Could Open be the Yellow Brick Road to Innovation in Genomics in North America?

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Medical research in genomics is advancing at an accelerated pace. Every new discovery or invention creates a new and even more ambitious set of promises and associated expectations for improved health care. However, despite some rapid advances, most of these promises have yet to come to full fruition. Proponents of the patent system and its traditional proprietary model of commercialization claim that it is the most effective instrument for providing the necessary incentives to allocate their financial resources and efforts to advance innovation. However, the use of patents in genomics has introduced major roadblocks, leading to a slower, less efficient, and more burdensome innovation process. Moreover, patented innovation tends to be particularly costly

Il est aujourd'hui impossible d'ignorer les avancées rapides de la recherche médicale dans le domaine de la génomique. Chaque découverte éveille de nouvelles ambitions, de nouvelles promesses et génère son lot d'attentes en matière d'amélioration des soins de santé. Toutefois, malgré ces développements fulgurants, la plupart de ces promesses n'ont toujours pas été réalisées. Les partisans du système de brevetage et de son modèle de commercialisation basé sur la propriété exclusive, maintiennent que celui-ci reste le meilleur moyen d'assurer que les acteurs du milieu conservent un intérêt suffisant à investir temps et argent dans l'innovation. Cependant, dans le domaine de la génomique, l'utilisation de brevets constitue une barrière significative en termes

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and has contributed to the recent rise in the price of drugs, tests, and medical devices. These high prices prevent poorer populations from obtaining the health care services they re-quire. For an improved innovation system in this field, a variety of open models of innovation have been proposed and used in addition to, or to replace, the patent system. This article considers whether open models of collaboration can pave a "yellow brick road" to future innovation. It explores the way in which the use of open models of collaboration in genomics can help reduce these roadblocks and extends beyond academic debates by analyzing real-world examples of projects in North America.

de rapidité et d'efficacité de l'innovation. De plus, dans un système de brevets, cette dernière se révèle particulièrement dispendieuse, contribuant aux récentes augmentations du prix des médicaments, des tests et des instruments médicaux. De ce fait, les populations défavorisées souffrent d'un manque d'accès aux soins de santé dont ils ont besoin. Dans le but d'améliorer la situation actuelle, des systèmes alternatifs basés sur des modèles de collaboration ouverte ont été proposés en marge ou en remplacement du système actuel. Le présent article vise à évaluer si ces modèles ont le potentiel de dégager le chemin vers l'innovation. Il y est exploré comment ceux-ci peuvent écarter les obstacles ralentissant le progrès et s'étendre en dehors des cercles académiques pour s'établir dans de véritables projets en Amérique du Nord.

Introduction

Medical research in genomics[1] and precision medicine is advancing at an accelerated pace. Each novel discovery or invention in these areas creates a new and even more ambitious set of promises and associated expectations for improved health care. Despite the many advances, most of these promises have yet to come to fruition.

The patent system, with its traditional proprietary model of commercialization, has been justified by its proponents as the most effective instrument for providing inventors, researchers, funders, and investors with the necessary incentives to allocate their resources and efforts to advance innovation. In particular, this justification has been used in the pharmaceutical and biotechnology industries. However, the use of the patent system in genomics comes at a high price since, by its very nature, it introduces at least two major roadblocks in the innovation process.

Firstly, despite the important scientific and technological advancements achieved in past decades, there is good reason to believe that if the closed, patent-based model remains the status quo in innovations based on genomic data, the hope of creating targeted and personalized therapies will remain unrealized, or at least take far longer and be more expensive than if done in an open model. This is due to the inherent nature of genomics research, which is characterized by the abundance, complexity, and unpredictability of genomic science.

Given the risk and complexity inherent to the innovation process in this field, the study, integration, and use of genomic data require a large number of human and material resources, consistent effort, and multiple approaches. Increasing the resources, time, and effort devoted to a specific research question can hasten its resolution, not only via the discovery of new information and approaches, but also by enabling researchers to more efficiently uncover and harness solutions in existing data. The classic, closed use of the patent-based development model limits access to existing data and resour-

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[1] We use the term "genomics" throughout the article in its broadest sense to encompass all areas of genomics. Our genome serves as the foundation of efforts to catalogue human genes, understand their structure and regulation, determine the extent of variation in these genes in different populations, and uncover how genetic variation contributes to disease. See generally Robert L Nussbaum et al, *Thompson and Thompson Genetics in Medicine*, 8th ed (Philadelphia, PA: Elsevier, 2016) at Chapter 1.

ces to those which are individually authorized. These limitations can lead to a slower, less efficient, and more burdensome innovation process.

Secondly, there is an ethical concern regarding access to genomics-based innovations. Patented innovation tends to be particularly costly and as a result, the high prices of medical products and services prevent poorer populations from accessing the health care services they need.[2]

To improve innovation in the field of genomics, a variety of open models of innovation have been proposed and used in addition to, or to replace, the patent system. This article explores the use of such open models of collaboration in genomics in three North American countries: Canada, the United States, and Mexico. These countries have the strongest economies and genomic innovation capacity in the region. Moreover, they represent an interesting variability of scientific and innovation approaches in the field of genomics.

We begin Part I with a brief background of the patent system, describing the legal framework in reference to the each of these three countries. We also present the main justifications and concerns raised in the literature regarding the patent system to date. This background will lay the basis for Part II, which describes the characteristics of the different models of open collaboration. In Part III, we build on the previous discussion of open models of collaboration by exploring concrete examples of biomedical projects that have adopted one or more open models of collaboration in each of the three countries included in our study. In the conclusion, we discuss the North American situation with respect to innovation in biomedicine and the ways in which open models of collaboration could help pave a "yellow brick road" to future innovation.[3]

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[2] Despite its undeniable importance, this issue is beyond the scope of our article. See generally Cloe Ying C Koh & Thomas P Seager, "Value-Based Pharmaceutical Pricing From the Patient Perspective Could Incentivize Innovation" (2017) 31:49 Pharm Med at 149; Paul Grootendorst et al, "New Approaches to Rewarding Pharmaceutical Innovation" (2011) CMAJ at 682; Stephanie A Robertson & Adam R Renslo, "Drug Discovery for Neglected Tropical Diseases at the Sandler Center" (2011) 3:10 Future Med Chem 1279.

[3] The metaphor of the yellow brick road, derived from the 1939 film *The Wizard of Oz*, commonly refers to a pathway to success.

I. Background

Innovation is regulated through three primary means: intellectual property laws, innovation policy, and ethics.[4] Each of these three normative pathways addresses different issues that concern the promotion, proper development, and use of innovation.

In theory, intellectual property laws and policies aim to "foster an environment in which creativity and innovation can flourish" by enabling people to obtain recognition as authors or inventors and to receive remuneration from what they create or invent.[5] In practice, there is no evidence to demonstrate that intellectual property accomplishes this function in the field of genomic research.[6] Recognition and remuneration are granted and implemented through the enforcement of different types of property rights (e.g. copyrights, patents, industrial designs, and trademarks) that give their holder the exclusive rights to use, make, sell, import, and reproduce the protected work or invention.[7]

Innovation policies are norms which governments use to encourage innovation that are alternatives to, or complementary to, intellectual property laws. The form of an innovation policy can vary widely depending on the jurisdiction and subject matter, but the most common forms are direct public or institutional funding and tax incentives. Both of these approaches use monetary incentives to direct innovation. Funding policies enacted by governments provide grants and awards, the amount, focus, and terms of

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4 See Knut Blind, "The Impact of Regulation on Innovation" in Jakob Edler et al, eds, *Handbook of Innovation Policy Impact* (Cheltenham, UK: Edward Elgar Publishing, 2016) 450.

5 See "What is Intellectual Property?", online: *World Intellectual Property Organization* <www.wipo.int/about-ip/en/> [perma.cc/ZK3G-KRZL].

6 See generally E Richard Gold et al, "Are Patents Impeding Medical Care and Innovation?" (2010) 7:1 PLoS Med e1000208.

7 See *ibid*.

which reflect the underlying policy objectives. Canada,[8] the United States,[9] and Mexico[10] all have public funding policies, though Mexico has one of the lowest expenditures among countries in the Organisation for Economic Cooperation and Development (OECD), while the United States and Canada are in the top fifty percent.[11]

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8 Some of the federal agencies involved are the Natural Sciences and Engineering Research Council, the Social Sciences and Humanities Research Council, and the Canadian Institutes of Health Research. See Government of Canada, NSERC, "Natural Sciences and Engineering Research Council of Canada: About NSERC" (18 April 2018), online: *NSERC-CRSNG* <www.nserc-crsng.gc.ca/NSERC-CRSNG/Index_eng.asp> [perma.cc/NKE5-5Z86]; Government of Canada, SSHRC "Social Sciences and Humanities Research Council: About SSHRC" (13 December 2017), online: *SSHRC-CRSH* <www.sshrc-crsh.gc.ca/about-au_sujet/index-eng.aspx> [perma.cc/ZA98-S6CZ]; Government of Canada, CIHR, "Canadian Institutes of Health Research: About Us" (21 August 2018), online: *CIHR-IRSC* <www.cihr-irsc.gc.ca/e/37792.html> [perma.cc/BUN3-VGFG].

9 The Office of Science and Technology Policy is in charge of giving policy advice and coordinating science, technology, and innovation (STI) policies. See "Office of Science and Technology Policy" (last visited 3 October 2019), online: *White House* <www.whitehouse.gov/ostp/> [perma.cc/DFB4-8JBT]. The National Science Foundation (NSF) is one of the main federal agencies that promotes science, advances national health, prosperity, and welfare by providing funding to federally supported basic research in colleges and universities. See Government of the United States, NSF, "National Science Foundation: At a Glance" (last visited 3 October 2019), online: *NSF* <www.nsf.gov/about/glance.jsp> [perma.cc/XP9T-B6X3].

10 The Consejo Nacional de Ciencia y Tecnología is the federal agency responsable for funding and supporting science and technology innovation and research in Mexico. The Sistema Nacional de Investigadores is an example of one of their programs to recognize quality research. See Government of Mexico, CONACYT, "Consejo Nacional de Ciencia y Tecnología: Sistema Nacional de Investigadores" (last visited 3 October 2019), online: *CONACYT* <www.conacyt.gob.mx/index.php/el-conacyt/sistema-nacional-de-investigadores> [perma.cc/2GTM-P8DW]; Government of Mexico, CONACYT, "Consejo Nacional de Ciencia y Tecnología: Fondos y Apoyos" (last visited 3 October 2019), online: *CONACYT* <www.conacyt.gob.mx/index.php/fondos-y-apoyos> [perma.cc/5KLC-9N4Q].

