:⁹⁹ the stronger the linkages, the stronger the feedback system. This is just as important for public interest groups as for self-interested firms and actors, underscoring the need for active participation across all system elements in order to maximize its fitness of purpose. Highlighting the importance of “synergies” of this nature (as they are referred to in management consulting circles) from a high level policy view represents a substantial departure point from hierarchical “command and control” models of organizational and political leadership, and can, provided the distributive goals of the system are never far from reach, mitigate tensions between so-called private and public interests in, for example, commercialization of the practical fruits of medical research.¹⁰⁰

Importantly, feedback loops can be used by a system to reach a form of stability even in an uncertain and changing environment. Agents that can predict can anticipate, thus having the advantage over their competitors;¹⁰¹ the caveat being the idea that given the uncertainties inherent in a complex system, agents could not possibly have full knowledge of their role or that of their competitors and thus could not predict outcomes with full certainty. According to Holland¹⁰² learning arises, not from anthropomorphic “consciousness” of a complex system, but due to continual adaptive feedback from the environment, which in turn gives rise to improvement in the functioning of the system.

As noted in the context of Internet technologies,¹⁰³ one way to enhance the functioning of a complex system is to root out “lurkers” and “cranks” and other actors not in service of the system. To this one can add individu-

98 Holland *Adaptation*, *supra* note 52 at 176; Johnson, *supra* note 14 at 133-138.

99 *Supra* note 15. For application of complexity frameworks in domestic and international political systems, see generally: Robert Jervis. *System Effects: Complexity in Political and Social Life* (Princeton, 1997); *Complexity in World Politics*. ed. Neil Harrison. (SUNY Press, 1997).

100 Bouchard “Balancing,” *supra* note 3.

101 Glimcher, *supra* note 26.

102 Holland *Adaptation*, *supra* note 52 at 179.

103 Johnson, *supra* note 14 at 150.

als, corporations and institutions engaged actively in deceptive market or political practices who participate in ways that are not easy to determine but who hijack the system to their advantage.¹⁰⁴ Indeed these and other “silent” participants such as free-riders give self-interested actors or institutions the opportunity to control the system and skew its benefits in their direction.¹⁰⁵ Skewing and hijacking in the form of undue mission creep, corporate lobbying and corporate malfeasance in technology-intensive sectors have been the subject of considerable media attention over the last decade and can lead to what Bozeman¹⁰⁶ has referred to as “policy failure,” which occurs when the benefits of a considered policy are hoarded by one of the enterprise partners. Competing interests of various public and private actors in the outcome of medical research and the potential sway of certain actors more cognizant of the need to learn and adapt to suit their own purposes underscore the need in a complex innovation ecology for public input and oversight of the public health enterprise as well as for strong empirical work on which to base policy decisions, particularly in the context of high-profile S&T policies.¹⁰⁷

Sixth, the goal of complex systems is not optimization of the fitness of discrete elements, but rather accommodation and adaptation among these elements in service of a robust system.¹⁰⁸ At least from a theoretical stance, this principle governs no matter how dominant certain actors or institutions may be in the operation of that system, for example highly successful or motivated corporations in a market economy. Privileging the utilitarian success of the system over that of individual actors or institutions has obvious and significant ramifications for the balancing of interests in commercializa-

104 For a discussion of the importance of “regulatory creep” in this context, see Marc-Andre Gagnon, “Finance and Differential Accumulation in the Global Pharmaceutical Industry” (Paper presented to the Canadian Economics Association, Concordia University, May 2006), online: <http://www.er.uqam.ca/nobel/ieim/IMG/pdf/NoteD_2006-12-07-Gagnon.pdf>; Marc-Andre Gagnon, “Capital, Knowledge and Power in the Global Pharmaceutical Business; Structural Competition for Differential Accumulation” (Paper presented at Rethinking Marxism conference, University of Massachusetts, October 2006), online: <http://www.er.uqam.ca/nobel/ieim/IMG/pdf/NoteC_2006-12-07-Gagnon.pdf>.

105 Johnson, *supra* note 14 at 150.

106 Bozeman, *supra* note 30.

107 Timothy Caulfield *et al.*, “Evidence and anecdotes: an analysis of human gene patenting controversies” (2006) 24 *Nature Biotechnology* 1091.

108 Waldrop, *supra* note 14 at 333-334.

tion of medical research, particularly in nations where market and lobbying forces are sophisticated and strengthened relative to competing distributive considerations. Even so, it is possible to work toward maximizing the robustness of the system in the face of uncertainty and an ill-defined future, placing emphasis on the system's flexibility and ability to learn and adapt from its positive and negative experiences. For this to occur however, requires the actors comprising the system to be aware of their function within the system to the optimal extent possible.

Finally, complex systems are not only indeterminate, spontaneous and emergent in nature. According to Barabasi,¹⁰⁹ order is inherent in complex systems in an *antecedent* fashion owing to the characteristics of networks themselves. This point makes good common sense for no better reason than most "systems" that people come into contact with in their lives are, or at least appear to be, highly ordered. This is true of large scale democratic systems, systems of law, economic systems and religious systems and, on a much smaller scale, the operation of various types of public and private institutions, corporations, informal groups and families. Even so, systems theories, invested in "balancing" order and chaos (or implicitly incorporating uncertainty) are recent developments, closely tracking the global evolution of the Internet and HPC technologies.¹¹⁰

In network systems, randomness and uncertainty play a critical role, but share the playing field with a certain degree of order also inherent to the system. Nascent network studies demonstrate that when analyzed, various types of complex adaptive networks tend to display similar properties and governing principles notwithstanding differing actors, institutions and fitness purposes. Order in complex networks can be realized in the form of broad structural and functional groupings called "modules" and "hubs," the latter of which serve to connect modules, individual actors and institutions. It is the modular structural and functional features of complex systems that we are familiar with as moderns and which give complex systems their order, even if it is at the edge of chaos. These can easily be analogized to large structural and functional characteristics of society (political parties, voting public, corporations, knowledge creation, information flows, technology) that have been so widely studied in the last two centuries.

109 *Supra* note 15.

110 *Ibid.* at 27.

Regardless, there are no typical modules: hierarchical modularity can exist in the form of small, highly linked modules, large, less linked modules or a combination of both. The advantages of modularity are fairly obvious; they permit parts of a system to evolve relatively independently and to “experiment” with new subsystems without wholesale damage to the entire system. Nevertheless, in many systems models advantages are at the service of the whole rather than modules. Hierarchical modularity in networks is consistent with earlier observations in complex systems whereby there can still be stability in a system continually moving towards chaos because once actors arranged themselves in a system, networks can settle into a “self-consistent pattern” of activation recognizable as “x.”¹¹¹ Thus, the possibility exists for local instability to occur concomitantly with stability at the larger network level. Order is provided under these conditions by the number and nature of the interconnections and feedback loops among actors and institutions.¹¹² Relevant to the present exploration, a broad generic rule of this nature comports with many of the distributive structural and functional features associated with the democratic state, market economies, the Rule of Law, entrenched human rights, and the concept of complex equality.¹¹³ As such, it might have particular relevance to the commercialization of publicly funded medical research in political systems dominated by market forces, where a comparatively larger fraction of the population may not have reasonable access to affordable medical products and services.

III. Toward a Complex Systems Model for Innovation

In addition to the applications discussed to this point, taking a systems approach to innovation in the medical sciences may ultimately lend itself to a number of pragmatic recommendations for national governments undergo-

111 Waldrop, *supra* note 14 at 289.

112 *Supra* note 15 at 220-238.

113 Michael Walzer posited, in *Spheres of Justice: A Defense of Pluralism and Equality* (New York: Basic Books, 1983), that in a system of “complex equality” 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 – i.e., a view clearly favorable to maximizing the fitness of society rather than specific actors, institutions or modules. Hence, no single good is allowed to dominate or distort the distribution of other goods in the same sphere or goods in other spheres required to maximize fitness of the system.

ing, or deciding upon, a phase transition aimed at leveraging their national S&T bases into global competitiveness and national prosperity. While this is not yet the vehicle for those recommendations, it is possible to begin constructing a systems-based conceptual model of national innovation in the medical sciences embedded within a still larger global system of publicly funded research and product development. The purpose of the remaining discussion is to begin thinking about how and why the concept of a systems-based innovation ecology may provide a legitimate and positive social policy in the current geo-political context.

(A) Innovation Ecology as Middle Road

A systems model of *innovation* flows logically from the inherently open, spontaneous, adaptive and emergent properties of complex systems, individual persons skilled in the art of technological research and development, the leading edge nature of life sciences research undertaken by publicly funded labs and SMEs, and the novel nature of coevolving conceptual models for interpreting data from these studies and addressing their philosophical challenges.¹¹⁴ Taken together, these factors can be seen as components of a complex system with a large degree of potential creativity and productivity that is balanced by an equal if not greater degree of uncertainty and instability. The size and impact of this transition on the public, and the intensity and determination of political, economic and other actors pushing the system forward, underscore the need for arm's length administrative, legal and scientific oversight of the process as well as the critical importance of appellate patent law from national and international courts to the construction, production and use of scientific knowledge by and for political, economic and scientific actors.¹¹⁵

A plausible conceptual starting point for a systems-based innovation policy is the dynamic middle ground defined in network theories and studies of complex systems where order and disorder co-exist to the largest degree possible. This is the "third way" referred to in earlier work on commercialization:¹¹⁶ balancing and embracing order and disorder, certainty and uncertainty, and individual and collective interests, while maintaining a focus

114 Este, *supra* note 23.

115 *Supra* note 10.

116 Ron A. Bouchard & Trudo Lemmens, "Privatizing medical research – A 'Third Way'" (2008) 26 *Nature Biotechnology* 31 at 36.

on the whole rather than the parts. It represents the desired state of robust criticality, where a system is best positioned to learn and adapt to changing conditions. As such, it represents a focal point in balancing public and private interests in a broad system of innovation. In order to achieve as robust a state as possible in a complex system, it is necessary to balance cooperation and accommodation with competition to provide optimal conditions for system growth under changing conditions. Rather than assuming that some “invisible force” connects individual interests to the collective interest, then largely letting the system “be,” without having adequate explicative or predictive models for why the system works the way it does, taking a complexity approach to innovation may allow governments to assume a greater degree of control over that invisible force by (1) understanding that the system, including its constituent individuals, will prosper even more than it has to date by allowing the system to take centre stage rather than focusing on individuals; and (2) constructing institutions, policies and procedures that embrace rather than reject uncertainty and that allow the system to be as highly responsive, adaptive and learning based as possible rather than passively reacting to changing conditions.