11 See OECD, *OECD Science, Technology and Industry Outlook 2012* (OECD Publishing, 2012) at 256–59, 404–07, 344–47, online: *OECD iLibrary* <dx.doi.org/10.1787/sti_outlook-2012-en> [perma.cc/Z7TT-H4TC].

At some stage in the innovation process, initial public funding, which usually concentrates on basic research, is most often combined with private investment.[12] Governments offer tax incentives to attract increased private investment in pre-selected fields. Examples include research and development (R&D) tax credits, R&D tax allowances, and payroll withholding tax credit for R&D wages.[13] Tax incentive schemes differ in amount, design, and targeted areas.[14]

Innovation in genomics is also influenced and regulated, to a certain point, by ethical norms. For instance, stem cell and embryonic research, gene editing, and cloning technologies have raised significant ethical concerns and concomitant oversight.[15] Existing views and concepts of human dignity, autonomy, and human identity tend to guide these ethical concerns, which influence funding decisions, ethics approval processes, and occasionally lead to outright bans on certain kinds of research.[16] The recent outcry around the use of CRISPR/Cas-9 to edit human embryos provides a vivid example of the significance of ethical norms and their global variation.[17]

The following Sub-Parts of the article focus on patents as the pursuit and enforcement of intellectual property. Notably, patents constitute the status quo in terms of innovation tools against which one can assess the relevance of open models of collaboration.

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12 See Linda A Hall & Sharmistha Bagchi-Sen, "A Study of R&D, Innovation, and Business Performance in the Canadian Biotechnology Industry" (2002) 22:4 Technovation 231 at 233.

13 Tax allowances are tax concessions that governments grant, up to a certain percentage of the R&D expenditure. Payroll withholding tax credit for R&D wages are deductions made from payroll taxes and social security contributions based on R&D expenditure. See OECD, *supra* note 11 at 164–66.

14 See *ibid*.

15 See Mathew Varkey & Anthony Atala, "Organ Bioprinting: A Closer Look at Ethics and Policies" (2015) 5:2 Wake Forest J L & Policy at 286; *Assisted Human Reproduction Act*, SC 2004, c 2.

16 See Phoebe H Li, "3D Bioprinting Technologies: Patents, Innovation and Access" (2014) 6:2 Law Innov Technol 282 at 286.

17 See e.g. Yuanwu Ma, Lianfeng Zhang & Chuan Qin, "The First Genetically Gene Edited Babies: It's 'Irresponsible and Too Early'" (2019) Animal Model Ex Med, online: <onlinelibrary.wiley.com/doi/full/10.1002/ame2.12052> [perma.cc/CM7H-WPMJ].

A. Patents

Patents are the dominant form of intellectual property law used to protect and promote innovative research in biomedicine, medical biotechnology, pharmaceuticals, and precision medicine.[18] Patents grant a 20-year period of exclusive rights to make, use, sell, and import the invention that they protect.[19] These rights may be assigned or licensed to third parties. Patents are granted on a country-by-country basis, which means that they only have national coverage; therefore, a patent needs to be obtained in each country in which protection is sought.[20] An invention can be patented if it is novel,

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[18] See Tania Bubela, Garret A FitzGerald & E Richard Gold, "Recalibrating Intellectual Property Rights to Enhance Translational Research Collaborations" (2012) 4:122 Sci Transl Med 1 at 3. See also Yann Joly, Angus Livingstone & Edward S Dove, "Moving Beyond Commercialization: Strategies to Maximize the Economic and Social Impact of Genomics Research," Policy Brief 5, *GPS: Where Genomics, Public Policy and Society Meet* (Canada: GPS-Genome Canada, April 2012); Palmira Granados Moreno & Yann Joly, "Intellectual Property and Innovation in Translational Medicine" in Martin Wehling, ed, *Principles of Translational Science in Medicine: From Bench to Bedside*, 2nd ed (Waltham: Academic Press, 2015) 281 at 282.

[19] This 20-year period starts on the date in which the patent application is filed. See *Patent Act*, RSC 1985 c P-4, s 44 [Canadian *Patent Act*]; *Patents*, USC, tit 35 §154(a)(2) (2012) [*US Code*]; *Ley de la Propiedad Industrial*, Diario Oficial de la Federación, 27 June 1991, art 23 [*Ley de la Propiedad Industrial*]. See also Granados Moreno & Joly, *supra* note 18 at 282–83.

[20] The costs of obtaining patents vary greatly depending on the type of business, the jurisdiction, the complexity of the invention, and mostly on whether the application is contested. The costs start at USD$4,000-$6,000 for uncontested patent applications and can reach up to USD$60,000. To litigate a contested patent can cost up to USD$1.6 million, and given that these amounts are rarely disclosed in the case of major pharmaceutical companies, may even exceed this number. See Tony Wilson, "When to Patent Something and How to Do It", *The Globe and Mail* (30 January 2018), online: <www.theglobeandmail.com/report-on-business/small-business/sb-growth/when-to-patent-something-and-how-to-do-it/article626823/> [perma.cc/3MFD-GVAS]; Yann Joly, "Open Source Approaches in Biotechnology: Utopia Revisited" (2007) 59:2 Me L Rev 386 at 388; BlueIron IP, "What Do Patents Actually Cost?" (11 May 2015), online: *BlueIron IP*, <www.blueironip.com/what-do-patents-actually-cost/> [perma.cc/C4Y9-AMY3].

non-obvious, useful (or has an industrial application), and falls within patentable subject matter.[21]

Four types of patents are relevant in genomics research: patents on products, patents on processes or methods, patents on compositions of matter, and patents on improvements. US courts have addressed composition of matter and process patents, most notably in the case of *AMP v Myriad Genetics*.[22] Myriad held composition of matter patents over BRCA gene variants and process patents over comparing those variants to those known to cause cancer. These patents gave Myriad a monopoly on BRCA testing which was used to charge higher than necessary prices for such tests. In other words, Myriad's patents were inhibiting innovation based on genomics knowledge of the BRCA genes, as well as access to those innovations by the socio-economically disadvantaged. This example encapsulates both of the concerns expressed in the introduction of this article.

Other examples – including the race between the Human Genome Project (HGP) and Craig Venter's Celera Genomics, and the ongoing battle over the CRISPR/Cas-9 patents – demonstrate the tension between private and open innovation. The HGP was a worldwide public effort to put the human genome in the public domain, or in other words, to keep it open. This initiative has had an estimated USD$178 per USD$1 spent return on investment for the US economy.[23] Had Celera successfully sequenced and patented, the reference genome cost of innovating in genomics may have been substantially higher as a result of Celera's legal right to charge licensing fees. Indeed, it is likely that the recent growth of genomics technologies, and orders-of-magnitude reduction in the cost of genome sequencing, would have taken years to develop, if at all.

Proponents of the patent system claim that innovation needs patents to occur.[24] According to this line of thought, researchers need patents in

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21 See *Ley de la Propiedad Industrial*, *supra* note 19, art 12; Canadian *Patent Act*, *supra* note 19, ss 2, 28.2(1), 28.3; *US Code*, *supra* note 19, §101, 103.

22 *Association for Molecular Pathology v Myriad Genetics, Inc*, 569 US 576 (2013).

23 See Meredith Wadman, "Economic Return from Human Genome Project Grows" (12 June 2013), online: *Nature* <www.nature.com/news/economic-return-from-human-genome-project-grows-1.13187> [perma.cc/3GSD-MA7G].

24 See Henry G Grabowski, Joseph A DiMasi & Genia Long, "The Roles of Patents and Research and Development Incentives in Biopharmaceutical In-

order to be rewarded and financially compensated for their work, as well as to attract investors to further develop and commercialize their projects. Having the exclusive rights to sell, make, use, or import their patented inventions allows them to commercially exploit their inventions and obtain further economic support. Investors and funders need patents to recoup their investments.[25] Businesses need strong, reliable patents to attract investment in risky R&D environments.[26] Proponents of the patent system also claim that they are particularly important for small and medium-sized companies, given that they usually engage in the innovation of new ventures and new entrant products. These companies therefore depend on patent protection to establish and maintain their presence and survive competition.[27] Large companies, on the other hand, tend to focus on continuous improvement, relying on their existing markets and using the patent system to maintain their competitive advantage.[28] Patent supporters also claim that the patent system favours the eventual creation of a knowledge commons that will serve as the basis for further innovation, since patents applications are public and upon expiration of the patentability period, the invention will fall in the public domain.[29] Finally, patent supporters argue that patents enable and facilitate information markets, since information and knowledge conveniently "packaged" in patents can be easily valued, and hence traded or assigned.[30]

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novation" (2015) 34:2 Health Affairs 302 at 303; F Scott Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science: A Response to Rai and Eisenberg" (2001) 95:2 Nw UL Rev 691 at 698–99.

25 See Granados Moreno & Joly, *supra* note 18 at 285; David Castle, "Introduction" in David Castle, ed, *The Role of Intellectual Property Rights in Biotechnology Innovation* (Massachusetts: Edward Elgar Publishing, 2009) at 80.

26 See Mateo Aboy et al, "After Myriad, What Makes a Gene Patent Claim 'Markedly Different' From Nature?" (2017) 35:9 Nat Biotechnol 820 at 824.

27 See *ibid*.

28 See *ibid*.

29 This is due to the obligation that patent applicants have to include in their application the description, details, components, uses, and functionality of the invention to the extent that it allows a person skilled in the art to reproduce the invention. See Granados Moreno & Joly, *supra* note 18 at 285.

30 See Janet Hope, *Biobazaar: The Open Source Revolution and Biotechnology* (Massachusetts: Harvard University Press, 2008) at 25, 82.

B. Concerns regarding patents

Patent critics raise a number of concerns. One of the main problems identified in the literature regarding traditional proprietary use of intellectual property, particularly with respect to patents, is the emergence of the "tragedy of the anticommons." This concept is a response to the tragedy of the commons theory wherein common resources are exhausted because no individual has property rights in the resource and therefore no sufficient incentive to protect the resource from overuse.[31]

The tragedy of the anticommons describes the opposite concern: the underuse of an important resource. Granting an abundance of overlapping property rights, as can happen when many patents are granted in a small innovation space, can give rise to a patent thicket. A patent thicket is a "dense web of overlapping intellectual property rights (in this case, patents) that a company (or a researcher) must navigate its way through in order to actually commercialize new technology."[32] Having to navigate a patent thicket can discourage investment in R&D because sorting out the boundaries of patents, determining what constitutes infringement, and which licenses are required to freely operate often require costly and lengthy court proceedings.[33] The consequent lack of investment in and engagement with the thicketed innovation space leads to the underuse of resources, as predicted by the tragedy of the anticommons, and a resulting slow-down of innovation.