In this configuration, a systems-based innovation ecology driven by legal and policy levers would be least likely to be over-regulated or under-regulated (including over-regulation masquerading as under-regulation). It would also recognize the non-linearity and dynamic nature of the relationship between IPR rights and commercialization. Importantly, it would encompass balancing public and private interests in so far as large IPR rights go, and as such may necessitate moving away from a narrow focus on deep and broad IPR rights towards some combination of IPR rights and “open source” or communal property rights.¹¹⁷ By no means does a complexity-based approach to innovation argue against the *per se* legitimacy of IPR rights – only that they are balanced by equally strong distributive means and mechanisms. Balancing of rights and interests is inherent to the constitutions and judicial determination of human rights in liberal democracies and is thus familiar in

117 Arti K. Rai, “Open and Collaborative Research: A New Model for Biomedicine” in Robert W. Hahn, ed., *Intellectual property rights in frontier industries: software and biotechnology* (Washington, D.C.: AEI-Brookings Joint Center for Regulatory Studies, 2005)131; Karim R. Lakhani & Jill A. Panetta, “The Principles of Distributed Innovation” (2007) 2 *Innovations: Technology, Governance, Globalization* 1, online: Social Science Research Network <<http://ssrn.com/abstract=1021034>>.

principal and operation to legislators and the courts. It would also provide a pragmatic ground for public policy to the degree that over-regulation or under-regulation constrains true breakthrough discoveries and innovations, as might occur subsequent to the repression of creativity and criticality at one end of the certainty-uncertainty spectrum or over-privileging them at the other.

Seeking an efficient departure point for maximizing the fitness of an innovation ecology that privileges largely spontaneous and serendipitous acts of creativity and invention (as opposed to privileging IPR rights intensive “invention by investment” strategies)¹¹⁸ is a logical fit with the idea that complex systems are characterized by perpetual novelty. It would also, of necessity, encompass distributive balancing of the tangible and intangible benefits of commercializing medical research in light of the scope and nature of public and private contributions and the risk-benefit-ratio of those contributions. A S&T-based policy for commercializing medical research which respects a systems approach would occupy a central position between wide historical swings of the pendulum between – on the one side – determinism, strong order, strong hierarchy, centralized power, and a closed static system and – on the other – indeterminism, disorder or very weak order, weak hierarchy, decentralized power and an open dynamic system. It would maximize the flexibility, adaptive capacity, and learning potential of the system, thus helping, rather than hindering, it to spontaneously evolve towards its own fitness of purpose. In a liberal democracy this refers to supporting innovative medical product development and enhancing national productivity and prosperity in a fashion that respects fundamental distributive considerations embedded within the governing legal-democratic state.

(B) Challenges for a Systems-based Innovation Ecology Rooted in Modernity

As implied in the above discussion, a systems-based model of innovation would of necessity be one where individuals, institutions and particularly governments responsible for driving policy understood their roles in the system and were active in maximizing system fitness, and where learning and adaptation occurred through cooperation and accommodation for the benefit of the system. Elements of this type of purposive balancing can be seen

118 *Supra* note 41.

in the rich interplay between IPR rights and competition law,¹¹⁹ which has been managed on an institutional level in the U.S. by a combination of forward-looking constitutional principals and contextual U.S. Supreme court patent jurisprudence. While decisions like *Hotchkiss*,¹²⁰ *Graham*¹²¹ and *KSR* demonstrate that some tension between competing interests is necessary to maximize fitness (provided that competition is unconstrained), this body of jurisprudence suggests that the goals of society and those of individuals can be appropriately prioritized and balanced and that it is the role of law to do so.

By this measure, the current standard for patentability in Canada misses the mark because it avoids using a purposive construction of obviousness which emphasizes the essence of an invention, including the steps taken to achieve it, instead favouring rigid binary notions of testing/no testing, scintilla/no scintilla of inventiveness, and whether a person having ordinary skills in the art (PHOSITA) would have/could have arrived at the invention. As discussed in the companion paper,¹²² the fulcrum for each of these binary stances is Canadian law to the effect that the PHOSITA has no scintilla of creativity whatsoever. Replacement of the mythical PHOSITA with a normative PHOSITA would help steer Canadian patent law in a systems direction which respects how medical inventions actually come into being, and would place Canadian inventors on equal systems footing with their American and European counterparts. Patent law of this nature represents the middle road between over-regulation and under-regulation by being objective yet contextual,¹²³ and would be conducive to competition that is unequivocal, predictable and fair to all parties.¹²⁴ This differs in theory and reality to a system of medical product development contingent upon strong and broad IPR rights, which by dint of operation of market failure theories, operates of necessity in an exclusionary manner.

From a complex adaptive systems perspective, self-maximizing behaviour, particularly when taken to the extreme, has the potential to substantially reduce the robustness of the system and can even lead to extinction, as may be true of the 90's "tech bubble" and its decade-long corporate fallout,

119 *Supra* note 1.