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[31] See Michael A Heller, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets" (1998) 111:3 Harv L Rev 622; Michael A Heller & Rebecca S Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280:5364 Science 698. See generally Garrett Hardin, "The Tragedy of the Commons" (1968) 162:3859 Science 1243.

[32] Carl Shapiro, "Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting" in Adam B Jaffe, Josh Lerner & Scott Stern, eds, *Innovation Policy & Economy* (Cambridge: MIT Press, 2001) 119 at 120.

[33] See Heller & Eisenberg, *supra* note 31 at 699; Timothy Caulfield et al, "Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies" (2006) 24:9 Nature Biotechnology 1091 at 1091; Arti K Rai, "Evolving Scientific Norms and Intellectual Property Rights: A Reply to Kieff" (2001) 95:2 Nw UL Rev 707 at 710–11; Louise Bernier, *Justice in Genetics: Intellectual Property and Human Rights From a Cosmopolitan Liberal Perspective* (Cheltenham: Edward Elgar Publishing, 2010) at 137–38; Amit Makker, "The Nanotechnology Patent Thicket and the Path to Commercialization" (2011) 84:5 S Cal L Rev 1163 at 1175.

Even if the thicket does not prevent investment, the costs associated with obtaining the necessary licenses from multiple patent holders diverts available resources away from development in other areas or products, leading to lost opportunity costs. Likewise, the time required to sort out the patent landscape and obtain the relevant licenses lengthens the innovation process in general, as innovative products cannot be commercialized until potential patent infringements are cleared.[34]

Patent critics also suggest that the current patent system encourages and facilitates rent seeking more than innovation, which hinders, decreases, or slows innovation as a result. For example, the pharmaceutical industry persistently increases expenditure on R&D (worldwide, pharmaceutical R&D spending has grown from USD$108.1 billion in 2006 to USD$156.7 billion in 2016), while the number of successful breakthroughs continues to decrease.[35] Specifically, there has been an increase of R&D in previously validated targets, me-too drugs, beauty products, and drugs that bear great resemblance to pre-existing ones near their patent expiration date.[36] These products usually translate to lucrative earnings and more patents for the biotechnology and pharmaceutical companies.[37]

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[34] See Arti K Rai & Robert Cook-Deegan, "Racing for Academic Glory and Patents: Lessons From CRISPR" (2017) 358:6365 Science 874 at 874–75; E Richard Gold, "Accelerating Translational Research Through Open Science: The Neuro Experiment" (2016) 14:12 PLOS Biology1 at 4; Robin Feldman & Mark A Lemley, "Do Patent Licensing Demands Mean Innovation?" (2015) 101 Iowa L Rev 137 at 173; Minna Allarakhia, "Open-Source Approaches for the Repurposing of Existing or Failed Candidate Drugs: Learning From and Applying the Lessons Across Diseases" (2013) 7 Drug Design Development & Therapy 753 at 759; Hall & Bagchi-Sen, *supra* note 12 at 238–42; Subhashini Chandrasekharan & Robert Cook-Deegan, "Gene Patents and Personalized Medicine: What Lies Ahead?" (2009) 1:92 Genome Med, DOI: <10.1186/gm92>.

[35] See Stephen H Friend & Thea C Norman, "Metcalfe's Law and the Biology Information Commons" (2013) 31:4 Nat Biotechnol 297 at 298; "Worldwide Pharmaceutical Company R&D Expenditure", online: *The Association of the British Pharmaceutical Industry,* <www.abpi.org.uk/facts-and-figures/science-and-innovation/worldwide-pharmaceutical-company-rd-expenditure/> [perma.cc/BTS4-GC7U].

[36] See Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It* (New York: Random House Publishing Group, 2004) at 76–80.

[37] See *ibid* at 74–93; Marc A Rodwin, "Conflicts of Interest, Institutional Corrup-

Additionally, patent critics argue that patents hinder access to health care and promote health inequity, particularly with respect to emerging health technologies. For instance, a course of treatment against melanoma using Bristol-Myers Squibb's drug Opdivo cost USD$120,000 in 2015, making it inaccessible to those who are not sufficiently insured.[38] In 2005, the US government, through state-funded programs, spent USD$210 billion on prescription drugs. However, a price comparison showed that the expenditure would have been merely USD$50 billion had only generic drugs been used.[39]

The patent thicket, rent seeking, and reduced access to health care are all concerns of particular importance in the genomics context because of the complexity and unpredictability of the human genome. As genomic science and knowledge advance, it is becoming clearer that genes cannot be thought of as separate and distinct entities, each serving a single, defined function. Instead, genes interact in a complex network of reciprocal regulation and a single gene may have different functions in different biological contexts.[40] Closing off access to genetic information through patent rights represents a roadblock to further innovation in the single function of a gene. It also stymies development in the multifarious and often unpredictable other functions of that gene.

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tion and Pharma: An Agenda for Reform" (2012) 40:3 J Law Med Ethics 511 at 513; Eric Low, Chas Bountra & Wen Hwa Lee, "Accelerating Target Discovery Using Pre-Competitive Open Science: Patients Need Faster Innovation More than Anyone Else" (2016) 10:57 ecancermedicalscience, online: <www.ncbi.nlm.nih.gov/pmc/articles/PMC4990051/> [perma.cc/VS2R-QTYE]; Aled Edwards, TEDx Talks, "Why Biomedical Philanthrophy Supports Redundant Science" (13 December 2016) at 00h01m24s, online (video): *YouTube* <www.youtube.com/watch?v=Wtp7R97jz5k> [perma.cc/VP2U-24P2].

38 See "A Question of Utility", *The Economist* (6 August 2015), online: <www.economist.com/node/21660559> [perma.cc/Q2UE-VWKB].

39 See *ibid*; Dean Baker, "The Upward Redistribution of Income: Are Rents the Story?" (2016) 48:4 Rev Radic Polit Econ 529 [Baker, "Upward Redistribution"]; Dean Baker, "A Free Market Solution for Prescription Drug Crises" (2004) 34:3 Int J Health Serv 517 [Baker, "Free Market Solution"]; Dean Baker, *Financing Drug Research: What Are the Issues?* (Washington: Center for Economic and Policy Research, 2004) [Baker, *Financing*].

40 See e.g. Amy E Pasquinelli, "MicroRNAs and Their Targets: Recognition, Regulation and an Emerging Reciprocal Relationship" (2012) 13 Nature Reviews Genetics 271.

Locking genomic information behind closed development models and patents hinders the broad engagement required to uncover novel functions of that genetic information. Developers do not want to pay licensing fees, nor do they believe that they have the freedom to operate that is required for efficient innovation. What follows is that, in the context of genomics, the patent thicket prevents innovation in areas the patents were never intended to cover.[41] This is true not because products and therapies based on new functions do not meet the novelty or non-obviousness criteria, but because of a practical blocking of the market explained by economic and freedom to operate analyses.[42] Similarly, rent seeking in the genomics context takes a toll not just on development in the known functions of genetic elements, but also on the diverse though still unidentified functions of those elements.[43] The result is inefficient innovation based on genomic information and ultimately, higher costs which make access to such innovations more difficult for socio-economically disadvantaged groups.

There are also substantial ethical concerns associated specifically with gene patents. Granting patents over genes raises concerns about the objectification and commodification of genes, which are seen as part of the human body. Turning genes into a commodity to be traded is offensive to some religious and moral perceptions of the dignity of the human body. Some ethicists also believe that allowing patents over genes enables human genes to be privately owned by a company or an individual.[44] This is contrary to the perception that the human genome is (or should be) common heritage for the benefit of all humankind. Another ethical and legal concern related specifically to gene patents focuses on the reality that patent holders discover genes, but do not create or invent them. This reality questions the assignment of property rights in the terms of the patent system, as these patents would not seem to meet the patentability criteria of novelty and in some cases non-obviousness. Finally, there is an ethical concern that genetic patents may prevent certain populations from accessing health care services (such as diagnostic tests) because patents would increase the market price and render them unaffordable, or because the patent holder could withhold

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41 See Lori B Andrews, "Genes and Patent Policy: Rethinking Intellectual Property Rights" (2002) 3 Nature Rev Genetics 803.

42 See Heller & Eisenberg, *supra* note 31.

43 See Baker, "Upward Redistribution", *supra* note 39 at 531–33.

44 See Wing Yin Chan, "Should Isolated Human Genes Be Patentable Subject Matter" (2016) 5 Manchester Rev of L Crime & Ethics 64 at 76–79.

the license that would allow the health care service provider to use the patented genes or tests and provide the necessary health care service.[45]

Critics of the patent system propose the adoption and implementation of alternative models or systems as a way to alleviate the previously mentioned concerns.[46] Open models of collaboration have become increasingly popular alternatives.[47]

II. Open Models of Collaboration

The innovation process consists of a series of mental and physical steps that turn an idea into a commercial product. The process includes several stages: basic research, product development, manufacturing, and distribution. Each stage involves players from several sectors and disciplines.

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45 See generally David B Resnik, *Owning the Genome: A Moral Analysis of DNA Patenting* (New York: State University of New York Press, 2004); David B Resnik, "The Morality of Human Gene Patents" (1997) 7:1 Kennedy Inst Ethics J 43.

46 See Thomas Pogge, "The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices" in Thomas Pogge, Matthew Rimmer & Kim Rubenstein, eds, *Incentives for Global Public Health: Patent Law and Access to Essential Medicine* (Cambridge: Cambridge University Press, 2010) 135 at 153; Joseph E Stiglitz & Arjun Jayadev, "Medicine for Tomorrow: Some Alternative Proposals to Promote Socially Beneficial Research and Development in Pharmaceuticals" (2010) 7:3 J Generic Med 217 at 225; "Our Model", online: *Medicines Patent Pool* <medicinespatentpool.org/who-we-are/our-model/> [perma.cc/VB9A-N6YF]; "Time to Fix Patents", *The Economist* (8 August 2015), online: <www.economist.com/news/leaders/21660522-ideas-fuel-economy-todays-patent-systems-are-rotten-way-rewarding-them-time-fix> [perma.cc/ZR4W-CYEP].