120 *Hotchkiss v. Greenwood*, 11 How. 248 (1851).

121 *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

122 *Supra* note 1, Section III.

123 Bouchard "Should," *supra* note 3.

124 Bouchard "Living," *supra* note 3.

including in the pharmaceutical industry.¹²⁵ Indeed, it has been suggested that failure of standard economic models to account for structural and economic transformations in the global pharmaceutical industry implies proactive industries are gaining ground on competitors by transforming socio-economic institutions,¹²⁶ in part by leveraging poorly conceived IPR rights-based legislation and regulations.¹²⁷

It must be emphasized that there is nothing wrong with self-interested behaviour by individuals, firms or institutions from the perspective of classical economic theories, owing to the assumption of these models that individuals and firms are rational self-maximizing agents and that some invisible yet palpable force connects the dots between individual self-interest and that of the collective. This assumption remains embedded within newer economic models allowing some form of bounded rationality such as game theory and neuroeconomics,¹²⁸ where the existence of uncertainty in the decision-making process is necessary for agents to win competitions under conditions of ambiguity and scarce resources. The reason for this is that the desired outcome is still success at the individual level. Even though maximizing self-interest makes eminent sense from this now common sense view grounded at the level of personal experience and presupposition, and while the complexity and network theories discussed above allow for some type of modular hierarchy and autonomy, a systems approach to innovation nevertheless offers a fundamental break from modernist theories and practices, as it explicitly privileges the success of the whole rather than that of the parts. A systems-based regulatory system of innovation in the medical sciences would therefore represent a substantial departure point from many existing legal and administrative models. Indeed most areas of law and policy strongly contingent on the "hard sciences" have lagged substantially behind the evolution of science itself and social studies of science in embracing more dynamic, emergent and adaptive models.

Some of the nuances of such a departure have been discussed by J.B. Ruhl in the context of environmental law.¹²⁹ Indeed, the application of change management and adaptive management principles to environmen-

125 See generally references in *supra* note 1 and Robert M. May, Simon A. Levin, and George Sugihara, "Ecology for Bankers" (2008) 451(21) *Nature* 893.

126 *Supra* note 104.

127 This point was discussed in detail in *supra* note 1, Section III.

128 Glimcher, *supra* note 26.

129 Ruhl "Fitness," "Regulation," *supra* note 17.

tal law is relevant to regulation of medical science, given that both areas of law and regulation remain grounded in modernist rather than post-modern, post-structural or post-industrial views of science and are strongly contingent on tacit and focal basic and applied science, and therefore equally in need of newer models of administrative competence. This does not mean that transitioning from older bureaucratic “front-loaded” models to more dynamic adaptive “back-loaded” models will be easy or swift. There appears, however, to be a generally recognized need that new models of decision-making are needed based on the principle of adaptive management,¹³⁰ and that the process must be an iterative and incremental one that has the capacity to continuously monitor the effects of regulatory decisions and to learn from and adjust decisions in a flexible manner which avoids the pitfalls of public participation and judicial review requirements based on older more linear regulatory models.¹³¹ A policy vehicle for innovation based on fuzzy complex adaptive systems may be an appropriate antidote to the “wicked problem”¹³² of deriving public policy in an area currently plagued by ill-defined and ill-fitting front-end design and planning problems.

In addition to back-loading v. front-loading, the “systems” nature of complex adaptive systems presents a much deeper challenge for S&T-based com-

130 C.S. Holling, ed., *Adaptive Environmental Assessment and Management* (Chichester: Wiley, 1978). For discussion relevant to drug regulation, see European Medicines Agency, “Report of the CHMP Working Group on Benefit-Risk Assessment Models and Methods (London, 19 January 2007).

131 Ruhl “Regulation,” *supra* note 17 at 28, 35. At 34, Ruhl notes the decision-making process is cyclical. It begins with defining the problem and objective, proceeds to selection of reference baseline and applicable conceptual models, selection and implementation of management actions, then monitoring and evaluation of performance, following which the cycle repeats as new facts and information are obtained and synthesized. LoPucki, *supra* note 17 (at 481,497-506), enumerates the process of systems analysis in the context of law to include: identifying the relevant system, discovering its goals or attributing goals to them, mapping the structure of subsystems and the function each performs, describing the relationships among system components, and identifying internal inconsistencies between goals and functions.

132 Horst Rittel & Melvin Webber, “Dilemmas in a General Theory of Planning” (1973) 4 *Policy Sciences* 155. So-called wicked problems are problems that have incomplete, contradictory, and changing requirements; solutions to them are often difficult to recognize because of the dynamic nature and scope of their complex interdependencies.

mercialization and innovation policy in jurisdictions where market economies and liberal democracies predominate – which is to say most jurisdictions that would value commercialization. The explicit policy goal of maximizing social efficiencies and minimizing social inefficiencies does not resonate on a deeper level with a historical emphasis on notions of utilitarian efficiency or rational or productive efficiency in policy-making or economic circles.¹³³ In their own way, all three focus narrowly on the individual, or agents of individuals such as corporations; the former by privileging subjective standards for behaviour and individual choice, and the latter two by fragmenting human society via a narrow focus on the mechanistic nature of human action and construction of society as a whole equal to the sum of its parts. At some level, the development of “radical individualism,” as Stein has called it, seems to be the rational and logical outcome of the causes of utilitarianism, early market theories, democracy, choice as a value (and, potentially, a right in affluent nations), coupled with the Rule of Law and entrenched human rights – which combine together to allow individuals to challenge sovereign nations and to put self interest forward based on the (untested) assumption that doing so somehow advances the cause of the collective.

However, as conceptual, technological and numerical models have evolved over the last half-century, it is becoming increasingly understood that easy extrapolations from individual to collective economic interests or from an understanding of the functioning of parts to functioning of the whole is fraught with many untenable assumptions and comprises a highly oversimplified model of human behaviour. This was the basis for the development of complexity and systems models to begin with. Further, as pointed out by Stein,¹³⁴ as more rights become attached to the individual rather than the collective, individuals are coming to the conclusion, quite rationally, that it is nevertheless the state that is at once the source and protector of individual rights and personal choice. Hence, in a culture where globalization and the knowledge-based economy continue to privilege individual rights and choice, some other mechanism must co-evolve to balance that force in favour of the collective. It is the possible role of complexity, and other systems-based theories, to provide this type of balance by focusing on the system rather than discrete individuals.

133 *Supra* note 59.

134 *Ibid.* at 53-69, 82, 130.

The question remains however, as to how best to leverage these new models into the 21st century in such a fashion that gains in empowerment of individuals over traditional power structures during the last millennium are not lost. One likely advantage will be that social inequalities associated with the operation of politics and markets¹³⁵ can be balanced by policies that are explicitly distributive in nature in that they are specifically aimed at an egalitarian distribution of the benefits of innovation arising from publicly funded scientific research once it has occurred.

A final major challenge for those exposed to systems theories for the first time, and for those engaged in modeling studies that privilege mathematical methodologies over what has at times been denigrated as mere “systems thinking,”¹³⁶ will be to move beyond numerical models into the messy and fuzzy world of policy development, where it may not be possible to collect meaningful data. In this sense, the goal of complex adaptive systems to maximize “mechanical efficiency” in phase space¹³⁷ has less relevance to policy development than may meet the eye for several reasons. First, in a policy context it is not possible to have a clear idea about the exact number or kind of variables at play, or the nature of the full range of their interactions. Similar difficulties arise when one attempts to define, with the type of precision required for quantification, the existence of an efficient policy state space, a phase transition towards criticality, or for that matter the potential range of state spaces in which policy may operate. Then there is the diffi-

135 *Ibid.* at 42: “politics tends to oligarchy while markets tend to oligopoly” under conditions where aggressive pursuit of personal goals is legitimately extrapolated to the pursuit of collective goals. The fragmented nature and lack of clarified interpolation between personal and collective goals in modern political and economic theories provide a basis for this command and control hierarchy, whereas the explicitly distributive nature of complex adaptive systems would provide for an identifiable if not completely explicable link between personal and societal interests.

136 Forrester, *supra* note 16, stating (at 17-18) that “Systems thinking can be a door opener and a source of incentive to go deeper into the study of systems. But I believe that systems thinking has no chance of instilling the lessons I have described [herein]. Systems thinking will change very few of the mental models that students will use in their future decision making. Systems thinking is not more than five percent of a systems education.”

137 For discussion of efficiency and function in complex systems, see the discussion around note 60, *supra*.

culty of measuring all necessary variables to derive reliable efficiency data, let alone having these variables hold still long enough in the context of their emergent nature for identification purposes in the first place. Finally, and particularly important in a market economy driven by self-interest, given the tendency of actors to disguise the self-maximizing nature of their contributions to the system (plus or minus legal, marketing or lobbying claims to the contrary), it is unlikely that quantitative efficiency could be a reasonable goal in the context of a systems view of innovation – particularly when the problem is framed in purely rational (i.e., mechanical) terms, as is true of the narrative to date regarding innovation in the life sciences embedded within a market economy.

It is only when values are added to the equation that efficiency becomes meaningful in a democratic state, because in the absence of values the political relationship between efficiency and accountability of elected government is hollow. As noted by Orsenigo *et al.* in the context of pharmaceutical and biotechnological innovation,¹³⁸ an open accountable medical research enterprise that underpins both medical product development and more general public health considerations is a universal entitlement precisely because the reasons for “doing science,” let alone commercializing it, are grounded in broad societal values and governments’ responsibility for their citizens that go beyond immediate and practical economic functions. The explicit goal of distributive fitness in a systems model of innovation clarifies the invisible force between individual and collective interests and thus identifies the basis for government accountability. As the topic of commercialization of medical research has become an increasingly popular one, not only in policy and scientific circles, but also in the media, the value and societal purpose of doing science has become a more frequent basis of discussion among medical researchers themselves, who are beginning to develop a stronger and more sophisticated discourse around the medical, economic and ethical values of their work to and in society. As such, the value of a systems-based approach for both making and assessing the usefulness of innovation policy is that it embraces new conceptual models of invention and innovation that encompass not only scientific and technological actors but also the wider network

138 Luigi Orsenigo, Giovanni Dosi & Mariana Mazzucato, “The pharma-biotech sector: Policy issues” in Mariana Mazzucato & Giovanni Dosi, eds., *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech* (Cambridge: Cambridge University Press, 2006) 402.

of political, economic and other actors within which invention and innovation occur. The sheer complexity of these networks underscores the potential value of new high performance computing technologies which allow simulations having as their aim the identification of not one but a range of potential future outcomes emanating from the same or similar initial starting conditions. Along with data from empirical studies of network effects, it may be possible to construct or at least enable a robust innovation space grounded in distributive considerations with the capacity to evolve within a broad network of political, economic, legal, scientific and social actors and operate as “efficiently” and “effectively” as possible across a wide range of future scenarios.