47 See Dean Baker, Arjun Jayadev & Joseph Stiglitz, "Innovation, Intellectual Property, and Development" (2017) Azim Premji University, University of Cape Town, Fundação Oswaldo Cruz, and Escola Nacional de Saúde Pública Working Paper at 68; Arjun Jayadev & Joseph Stiglitz, "Two Ideas To Increase Innovation And Reduce Pharmaceutical Costs And Prices" (2009) Health Affairs w165 at w167; Li, *supra* note 16 at 300, 302–03; Nuffield Council on Bioethics, "Emerging Biotechnologies: Technology, Choice, and the Public Good" Nuffield Council on Bioethics Working Paper at xxvi, online (pdf): <nuffieldbioethics.org/wp-content/uploads/2014/07/Emerging_biotechnologies_full_report_web_0.pdf> [perma.cc/W9ZX-F592].

Although some companies and researchers see the complete innovation process through from basic research to distribution, many specialize in a particular stage of the process.[48] Each stage also requires feedback in order to assess results (including partial results), which prevents the process from being strictly linear. These two characteristics contribute to the already scientifically complex, lengthy, and costly innovation process and the stringent approval processes that are necessary for ensuring safety and efficacy. Opening the innovation process to external parties and implementing strategies of alliances and collaboration among different players can be helpful in tackling these challenges, for the reasons we discuss below.[49] The type or model of collaboration and the time needed to use and implement these strategies varies depending on the stage of innovation, field, objectives, and even size of the company.

A. Definition

Open models of collaboration refer to the strategies and agreements that promote and facilitate collaboration and transparency in the creation and dissemination of products, services, and the associated information and knowledge.[50] Proponents of open models state that they uphold principles

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48 For example, drug discovery companies focus on basic research and product development and then license their technologies to biotechnology and pharmaceutical companies. Large pharmaceutical companies manufacture and distribute the products resulting from the technologies that drug discovery companies licensed to them. Clinical laboratories on the other hand focus on the clinical trials required for new drugs: see Hall & Bagchi-Sen, *supra* note 12 at 233.

49 See *ibid* at 232–33. See also Daniel L Shaw, "Is Open Science the Future of Drug Development?" (2017) 90:1 Yale J Biology Medicine 147 at 147–48.

50 See Yann Joly, "Propriété intellectuelle et modèles de collaboration ouverte" in Pierre Emmanuel Moyse, ed, *JurisClasseur Québec* (Montreal, Canada: Lexis CanadaCanada, 2016) 3.4 at para 27 [Joly, "Propriété intellectuelle"].

of egalitarianism,[51] meritocracy,[52] and self-organization,[53] so that everyone, including the most qualified people, are allowed and encouraged to contribute, and the R&D process is organized in a way that best suits their needs.[54] These principles contrast with traditional corporate models of production of top-down assigned jobs, hierarchical decision-making, and imposed processes.[55]

Open models of collaboration take advantage of the development of information technologies, advanced computers, and storage tools. They also may use forms of intellectual property in more open and collaborative ways to achieve their goals.[56]

B. Goals and reported benefits

Pharmaceutical and biotechnology industries encounter inherent complexities and risks in R&D in genomics, such as expensive and lengthy innovation processes, sustainability challenges, and high rates of failure. These risks stem from the shortcomings of the patent system, as well as a variety of other factors including the complexity of the field itself, clinical trial designs, stringent regulatory policies and procedures, difficult economic circumstances, and the high cost of technology.[57] Stakeholders believe

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51 Egalitarianism is based on the statement that all people are equal and are entitled to the same rights and opportunities. See Richard Arneson, "Egalitarianism" in Edward N Zalta, ed, *Stanford Encyclopedia of Philosophy*, (Stanford: Metaphysics Research Lab, 2013), online: < plato.stanford.edu/entries/egalitarianism/> [perma.cc/34K4-7KY8].

52 Meritocracy is based on the understanding that people are selected on the basis of their abilities: *Shorter Oxford English Dictionary*, (Oxford: Oxford University, 2002) sub verbo "meritocracy".

53 Self-organization is a process where an overall order spontaneously arises from the interactions of the parties involved: *Oxford English Dictionary*, (Oxford: Oxford University, 2019) sub verbo "self-organization".

54 Dirk Riehle et al, "Open Collaboration within Corporations Using Software Forges" (2009) 26:2 IEEE Software 52 at 53.

55 See *ibid*.

56 See Joly, "Propriété intellectuelle", *supra* note 50 at 3.

57 See Friend & Norman, *supra* note 35 at 298.

that open models of collaboration may help address many of these challenges.

One of the benefits of open models of collaboration is the possibility of accelerated innovation. The principles on which open models of collaboration are based (egalitarianism, meritocracy, and self-organization) tend to attract a certain type of contributor. These contributors are more likely to be genuinely motivated, as it is probable that they choose projects in accordance with their personal interests and convictions. This type of motivation is likely to foster contributors' strong attachment and commitment to the project. It also stimulates and attracts volunteers. The combination of paid and volunteer contributors can result in a broader network of people with more diverse expertise.

The uniqueness of genomic innovation makes it particularly amenable to a motivated community of collaborators. If such a community, with diverse expertise and abilities, is able to access genomic information as openly as possible and is not limited by patents and other closed innovation strategies, they stand the best chance of taking the creative and imaginative steps required to find new connections within genomic science, and to deliver on multiple outcomes.[58] These benefits can improve not only the R&D process, but also the pre-market stages, such as clinical trials and regulatory approvals, by increasing the transparency of the process. Increased transparency reduces the possibility of duplicating efforts and increases the possibility of determining where partnerships can be created to effectively distribute tasks and resources.[59]

Another benefit of open collaboration is the reduction and sharing of costs and financial burdens linked to the R&D process. Knowledge dissemination, data access, and technology transfer tend to have fewer restrictions and require less bureaucratic processes under open models of collaboration. In some of these models, dissemination and access to information, data, works, and inventions do not even have a cost. Consequently, in most of these models, cumulative and further innovation, collaborations, and partnerships require fewer monetary resources (due to, for example, no royalties or licensing fees and no legal fees) and take less time than proprietary

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[58] See Edwards, *supra* note 37 at 00h14m15s; Granados Moreno & Joly, *supra* note 18 at 286; Joly, "Propriété intellectuelle", *supra* note 50 at para 3; Gold, *supra* note 34 at 2–3; Low, Bountra & Lee, *supra* note 37.

[59] See Gold, *supra* note 34 at 3; Shaw, *supra* note 49 at 150 .

models. This characteristic can lead to greater collaboration and the inclusion of more players.[60]

Open models of collaboration can also help to promote innovation in neglected areas. In medical research, these areas are usually tropical or disregarded diseases. These diseases are more common in low-income countries usually located in Africa, Asia, and Latin America. Fewer patients in these countries are able to afford highly priced patented drugs and inventions. This in turn leads to much less intense research efforts, as practically and economically speaking, it is not where the greatest profit is likely to be made. Thus, research into these ailments is most likely to be exclusively funded by the public sector, and consequentially left underresearched and underdeveloped.[61] This underdevelopment problem can easily be extended into genomics. For instance, nowadays, the genes associated with breast cancer are the genes that are studied and funded the most.[62] Other genes, however, relevant in research into less economically profitable diseases or disorders remain underresearched. Open models of collaboration such as public-private partnerships and open source initiatives may be helpful in enabling R&D in many of these tropical diseases and neglected areas. By opening up the innovation process, the relatively low cost of information sharing and the capacity for broad engagement and collaboration make it possible for discoveries in neglected areas of genomic science to move forward without the hindrances of patents, licenses, and freedom to operate analyses.[63]

The use of open models of collaboration can also increase the economic value of projects, products, companies, research centres, and even of researchers. The open access/sharing and fast dissemination that open models of collaboration promote allow a wide and constant use of the information, data, works, and inventions they cover. It is not always obvious what in-

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60 See Gold, *supra* note 34 at 2–4.

61 See especially Stephen M Maurer, Arti Rai & Andrej Sali, "Finding Cures for Tropical Diseases: Is Open Source an Answer?" (2004) 1:3 e56 PLoS Med 183 at 183.

62 See Elie Dolgin, "The Most Popular Genes in the Human Genome" (2017) 551 Nature 427 at 427.

63 See generally Fernán Agüero et al, "Genomic-scale Prioritization of Drug Targets: The TDR Targets Database" (2008) 7:11 Nat Rev Drug Discov 900 (for example, consider the success of the TDR Targets Database in providing resources for drug targets in tuberculosis, leprosy, and more).

novations might occur from given research until this kind of wide access is available; many innovations in biomedical research have a grounding in basic research (for example, the development of CRISPR technology stems from research on bacterial immunity).[64] This wide and constant use can increase the economic value of the project and build or increase public and peer interest and trust in an open project.

Another benefit of open models of collaboration is that they can improve access to health products and services. As mentioned above, these models can affect the costs of the R&D process by enabling partnerships and collaborations; by reducing the costs of disseminating and sharing information, data, and knowledge; and by facilitating cumulative innovation and avoiding duplication of efforts. The reduction of the R&D process costs is likely to reduce the market prices of the products and services since firstly, the amount of money invested that would need to be recouped is lower and secondly, the amount of what would become profit could be higher. Lastly, the increased and accelerated innovation associated with open models of collaboration brings about more options for consumers and competition in the market and often brings prices down. The price difference between patented drugs and generics, as well as between diagnostic tests with and without patents, are indicators of this effect.[65]

C. Models

Developing a typology of open models of collaboration is a challenging undertaking. Names of specific models are often misused or misappropriated to promote non-conforming initiatives, and collaboration models associated with a specific name may have evolved since their origin. It is also possible to find substantial overlap between some of the models (for example, between open science and public domain). There are, however, strong argu-

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64 See National Science Foundation, "How Research on Bacterial Immune Systems Led to CRISPR" (1 February 2016), online: *National Science Foundation* <www.nsf.gov/news/mmg/mmg_disp.jsp?med_id=80043> [perma.cc/ZW3A-UTLM].