(C) Advantages of a Systems-based Innovation Ecology

Just as the challenges of obtaining buy-in and implementing a systems-based innovation ecology policy are great, so too are the potential rewards. We are entering an unprecedented time of change and growth in human societies, which to this point has largely revolved on increasing emphasis on individual rights and choice, the latter expressed most effectively through operation of market economies and liberal democracies. This has been paralleled by unprecedented growth in science (particularly in the life sciences), which has seen the development of new models for cosmology, behavior of natural systems and cellular building blocks of life in humans and other species come into being in a mere hundred years. Similar tectonic shifts in transportation and Internet and communications technologies have connected us into an increasingly global population that was unimaginable a hundred years ago. These developments in the life and computer sciences have extended life and empowered people at the individual level, but there is significant discontent across jurisdictions with regard to how far these individual-based models will take us as a society,¹³⁹ particularly as government farms out an increasing percentage of their responsibilities to public and private markets.

139 For a touchstone on the current debate in North America, see Margaret Wentz, “It’s our fault they can’t grow up” *The Globe and Mail* (18 August 2007) A19 and Tralee Pearce, “Adolescence is obsolete” *The Globe and Mail* (24 August 2007)(discussing the “common sense” applications of Robert Epstein, *The Case Against Adolescence: Rediscovering the Adult in Every Teen* (Sanger, Cal.: Quill Driver, 2007)).

From complexity theory, one can say that it is the inherent nature of humans to continually grow and evolve, but that even so, given the patterns that have developed over the last two centuries of privileging individual rights and choice, we may be coming to a place of detail mode, where increasingly radical forms of individualism are beginning to predominate and certain aspects of the system are beginning to stagnate. As argued above, certain kinds of innovation seem to have arrived at this point, for example in the pharmaceutical and, increasingly, biotechnology sectors.¹⁴⁰ It appears reasonable to speculate that public discourse on the desirability of radical forms of individualism is reaching the ears of key government players. Hence the possibility arises of the need for a phase transition of the type discussed above in order to pull the system back into a state of criticality, where order is that at the edge of chaos (and thus where the two are “balanced”) and where the system can be more responsive to the challenges of an increasingly globalized world. Public-private partnerships aimed explicitly at the system level rather than the modular may then offer an exponential jump in research and development resources, both at the sheer dollar level and in terms of the scope of interconnected nodes and hubs of resources. Hub and spoke models of this nature are not new. What is new however is the explicit goal of maximizing the fitness of the system rather than of individuals. As globalization continues apace notwithstanding differing governments and economic systems, it may be time to place more emphasis on the common ground (i.e., broad generic rules) rather than privileging one, or a small, set of values.

In this regard, one of the potential leverage points of complex adaptive systems, and other systems-based approaches, is the acceptance of uncertainty as an inherent and positive force in life, rather than a force to be restrained and contained at all costs. It is this uncertainty, and the spontaneous and emergent nature of inventive acts of creativity, that provides the fertile ground for innovation generally, and particularly in fields of endeavor such as medical research, where the complexities and interconnections between systems are just being identified and understood and where new conceptual

140 John Horgan has claimed that the entire scientific enterprise now operates in detail mode, where most breakthrough discoveries have already been made and therefore where almost all existing scientific activity is aimed at incremental advances layered over top of past discoveries. See John Horgan, *The End of Science* (New York: Broadway, 1996).

models are just being developed. For a policy to truly facilitate invention and innovation under such conditions, it must be coherent with and accept the broad generic rules undergirding the system. To the extent it does not, or moves in another direction, the more likely it will be to constrain the very thing it seeks to facilitate.

(D) Beginning to Pave the Middle Road

The answer of how to begin employing a systems-based innovation ecology framework may revolve around a combination of re-setting the level of control that policy-makers feel is important to exert over their creations from one time point to the next; accepting a degree of uncertainty in the processes of policy-making; monitoring the results of those policies, including allowing for reasonable, if not maximal, organizational learning via feedback loops; and finally, answering some fairly important questions regarding the role of government in supporting individuals, corporations and society in a new global economy and the degree to which it will outsource its public health responsibility to corporations. Answers to these questions will determine the degree to which citizens and leaders (government, non-governmental organizations, corporations) understand their role in a complex adaptive system and act to maximize fitness of the system rather than that of themselves. It is understandably a difficult proposition in a time of radical individualism to yield a certain degree of control over and prioritization of oneself in favour of a system (or indeed anything else), as it involves more than a modicum of faith in the *per se* existence of the system, the notion that it operates to maximize its own fitness rather than that of individuals, and the idea that constraining the system to focus narrowly on individuals actually inhibits growth of all elements of the system and thus of individuals, in the long term.