65 As mentioned above, despite the importance of this subject, this issue is beyond the scope of our article, as we are only focusing on the effect that open models of collaboration have on the innovation process. See Li, *supra* note 16 at 297; Baker, "Free Market Solution", *supra* note 39; Baker, *Financing*, *supra* note 39; Baker, Jayadev & Stiglitz, *supra* note 47.

ments in favour of attempting such a typology. Some models, for example the public domain and open innovation models, are radically distinct. Their fundamental differences need to be well understood by stakeholders. Moreover, large-scale collaborations, comparisons, and assessments, which are vital for the development and integration of open collaboration endeavours in science and innovation policies, will require that the community achieve a minimal consensus on the key elements that define each model.

1. Public domain

Without having an explicit legal definition, the public domain is generally thought to refer to information, works, or inventions that are not protected by any form of intellectual property and whose use cannot be excluded or limited by anyone. In other words, everyone can freely and equally use the information, works, or inventions.[66] The public domain is composed of three categories: (1) information, works, or inventions whose intellectual property has expired; (2) information, works, or inventions that were never protected by any form of intellectual property (usually because they either do not comply with the requirements to be entitled to protection or because they do not fall within the protectable subject matter); and (3) information, works, or inventions whose intellectual property holders expressly and intentionally place in the public domain, either contractually or through defensive publication.[67] Additionally, some authors consider that the information, works or inventions to which the law allows access without the need of the intellectual property holder's authorization (i.e. users' rights) also form part of the public domain. The value of the public domain lies in its role as the foundation or source of further creativity and innovation.[68] From a

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66 See Yochai Benkler, "Free as the Air to Common Use: First Amendment Constraints on Enclosure of the Public Domain" (1999) 74:2 NYUL Rev 354 at 360.

67 Defensive publication refers to the intentional publication or disclosure of a product or invention without having applied for a patent. Its purpose is to release the invention and the information associated with it into the public domain and integrate it into the state of the art to be used freely, while at the same time, preventing others from appropriating it. See Joly, "Propriété intellectuelle", *supra* note 50 at 8–9; Hope, *supra* note 30 at 162.

68 See Joly, "Propriété intellectuelle", *supra* note 50 at 2; Benkler, *supra* note 66 at 360–1; see especially Jessica Litman, "The Public Domain" (1990) 39 Emory LJ 965 at 1001.

legal point of view, the public domain is defined by exclusion or *a contrario sensu*. Intellectual property laws and case law state that all the information, works, and inventions not protected by patents or copyrights should be considered to be in the public domain. It is these laws that delimit the public domain and its use. The part of the public domain that is composed of the information, works, and inventions that are intentionally released by their intellectual property holder is regulated by the terms of the owner's written or factual waiver. The importance and value of the public domain, as a source of innovation and creativity, is also discussed in case law.[69]

The public domain contributes to open collaboration by enabling the free use of all the information, works, and inventions it encompasses. In the case of genomics, this might include publicly accessible repositories of genomic data.[70] Given that anyone can freely access, review, use, and build on the information, works, or inventions existing in the public domain, this model enables the creation of a large network of collaborators (hired and volunteers). Benefits of a large network include accelerated R&D process, better quality control, transparency and trust, efficiency, potentially new and better ways to reach the same results, and increased economic value. Likewise, by allowing free use of all the information, works or inventions, the public domain facilitates collaboration by not requiring any licenses, negotiations or fees, which results in reduced R&D costs and timelines. It also contributes to open collaboration by allowing free and unconditional sharing of information that leads to easier, faster, and less expensive training and knowledge dissemination, as anyone can access relevant information and knowledge.[71] Finally, the open access and sharing that the public domain upholds enables transparency about the subjects being studied, the state of the research, existing gaps and challenges, and the methods used. Transparency contributes to open collaboration by informing potential collaborators of the tasks, phases, and resources that are needed, therefore helping participants structure the collaboration in an efficient way.[72]

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69 See e.g. *Théberge v Galerie d'Art du Petit Champlain inc*, 2002 SCC 34 at para 32; *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 at para 66.

70 See Jorge L Contreras & Bartha M Knoppers, "The Genomic Commons" (2018) 19 Annu Rev Genomics Hum Genet 429 at 430.

71 See Joly, "Propriété intellectuelle", *supra* note 50 at 6.

72 See Sarah E Ali-Khan et al, "Defining Success in Open Science" (2018) 2:2 Mni Open Res 1 at 4, 6; Shaw, *supra* note 49 at 148; Manica Balasegaram et al, "An Open Source Pharma Roadmap"(2017) 14:4 PLoS 1 at 3.

One common concern is that anyone can appropriate information, works, or inventions that are in the public domain by incorporating them into their own work or invention, which they then may protect with a new form of intellectual property, thus enclosing part of the public domain. This is possible because once information, works, or inventions are released in the public domain, there can be no limits or conditions imposed on their use.[73] Another concern about the public domain is the difficulty of maintaining a source of income for funding further R&D and financially supporting the inventor, researcher, or company. The inventor, researcher, or company will be unable to obtain any compensation for the information, works, or inventions released into the public domain. As a result, funders and investors will be unable to recoup their investment and support further innovation, and researchers may have to devote effort, time, and resources to other endeavours in order to earn a living wage.[74]

The Human Genome Project (HGP), aimed at identifying and mapping all of the genes of the human genome and completed in 2003, remains the exemplar project for using the public domain in genomics. The HGP constitutes the first large-scale project in which data and resources became freely and readily accessible to the public as genes were sequenced.[75]

2. Open science

Open science is a model characterized by principles of open data sharing, fast dissemination of knowledge, cumulative research, and cooperation. Its intention is to foster scientific progress, maximize impact, and achieve humanitarian goals.[76] Its principles are inspired in part by Merton's norms

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73 See Joly, "Propriété intellectuelle", *supra* note 50 at 5–6.

74 See Balasegaram et al, *supra* note 72 at 2; John Hagedoorn & Ann-Kristin Zobel, "The Role of Contracts and Intellectual Property Rights in Open Innovation" (2015) 27:9 Technol Anal Strateg Manag 1050 at 1057–58.

75 See Francis S Collins et al, "The Human Genome Project: Lessons from Large-Scale Biology" (2003) 300:5617 Science 286 at 287–88.

76 See Timothy Caulfield, Shawn HE Harmon & Yann Joly, "Open Science Versus Commercialization: A Modern Research Conflict?" (2012) 4:17 Genome Medicine at 6; Granados Moreno & Joly, *supra* note 18 at 285; Guy Rouleau, "Open Science at an Institutional Level: An Interview with Guy Rouleau" (2017) 18:14 Genome Biol 1 at 1.

of science: communalism, universalism, disinterestedness, originality, and skepticism.[77] Open science is one of the broadest categories of open models of collaboration and has been used to describe, sometimes erroneously, a large number of scientific projects emanating from a great diversity of disciplines. The open science model functions in a similar way to the third type of public domain, which requires researchers to share their information, data, works, and inventions without any restrictions. However, it differs from the public domain in that open science advocates share a strong belief in the importance of Mertonian norms, as well as the scientific and ethical values of open access. The use of access agreements that impose terms conducive to the public good while not unduly restricting access is tolerated under this model.[78] Whereas the release of information, data, works, and inventions into the public domain may have a philosophical motive, this is not necessarily present in all cases. A public domain-based strategy may be motivated by an interest for defensive publication. As mentioned above, the rationale for defensive publication is that releasing an invention into the public domain destroys its novelty. This impedes its patenting, ensures open access to it, and advances the state of the art.[79] Defensive publication is generally a strategic decision. A number of international policies and guidelines promote the key principles that the open science model upholds, such as the OECD Principles and Guidelines for Access to Research Data from Public Funding,[80] the Human Genome Organisation's (HUGO) Statement on Hu-

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77 See Hope, *supra* note 30 at 74–76.

78 For example, clauses to promote the protection of participants' genetic data in a biobank project or to exclude or limit the liability of an innovator openly providing data are acceptable.

79 See Joly, "Propriété intellectuelle", *supra* note 50 at 8–9.

80 See Organisation for Economic Co-operation and Development, Secretary-General, *OECD Principles and Guidelines for Access to Research Data from Public Funding* (France: OECD, 2007).

man Genomic Databases,[81] Genome Canada,[82] and the US National Institutes of Health Final Statement on Sharing Research Data,[83] among others.[84]

The open science model contributes to open collaboration in the same way that the public domain does. The open access and sharing and fast dissemination policies upheld in open science allow anyone who is interested to learn, join, and contribute to the project that has adopted this model, thus enabling the creation of a broad and diverse network of collaborators. This collaboration leads to accelerated innovation, better quality results, efficiency, transparency, trust, and increased economic value. Open science policies also minimize the costs (licensing and legal fees) and formal requirements (licenses and negotiations) associated with transferring, accessing, and using information, works, and inventions. This facilitates collaboration, training, and knowledge dissemination, and makes them less expensive. The transparency that results from open science policies also contributes to efficient collaboration by communicating the project's gaps, challenges, resources, and needs to anyone who is interested in collaborating, allowing for a more organized assignment of tasks and responsibilities.[85]

The main concerns associated with the open science model are similar to those raised in regard to the public domain. The first concern is that third parties' patents may appropriate the information, works, and inventions originally released under an open science model and incorporate them into works and inventions that are subsequently released under proprietary models. Once the information, works, or inventions are patented or copyrighted, their owners can prevent others from using or benefiting from them. The

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81 See Human Genome Organisation, Ethics Committee, *HUGO Statement on Human Genomics Databases* (United Kingdom: HUGO, 2002).

82 See *Genome Canada Data Release and Sharing Policies* (Canada: Genome Canada, 2016).

83 See "NIH Data Sharing and Privacy", online: *National Human Genome Research Institute* <www.genome.gov/27569050/Data-Sharing-and-Privacy> [perma.cc/XNK2-F2J8] ["NIH Data Sharing"]; US, National Institutes of Health, *Final NIH Statement on Sharing Research Data* (Maryland: NIH, 2003).

84 For additional examples of international guidelines and policies, see Caulfield, Harmon & Joly, *supra* note 76 at 7–8.