In a complex innovation ecosystem embracing democratic and utilitarian principles, and which depends for its success on the salience and sapience of its agents, it is the responsibility of elected government to ensure the playing field remains as even as possible and focused on system fitness rather than that of discrete system components. This has direct relevance to innovation in medical research, where competing objectives of public health protection and private commercialization of innovative medical research are not only embraced equally but are converging over time, and where domestic deregulation and global harmonization of regulatory standards are increasingly becoming the norm. One step in the right direction in the area of medical product development is currently underway in the

form of the Government of Canada's Progressive Licensing Framework for drug approval.¹⁴¹

In its *Blueprint for Renewal*,¹⁴² Health Canada is seeking to move from a front-loaded system of approval of regulatory approval to a back-loaded "life-cycle" approach,¹⁴³ whereby probationary approval contingent on post-marketing surveillance comprises a dominant form of market licensure for new essential therapies. A similar approach to drug regulation is being contemplated in the United States¹⁴⁴ and European Union.¹⁴⁵ While it is still early days compared to analogous experience with American environmental law and policy, given the inherently dangerous nature of novel biotherapeutics combined with the large degree of partnership between government and industry in crafting the licensing framework, it will be important for Health Canada to take an approach to adaptive management that respects the features of a complex adaptive systems view of medical product development for the reasons described above. This will help sidestep predictable flaws in organizational strategies based on deterministic, linear and constrained conceptual models¹⁴⁶ and the moral and physical dangers of their improper application in a public health context.¹⁴⁷ It will also help to balance flaws inher-

141 Trudo Lemmens & Ron A. Bouchard, "Regulation of Pharmaceuticals" in Jocelyn Downie, Timothy Caulfield & Colleen M. Flood, eds., *Canadian Health Law and Policy*, 3rd ed. (Toronto: LexisNexis, 2007) 311 at 361-364; Neil Yeates, David K. Lee & Maurica Maher, "Health Canada's Progressive Licensing Framework" (2007) 176 *Canadian Medical Association Journal* 1845.

142 Health Products and Food Branch, *supra* note 7. Amendments to the Food & Drug Act are currently enshrined in Bill C-51, which is in its second reading at the time this article is going to press.

143 *Ibid.* at 16.

144 Committee on the Assessment of the US Drug Safety System, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (Washington, D.C.: Institute of Medicine of the National Academies, 2006), online:

<<http://www.iom.edu/CMS/3793/26341/37329.aspx>>. As this article was going to press, the U.S. FDA announced its "sentinel initiative" which paralleled the progressive licensing regime embodied by Bill C-51: Gardiner Harris. "FDA to expand its scrutiny of risks from drugs after they're approved for sale" *New York Times* (May 23, 2008).

145 For comment by the Government of Canada, see Yeates, Lee & Maher, *supra* note 141.

146 Kurtz and Snowden, *supra* note 23.

147 Este, *supra* note 23.

ent to older hierarchical command and control models of regulation, which Health Canada appears intent on importing into its new framework.¹⁴⁸

Taking a complex systems approach to innovation and drug regulation involving strong IPR rights would ensure that public health considerations remain at the forefront when federal governments consciously and purposively push their countries towards phase transition, especially one in which public-private partnerships and public markets are front and centre. As noted above, in a phase transition, no one is exempted. An important ramification of complex systems in this regard is that newer systems may be more labile, and thus more uncertain, than older, more established systems. Consequently, it may be pertinent for governments in this position to leverage, *inter alia*, existing and developing conceptual and technology-based systems models of public health¹⁴⁹ in order to understand and anticipate the impacts (positive and negative) of undergoing such a large scale transition on the general population (i.e., the full range of system actors). Taking this approach would also assist national governments to avoid charges of bias and unfairness. As noted previously,¹⁵⁰ to the extent federal health agencies consult and partner 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 not only to maintain the integrity of government-industry relations, but also to be seen to be doing so publicly.

A final consideration in beginning to pave a middle way is the idea that the concept of balance is favoured over that of the extreme. While this may offend the drive to be “number one” and to be seen accordingly as powerful in today’s media-intense culture, over the long run taking a systems approach to innovation policy, which cannot be separated from other cultural – indeed philosophical – aspects of human society as it moves forward in a

148 Lemmens & Bouchard, *supra* note 141.

149 For example, see John D. Sterman, *supra* note 16; John D. Sterman, “All models are wrong: Reflections on becoming a systems scientist” (2002) 18(4) *Systems Dynamics Review* 501; John D. Sterman, “Learning from evidence in a complex world” (2006) 96 *American Journal of Public Health* 505; Homer & Hirsch, *supra* note 16; Yaneer Bar-Yam, “Improving the effectiveness of health care and public health: A multiscale complex systems analysis” (2006) 96 *American Journal of Public Health* 459.

150 Bouchard “Balancing,” *supra* note 3; *supra* note 116.

global environment,¹⁵¹ may help to move society generally, and innovation policy specifically, towards a state of criticality, where accommodation and cooperation are as valued as competition among rivals. Taking a more balanced and long term approach to innovation may also steer us in the right direction towards development of a sustainable knowledge-based economy.