85 See Balasegaram et al, *supra* note 72 at 4; Shaw, *supra* note 49 at 149; Allarakhia, *supra* note 34 at 762–63; Granados Moreno & Joly, *supra* note 18 at 286.

second concern is that under the open science model, inventors, researchers, or investors are not able to commercially exploit the information, works, or inventions they have created or funded. This inhibits their ability to recoup their investment or to ensure an income, and can undermine future funding and disincentive continued innovation. This challenge can lead to yet another challenge: the sustainability and growth of the open science model and philosophy. The success of the open science model depends on the existence of a sustainable network of users and contributors. The more researchers and projects that adopt the open science model, the more other users and contributors will trust the model's logistic and economic viability. The fewer projects there are that adopt the open science model, the lesser the impact the model will have on the overall innovation process.[86]

The International Cancer Genome Consortium's 25K project, which defines the genomes of 25,000 primary untreated cancers and makes these genomes available to the scientific community through open and controlled access databases is a good example of an open science genomic project.[87]

3. Open source

The open source model[88] uses the intellectual property system, copyright, and patent licenses in particular to maximize access and use by others.

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[86] See Hope, *supra* note 30 at 23.

[87] See Yann Joly et al, "Data Sharing in the Post-Genomic World: The Experience of the International Cancer Genome Consortium (ICGC) Data Access Compliance Office (DACO)" (2012) 8:7 PLoS Computational Biology 1 at 3.

[88] There are also free software licenses, which are also similar to open source licenses. Both types of licenses aim to enable users to access, use, study, adapt, reproduce, and distribute a program's software. However, there are slight differences between them. The first difference is the term used: the open source model explicitly avoids the ambiguity of the term "free," which can be interpreted as "gratis" when in fact it refers to "freedom." The second difference is that open source licenses do not have to require that derivative works be distributed under the same terms. For the purposes of this article, when we use the term "open source licenses," we are referring to both "open source licenses" and "free software licenses." Creative Commons licenses are other type of licenses that conform to the open source model. These licenses are used for literary, musical, and overall artistic works. See e.g. Free Software Foundation, "What is Free Software", online: *GNU Org* <www.gnu.org/philosophy/free-sw.en.html> [perma.cc/HHL7-FDB4]; "Creative Commons: Share Your

This model originated in the software industry to ensure that every user has the right to access, use, copy, modify, integrate, and distribute the source code. These rights give users true access to the invention or work, its methodology, and its functionality, allowing them to learn from it, reproduce it if desired, and modify it if needed. The aim of open source licenses is to empower users.[89] When used outside of the software industry, the open source model can be used to facilitate access to research tools.

For example, in 2003, key research institutes credited with independently discovering the SARS genome, and several contributing laboratories, filed patent applications incorporating SARS genomic sequence data. Their intent was to provide access to SARS' genetic signature without ceding exclusive rights to any of them and losing their own access privileges. While the envisioned patent pool remains incomplete, the BC Cancer Agency uses its own SARS patents in an open source manner. It currently uses its patents to allow the global research community and pharmaceutical companies access to SARS' genetic signature to develop therapeutics and vaccines, while preventing any appropriation and commercialization of the original data.[90]

The open source model differs from the public domain and open science models in three respects. Firstly, the information, works, and inventions released under an open source license are protected by either copyright or patent. These patent and copyright protections are therefore a prerequisite for the works or inventions to be released under an open source model. Secondly, open source licenses impose certain restrictions on the use of the information, works, and inventions. For example, some open source licenses specifically require that attribution or authorship be recognized. Other licenses (for example, copyleft licenses such as the General Public License) also impose the viral obligation to release any derivative work under the same terms and conditions of the initial license. Thirdly, under an open source model, patent and copyright holders can grant open source

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Work" (15 December 2018), online: *Creative Commons* <creativecommons.org/share-your-work/> [perma.cc/A4VX-KFCZ].

89 See Free Software Foundation, *supra* note 88; Open Source Initiative, "The Open Source Definition (Annotated)", online: *Open Source Org* <opensource.org/osd-annotated> [perma.cc/NKK4-H3GP].

90 See Sheryl Ubelacker, "Status of Gene Patents in Canada Unresolved, Despite Successful Challenge" *CTV News* (20 March 2016), online: <www.ctvnews.ca/health/status-of-gene-patents-in-canada-unresolved-despite-successful-challenge-1.2824957> [perma.cc/E7TW-FGFQ].

and proprietary licenses simultaneously to different parties or in different circumstances.[91]

From a legal point of view, the open source model is based on an intellectual property license. It requires the prior existence of copyright or patent protection covering the information, works, or inventions, as well as the enforcement of the rights granted. Based on this preliminary condition, those who opt for the open source model grant their users licenses with terms that accord to the principles and goals of maximized access and use. The terms of these licenses are usually considered valid if they observe the formalities linked to regular licenses[92] (for example, that the terms and conditions are cleared and accessible prior to its acceptance, and are granted by the copyright or patent holder in writing).[93]

The principles that the open source model upholds are open access and sharing and fast dissemination. The role that this model has in open collaboration is similar to that of the public domain and open science: one of enablement and decentralization. The principles and practices of open source models in biomedicine enable researchers, companies, and volunteers to

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91 See Joly et al, *supra* note 87 at 12–13; Free Software Foundation, *supra* note 88; Free Software Foundation, "What is Copyleft?" (2018), online: *GNU Org* <www.gnu.org/licenses/copyleft.en.html> [perma.cc/M5TT-VVGX]; Hope, *supra* note 30 at 162–63.

92 There are concerns regarding the validity of the clause in copyleft licenses that imposes an obligation to release derivative works under the same terms and conditions. The concerns about this clause are twofold: (1) it extends the protection of the work beyond the statutory term; and (2) it creates anticompetitive and abusive conditions. None of these concerns have been proved in court. In fact, open source licenses (General Public License, Creative Commons, and other open source licenses) have been held valid in the Courts. See e.g. Joly, "Propriété intellectuelle", *supra* note 50 at 18–24; Andres Guadamuz, "US Court Interprets Copyleft Clause in Creative Commons Licenses" (24 October 2015), online: *TechnoLlama* <www.technollama.co.uk/us-court-interprets-copyleft-clause-in-creative-commons-licenses> [perma.cc/56L3-KE7C]; *Drauglis v Kappa Map Group*, (DC Dist Ct 2015) at 6–8.

93 See *Ley Federal del Derecho de Autor de México, 1996,* arts 30–41; *Ley de la Propiedad Industrial*, *supra* note 19, arts 62–77; Joly, "Propriété intellectuelle", *supra* note 50 at 16–24; Canadian Intellectual Property Office, *Manual of Patent Office Practice* (Canadian Intellectual Property Office, 1998), s 6.04; Canadian *Patent Act*, *supra* note 19, s 50; *Copyright Act,* RSC 1985, c C-42, art 13; *US Code*, *supra* note 19, §261; *Copyrights*, 17 USC, §201–203.

search for new protein targets; to share and access data obtained from their projects, as well as other research tools and resources (e.g. chemical, biological, and medical databases); to disseminate their discoveries; and to initiate debates regarding future research directions on online platforms.[94] Open access accelerates and improves innovation by facilitating the creation of a broad network of potential contributors, in ways similar to the public domain and open science models described earlier. Open source models can also enable collaboration by containing costs related to licensing (legal and licensing fees) and training. Finally, the open access and sharing and fast dissemination that the open source model permits leads to transparency and understanding of the project and its specific needs, which enables efficient self-organization among the different contributors.[95]

An additional way in which the open source model contributes to collaboration, which is not found in the public domain or open science, is that given that the model requires copyrights or patents, it can use those copyrights and patents to attract further contributors. Patents are granted for inventions that have industrial applications. Patent holders must consider those industrial applications to be profitable enough before making the decision to devote resources to pursuing those patents. Therefore, supporters of proprietary commercialization can presume that because an invention is patented, further development in such an invention is worth supporting. Likewise, because of the patent and the open source license under which the invention is released, those who support open sharing of information can deduce that the researcher is committed to the principles upheld by the open source model for two reasons. The first reason is that despite being able to commercialize the invention by having a patent, the patent holder took active steps to make it freely available by releasing the invention under an open source license. The second is that by having a patent, the patent holder can enforce the terms of the open source license and impose compliance with the open source principles.[96]

The open source model faces five main challenges. Firstly, there are challenges associated with open source licenses that do not have clauses imposing the same terms to derivative works (i.e. non-copyleft licenses). The challenge with non-copyleft licenses, like with the public domain and with

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94 See Maurer, Rai & Sali, *supra* note 61 at 184; Joly, "Propriété intellectuelle", *supra* note 50 at 14.

95 See Maurer, Rai & Sali, *supra* note 61 at 184.

96 See Hope, *supra* note 30 at 163.

open science models, is preventing users from enclosing the information, works, and inventions released under the open source model in new works and inventions released under proprietary models.[97] The second challenge concerns information, works, and inventions released under copyleft licenses. The reach-through terms (i.e. that derivative works must be released under the same terms) of copyleft licenses may deter some contributors from collaborating, since reconciling the open requirements of this license with other licenses or terms of commercialization may become complicated.[98] The third challenge is enforcing the terms of the open source license. Since the license provides open access to the information, works, and inventions to anyone, keeping track of who uses them and whether they comply with the terms imposed by the license, as well as enforcing those terms, can be difficult, and in many cases, also expensive.[99]

The fourth challenge relates to maintaining a source of funding and income. The open source model can be an expensive strategy to promote open sharing, as it requires obtaining and maintaining the patent, which is quite costly. Once the information, works, and inventions are released, it is hard to request compensation for their use, unless they are offered with extra features or a different presentation (for example, with technical or customer support or with a more user-friendly interface). Furthermore, supporters of both proprietary commercialization and open source may deem the hybrid nature of open source licenses an unsatisfactory compromise. On the one hand, the model requires patents and licenses that impose limitations in the use of the information, works, and inventions, thus making the model not free enough compared to completely open science projects. On the other hand, the open terms of the license may be deemed irreconcilable with the business plans of supporters of the traditional proprietary commercialization model.[100] It is important to mention that in areas such as biomedicine, it is still difficult to convince companies, research centres, and universities

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97 See *ibid* at 161, 178–179; Hagedoorn & Zobel, *supra* note 74 at 1058; Molly Morgan Jones et al, *The Structural Genomics Consortium. A Knowledge Platform for Drug Discovery* (United States of America: RAND Europe, 2014) at 25.

98 See generally Hope, *supra* note 30 at 159.

99 See Brian W Carver, "Share and Share Alike: Understanding and Enforcing Open Source and Free Software Licenses" (2005) 20:1 BTLJ 443 at 462.

100 See Hope, *supra* note 30 at 159–60, 179–81; Balasegaram et al, *supra* note 72 at 2; Morgan Jones et al, *supra* note 97 at 26, 35–36.

that the open source model is feasible and sustainable,[101] whereas this is no longer an issue in the software industry.[102] The last challenge is ensuring the sustainability and development of the open source model. Similar to the open science model, when it is adopted by multiple projects, the open source model increases its chances of being sustainable and successful in providing the benefits it proposes. The more that projects adopt an open source model, the more trust in the model other investors and researchers will have, and consequently, the larger the network of contributors following the same principles there will be.

4. Protected commons

A protected commons is a model that combines the type of access granted in a commons[103] (i.e. open access) with elements of traditional proprietary intellectual property practices. The commons part of the model provides and requires open access to information, data, works, and inventions among a well-defined and limited group of parties or collaborators. In addition to open access, this group is granted and is required to grant authorization (license) to use, integrate, and adapt the commons' information, data, works, and inventions into their own creations and research under very favourable conditions. The members of the group are selected based on specific factors, such as territory (for example, the European Union or California) or funder (for example, the California Institute of Regenerative Medicine or the National Institutes of Health). Parties and collaborators are still allowed to pursue intellectual property protection, but they are obligated to grant the other collaborators of the protected commons permissive licenses in order to maintain the commons within the group. Sharing and providing access to the same information, data, works, and inventions to researchers or groups

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101 See Shaw, *supra* note 49 at 147; Balasegaram et al, *supra* note 72 at 2; Hope, *supra* note 30 at 17–24, 142–45.

102 See Balasegaram et al, *supra* note 72 at 2; Hope, *supra* note 30 at 11–17, 126–27.

103 Commons is a general term used to refer to shared resources whose use and disposition are not controlled by one single person. See Vasilis Kostakis et al, "The Convergence of Digital Commons with Local Manufacturing from a Degrowth Perspective: Two Illustrative Cases" (2016) 197:2 J CleanProd 1684; Yochai Benkler, *Wealth of Networks* (New Haven: Yale University Press, 2006) at 60–61.

outside the commons can be done under terms that are less favourable and more akin to regular proprietary commercial exploitation.[104]

The objective of this model is to promote economic, scientific, and technological benefits for the members of the selected group. The intended benefits in a protected commons can include scientific advancement or ensuring that residents of a select territory have access to health care products and services under more favourable terms than outsiders.[105] From a legal point of view, the adoption of a protected commons model often stems from the regulations and policies of funders. These funders are usually from the public sector and their policies are aligned with governmental laws, plans, and programs (for example, the CIRM and Proposition 71 in California[106] or the EU 7th Program Framework[107]). The source of funding as well as the alignment with governmental laws, plans, and programs constitutes the main difference between the protected commons and the open innovation model. The execution and implementation of the protected commons model requires a series of contracts of collaboration, licensing, and confidentiality to regulate the terms of collaboration and the use of patented or copyrighted information, works, and inventions.

A key advantage associated with a protected commons model is the promotion of sharing and dissemination of knowledge within a closed, collaborative network. As with the previous models, this access is conducive to faster, cheaper, and more efficient innovation. It also facilitates the training of those in the protected commons. The resulting innovation is likely to increase the economic value of the projects and the groups involved in the protected commons. Moreover, given that the model also allows traditional commercial exploitation with outside third parties, the commercial prospect can be higher, which can attract greater collaboration. Despite the fact that the protected commons facilitates self-organization through the open access

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104 See Maroussia Lévesque et al, "Stem Cell Research Funding Policies and Dynamic Innovation: A Survey of Open Access and Commercialization Requirements" (2014) 10:4 Stem Cell Rev & Reports 455 at 459, 466; Cori Hayden, "The Proper Copy" (2010) 3:1 J Cult Econ 85 at 91.

105 See Lévesque et al, *supra* note 104.

106 See "NIH Data Sharing", *supra* note 83.

107 See "FP7: Research & Innovation Europe" (last modified 29 January 2019), online: *European Commission Research & Innovation FP7* <www.ec.europa.eu/research/fp7/index_en.cfm> [perma.cc/6AHV-5QC7].

principles like the previous models do, the coordination and management of this model is likely to be easier because the number of people and institutions involved is lower than in the other models.[108]

An obvious shortcoming of this model is that the collaboration network it creates is smaller than in projects adopting full open access models, given that it is a limited version of the latter. This is likely to make the innovation process less efficient and perhaps even slower and less diverse. Reconciling the commons and its commitments (notably, to open access policies and favourable terms of licensing with members of the protected commons) with the expectations of potential partners who adopt proprietary intellectual property practices is another significant challenge. Difficulties reconciling these expectations can result in hindered or reduced collaborations.[109]

5. Open innovation

Open innovation is a model that recognizes that the process of R&D and innovation is more successful and efficient when it incorporates ideas, resources, and strategies from parties that are both internal and external to the company. This model differs from other open models of collaboration in that it seeks not only to make the R&D process quicker and more efficient, but also to expand markets and maximize revenue. The model uses intellectual property rights to establish collaborations and partnerships with different parties throughout the R&D process, but differs from the open source model in their use. Whereas the open source model uses intellectual property rights with the intention of enabling and securing an open collaboration, the open innovation model uses them with the more traditional purpose of maintaining ownership over information, works, and inventions, and securing a competitive advantage and a maximization of revenues.[110] This model

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[108] See Claire H Luby & Irwin L Goldman, "Freeing Crop Genetics through the Open Source Seed Initiative" (2016) 14:4 PLOS Biol, online: <journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002441> [perma.cc/N7SC-FSY2]; Lévesque et al, *supra* note 104; Nele Berthels, "Case 8: CAMBIA's Biological Open Source Initiative (BiOS)" in Geertrui van Overwalle, ed, *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (Cambridge: Cambridge University Press, 2009) 194.

[109] See Lévesque et al, *supra* note 104 at 459.

[110] See e.g. Henry Chesbrough, Wim Vanhaverbeke & Joel West, *Open Innova-*

requires a series of contracts to establish the terms of collaboration, partnership, and ownership over the pre-existing information, data, works, and inventions shared, as well as any that are newly created. Given the multiple collaborators, these contracts need to be as clear as possible, and confidentiality agreements are usually required.[111]

A significant benefit of the open innovation model is that, like the previous models, it recognizes the social aspect of the innovation process, and therefore acknowledges the importance of being open to collaboration with parties and peers outside of the company.[112] These types of collaborations can help foster robust social norms around reflexive and inclusive research that scholars in the field of science and technology studies (STS) have found to bolster a culture of innovation.[113] The openness to external collaboration contributes to the creation of the large network of contributors who share ideas, information, research tools, and strategies regarding the R&D process and the commercialization of the resulting products. This translates to welcoming and encouraging contributions from different angles, which enrichs and speeds up the innovation process. It also avoids duplicating efforts. The second benefit of the open innovation model is that, while it promotes open collaboration, it still preserves and pursues a major private sector goal: maximization of revenues.[114] Consequently, this model better

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tion: Researching a New Paradigm (Oxford: Oxford University Press, 2006); Henry Chesbrough & Eric L Chen, "Using Inside-Out Open Innovation to Recover Abandoned Pharmaceutical Compounds" (2015) 3:2 J Innovation Mgmt 21; Joel West et al, "Open Innovation: The Next Decade" (2014) 43:5 Research Policy 805 at 805; Joly, "Propriété intellectuelle", *supra* note 50 at 26–28; Granados Moreno & Joly, *supra* note 18 at 287.

111 See Joly, "Propriété intellectuelle", *supra* note 50 at 27–34.

112 See e.g. Chesbrough, Vanhaverbeke & West, *supra* note 110; Hagedoorn & Zobel, *supra* note 74 at 1050, 1057.

113 See Wendy Lipworth & Renata Axler, "Towards a Bioethics of Innovation" (2016) 42 Public Health Ethics 445 at 446.

114 See e.g. Henry W Chesbrough, *Open Innovation: The New Imperative for Creating and Profiting from Technology* (Boston: Harvard Business School Press, 2006) at xxiv, 155; Chris Grams, "Open Innovation and Open Source Innovation: What Do They Share and Where Do They Differ?" (1 November 2010), online: *Opensource.com* <www.opensource.com/business/10/10/open-innovation-and-open-source-innovation-what-do-they-share-and-where-do-they-diffe> [perma.cc/AV78-33GV]; Henry W Chesbrough, "The Era of Open Innovation" (2003) 44:3 MIT Sloan Management Rev 35 at 38.

suits the expectations that the private sector has when engaging in R&D and therefore provides them with stronger incentives to adopt this model.[115] There are two positive effects of this attribute. The first is that the network of potential collaborators could increase and include powerful and affluent allies. The second is that the adoption of this model by the industry is likely to be smoother, as it does not represent as significant a change in philosophy and strategy from the traditional proprietary model as in any of the previous models. Overall, these conditions could also persuade other companies, institutions, and researchers who support proprietary models of commercialization of the importance of open and inclusive collaboration in the innovation process.[116]

Considering that the open innovation model upholds maximizing revenue and maintaining ownership over protected information, works, and inventions, some challenges associated with this model are worth mentioning. An important challenge is establishing ownership. Determining the extent and limits of ownership on all the parts, products, and information associated with the project can become complicated due to the different parties involved in their creation. The second challenge is navigating the web of intellectual property rights. Considering that there are different forms of intellectual property covering various parts of the project, and that those intellectual property rights are owned by the different parties involved in its creation, the licensing negotiations can become lengthy, complex, and costly. This may impede collaboration. The third challenge is the risk of losing control over the information, works, and inventions shared as part

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[115] For instance, in 2012, Roche made a collection of 300 compounds available to the Broad Institute through an open innovation model in order promote drug repurposing in neglected tropical diseases. Likewise, in 2013, the European Lead Factory adopted an open innovation model under which it provided free access to approximately 500,000 novel compounds for its pan-European drug discovery project. See Allarakhia, *supra* note 34 at 756; Tania Bubela et al, "More Haste, Less Speed: Could Public–Private Partnerships Advance Cellular Immunotherapies?" (2017) 4 Front Med at 9, online: <www.frontiersin.org/articles/10.3389/fmed.2017.00134/full?utm_source=FRN&utm_medium=EMAIL_IRIS&utm_campaign=EMI_FRN_ARTICLEPUBLISHED_COAUTHORS&utm_content=ARTICLE_TITLE#h6> [perma.cc/25PS-VBU9].