IV. Summary & Conclusions

Decisions such as *KSR* illustrate that Canadian firms and inventors do not operate within a purely local sphere, but rather are embedded within a complex domestic network of scientific, legal, regulatory, economic and political actors enfolded within a still larger global innovation ecology. It was reasoned that a system of this nature has many of the hallmark characteristics of an open and continually evolving complex adaptive system. A complex systems approach to innovation privileges the interrelationships among actors and institutions and their interdependence in maximizing system fitness – in this case innovation in the medical sciences and enhancing national productivity and prosperity. Of importance from a health law and policy perspective, a systems approach is conducive to accomplishing these goals in a manner that respects many of the fundamental distributive and egalitarian considerations embedded within the democratic state, common law, Rule of Law and entrenched human rights.

That the goal of a robust complex adaptive system is not optimization but operational efficiency from the perspective of the whole, underscores the importance of maximizing social efficiencies and minimizing social inefficiencies. When drafting law and policy with the goal of respecting the characteristics of a complex system, it is therefore important to balance accommodation and cooperation with competition among system elements so as to maximize the flexibility and responsiveness of the system to changing conditions. As discussed in the context of pharmaceutical innovation, placing too much emphasis on controlling or regulating an inherently indeterminate and emergent system without paying sufficient attention to states of criticality and phase transitions can lead to inefficient behaviors of a system that contradict its stated policy objective. Over-regulation of innovation by excessive or narrowly circumscribed IPR rights may allow for escape of creative energy away from the desired policy goal towards less innovative, less

151 Bruno Latour, *We Have Never Been Modern* (Cambridge, Mass: Harvard University Press, 2007).

resource heavy yet more constrained pathways that benefit discrete actors and institutions rather than the system. A highly constraining IPR rights regime not only has the potential to skew the benefits of innovation towards discrete modules (corporations, individuals), but also to skew function of the system more broadly by influencing the general pattern and scope of innovative activity by persons skilled in the art as well as the manner in which newly synthesized scientific knowledge is used by legal, regulatory, economic and political actors. The ironic result of this is that innovation can be stifled by the very policies meant to stimulate it. Indeed, in its leading patent jurisprudence, SCOTUS, from *Hotchkiss* through *Graham* and *KSR*, has maintained the position that the grant of patents for non-inventive products and processes inhibits rather than stimulates innovation and competition.

There is some evidence to suggest that a conceptual model of innovation as a global systems ecology may have particular resonance for Canada, as well as other nations seeking to leverage their national S&T base in the medical sciences, in light of several signs signifying Canada is nearing a major phase transition in its system of public health. These include: (a) the CIHR moving from a system of medical research focused on accrual of new knowledge by university-based researchers to one which underscores the importance of translating knowledge into marketable products through public-private partnerships; (b) attempts by the CIHR and other national and provincial funding agencies to emulate the successes of the United States in commercializing university-based medical research through accumulation of IPR rights; (c) the TPD positioning Canada as one of the first jurisdictions in the world to transition from a regime of drug approval and regulation based on the precautionary principle to a corporate-based risk management style regime; (d) the move by Health Canada generally away from a traditional political “gatekeeper” role in protecting public health to a hybrid position where government is equally responsible for public health and ensuring a high return on investment on medical research; (e) the move by the Government of Canada towards both deregulation and regulatory harmony with other federal agencies funding medical research and regulating the products of that research; (f) the possibility of a two-tiered medical system following *Chaoulli*; and (g) the Government of Canada’s avowed purpose in engaging in many of these activities to succeed not only domestically, but globally, in order to enhance national productivity and prosperity on the back of “leading edge” medical research.

The observation in an array of natural, biological and technological complex adaptive systems that newer systems are more labile and uncertain than older established systems suggests a certain degree of prudence in

pushing for such a large scale transition. Several considerations support a note of caution, including the possibility that a large fraction of the physical and economic risks of a new public health system would be shifted away from government and corporations and onto the public, and the willingness shown by the government to enter into public-private partnerships with increasing frequency over the development of policy, legislation and regulations pertaining to a variety of public health issues. This is not to say the government should rely on older back-loaded models of policy development and regulation instead of newer organizational models. Rather, in order to grapple with particularly “sticky” or “wicked” policy problems, such considerations underscore the need for just such novel models and therefore the need to thoroughly explore evolving conceptual and technological models of complex adaptive systems. By taking an approach that respects rather than avoids the complex nature and inherent uncertainties of global innovation and product development, nations entering large-scale phase transitions related to medical research can avoid both the flaws inherent to organizational strategies based on deterministic, linear and constrained conceptual models and the moral and physical dangers of their improper application in a public health context.

One of the major leverage points of complex adaptive systems, and other systems-based approaches, is the acceptance of uncertainty as an inherent, unavoidable and positive force, rather than something to be restrained and constrained at all costs. This has some fairly straight forward implications for innovation, in the medical sciences or otherwise. This is because the *sine qua non* of innovation is invention, which is at heart a highly serendipitous process rather than one that can be quantified by narrowly circumscribed or measurable IPR rights-intensive S&T policies. This is particularly true where, as in the present instance, the conceptual models for obtaining, synthesizing and explicating new forms of knowledge are themselves new and evolving.

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