[116] See Yochai Benkler, "Law, Innovation and Collaboration in Networked Economy and Society" (2017) at 240, online: <dash.harvard.edu/handle/1/30704158>[perma.cc/TJK7-UB5P]; Joly, "Propriété Intellectuelle", *supra* note 50 at 25–26.

of the collaboration process. Collaboration requires disclosure of relevant and valuable scientific and commercial information. The involvement of external parties can make disclosure risky for certain parties, although this risk can be mitigated by judicious use of confidentiality agreements and material transfer agreements.[117] Open innovation is thus very distinct from open science, in that it promotes the use of intellectual property rights and the commercialization of scientific research.

6. Collaborative use of intellectual property

Collaborative forms of intellectual property are models or strategies that combine the adoption of traditional forms of commercial exploitation with an environment that facilitates external collaboration. As with the previous models, these collaborative forms originate from the acknowledgement that the innovation process is too complex and burdensome for one party to take on alone.[118] Two examples are public-private partnerships (PPP) and crowdsourcing.

A PPP is a cooperative arrangement between parties of the public and the private sectors who work together towards mutually agreed upon objectives while sharing resources (such as economic funds, knowledge, data, and samples, clinical expertise, patient base, and infrastructure), risks, and responsibilities as partners. This model not only recognizes that the innovation process requires the participation of several parties, but also acknowledges that the innovation process often requires contributions from both the private and public sectors. An innovation process developed solely in the public sector may be too slow and ineffective, whereas one solely maintained in the private sector may be too financially burdensome and may lead to unequal distribution of products and services. Hence, the objective of a PPP is to tackle the different stages of the innovation process conjointly to facilitate the process. It may also aim to increase the chances of equal access

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[117] See Chesbrough, Vanhaverbeke & West, *supra* note 110; Joly, "Propriété intellectuelle", *supra* note 50 at 27–28; Granados Moreno & Joly, *supra* note 18 at 287; Hagedoorn & Zobel, *supra* note 74 at 1051.

[118] See Bubela, FitzGerald & Gold, *supra* note 18 at 1; Granados Moreno & Joly, *supra* note 18 at 287; Palmira Granados Moreno, Yann Joly & Bartha Maria Knoppers, "Public–Private Partnerships in Cloud-Computing Services in the Context of Genomic Research" (2017) 4 Front Med, online: <www.ncbi.nlm.nih.gov/pmc/articles/PMC5247451/>[perma.cc/U8TM-YTFE].

to the innovative products. In health-related research, this means a more efficient translation of basic research into clinical applications and improved access to health care services, particularly in developing countries and for vulnerable populations.[119] The main difference between a PPP and open innovation is that the involved parties act as partners when sharing resources, risks, and responsibilities in the former, but not in the latter. Furthermore, a PPP can adopt other models of collaboration.[120] For instance, a PPP can be based on an open science model like the Structural Genomics Consortium, which we will discuss more thoroughly below.

Contract law regulates PPPs. Contracts determine the terms and conditions of the partnership, including the extent of risks and responsibilities partners undertake, the resources they bring in, and those to which they acquire access. Contract law also defines the terms according to which any existing or resulting intellectual property will be pursued, managed, used, shared, and exploited. The model each PPP decides to adopt will determine the type of licenses that will be used to share and access the relevant information, works, and inventions.[121] PPPs are a valuable option for the innovation process for a number of reasons. Sharing resources, risks, and responsibilities amongst partners can encourage collaboration, unburden the innovation process, strengthen each partner's commitment to the project, and attract more stable and reliable partners. Sharing resources such as knowledge, data, samples, clinical expertise, patient base, and infrastructure can also expand the partners' training. Likewise, given that a PPP model promotes cooperation among the partners, the collaborators' network becomes larger, thereby enabling the innovation process to accelerate, focus on neglected areas, and improve the quality of the products.

The main challenge, on the other hand, is handling the partners' different expectations, objectives, and interests, especially since they are from distinct sectors. Additionally, since PPPs can adopt any model (such as open science, open source, or traditional proprietary commercialization),

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119 See Granados Moreno & Joly, *supra* note 18 at 289; Granados Moreno, Joly & Knoppers, *supra* note 118 at 2–3; Bubela, FitzGerald & Gold, *supra* note 18 at 2.

120 See Bubela, FitzGerald & Gold, *supra* note 18 at 2.

121 See Joanne Evans & Diana Bowman, "Getting the Contract Right" in Graeme A Hodge & Carsten Greve, eds, *The Challenge of Public-Private Partnerships: Learning from International Experience* (United Kingdom: Edward Elgar Publishing, 2005) 62 at 63.

the challenges associated with the enclosure of shared information, works or inventions; maintaining a steady and sustainable source of funding; or impacting the pace of innovation, as discussed above, will depend on the innovation model chosen.[122]

The second example of a collaborative form of intellectual property is crowdsourcing. Crowdsourcing is a model that aims to obtain information, funding, or collaboration from the collective intelligence of a crowd. Crowdsourcing acts as a form of citizen science, where individuals from outside of the scientific community are mobilized to assist with research in a variety of ways.[123] It frequently uses the Internet to recruit crowds as a form of online challenges. The specific group of individuals that responds to the challenge (crowd) is undefined, and despite having a clear mechanism for compensation, they are not employed by the person or group that posts the challenge, which is what differentiates crowdsourcing from outsourcing. Unfortunately, crowd members generally show a lower level of engagement and involvement than the collaborators in an open innovation model.[124] An important difference between crowdsourcing and open innovation models is that while open innovation focuses on collaborating firms, crowdsourcing also includes individuals as potential collaborators.[125]

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122 See James Mittra, "Exploiting Translational Medicine Through Public-private Partnerships: A Case Study of Scotland's Translational Medicine Research Collaboration" in James Mittra & Christopher-Paul Milne, eds, *Translational Medicine: The Future of Therapy* (Boca Raton, FL: Pan Stanford Publishing, 2013) at 213; Granados Moreno, Joly & Knoppers, *supra* note 118 at 1–2; Granados Moreno & Joly, *supra* note 18 at 287.

123 See Christopher Kullenberg & Dick Kasperowski, "What is Citizen Science? A Scientometric Meta-Analysis" (2016) 11:1 PloSONE, online: <doi.org/10.1371/journal.pone.0147152> [perma.cc/F5LN-2ZNK].

124 See Yuxiang Zhao & Qinghua Zhu, "Evaluation on Crowdsourcing Research: Current Status and Future Direction" (2014) 16:3 Inf Syst Front 417 at 421; Michel Neumann, "Open Innovation vs Crowdsourcing vs Co-creation" (3 August 2017), online: *Wazoku* <www.wazoku.com/open-innovation-vs-crowdsourcing-vs-co-creation/> [perma.cc/9WTA-NKPR].

125 See Jeff Howe, "The Rise of Crowdsourcing" (June 2006), online (pdf): *Wired* <sistemas-humano-computacionais.wdfiles.com/local--files/capitulo%3Aredes-sociais/Howe_The_Rise_of_Crowdsourcing.pdf> [perma.cc/SG7D-GQCR]; Zhao & Zhu, *supra* note 124 at 417, 421.

Lego Ideas, which calls for ideas for new Lego sets, is an example of this model outside the field of medical research.[126] An example involving DNA is the Genographic Project, which aims to map historical human migration patterns by collecting and analyzing DNA samples.[127]

One key benefit of the crowdsourcing model is its ability to create a large network of collaborators, which can enrich, diversify, and accelerate the innovation process and the resulting products and services; enable peer and multidisciplinary review; and possibly lower R&D costs.[128] It is worth mentioning that, given that there is often no formal collaboration with the members of the crowd that contribute to the innovation process, the different intellectual property rights that result from the process may not merge. In other words, the company launching the challenge will own and retain any intellectual property right that result from the project, without attributing or sharing any copyright or patent with the members of the crowd.[129] Unlike the previous models, there is neither an opportunity to enable training among the contributors, nor a chance to enable transparency or self-organization, as contributors are only given access to the information necessary for them to carry out the challenge and the parameters that they need to meet, without having access to the complete innovation process.[130] An important concern associated with crowdsourcing is the protection of information disclosed during the innovation process. As part of the crowdsourcing model, the researcher, company, or centre posting the challenge has to disclose to anyone in the "crowd" the information necessary to enable them to understand the project and the task at hand, and to be able to perform accordingly. Despite the possibility of trying to protect the information disclosed through

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126 See Andrew Yoo, "Lego Ideas: Crowdsourcing the Next Big Hit: Digital Innovation and Transformation" (20 March 2017), online: *Digital Initiative* <digit.hbs.org/submission/lego-ideas-crowdsourcing-the-next-big-hit/> [perma.cc/4PS3-KGJ2].

127 See "National Geographic Geno DNA Ancestry Kit" (last visited 4 October 2019), online: *National Geographic* <genographic.nationalgeographic.com/> [perma.cc/4XDN-EV4T]; Molly K McLaughlin, "National Geographic Genographic Project" (30 October 2017), online: *PCMAG* <www.pcmag.com/article2/0,2817,2490077,00.asp> [perma.cc/Y945-TQTL].

128 See Zhao & Zhu, *supra* note 124 at 425–427.

129 See *ibid* at 421.

130 See *ibid* at 421–422.

a confidentiality agreement, this disclosure may still be risky and harm the researcher, company, or centre's competitive position in the future.[131]

The open models of collaboration described in the above Sub-Parts are just a few examples of the various existing models. Projects may also combine models throughout the stages of the innovation process.

III. Open models of collaboration in North America

Governments in Canada, Mexico, and the United States have adopted laws and implemented policies and programs that strive to create the necessary economic incentives for the promotion of innovation, such as patent laws and tax credits, as described above. They have also decided to directly allocate significant resources to fund medical and genomic research. For instance, the Canadian government funds a larger share of public research than most OECD countries, and its spending on higher education is one of the highest. The country's public expenditure is situated in the top half of OECD countries. Genome Canada and the Canada Brain Research Fund are two examples of governmental research funds that greatly contribute financially to the country's R&D. Canadian provinces also fund and implement policies to encourage local innovative activities, boost their economies, and improve education.[132] US R&D relies heavily on their domestic business sector, which the government also boosts by offering tax credits. The expenditure of its public sector in R&D is within the OECD median.[133] The three countries also encourage and support formal training and education. Canada, for example, supports and provides funds for Excellence Research Chairs, student loans and grants, and assistance to post-secondary studies abroad.[134] The United States has some of the best higher education institutions in the world.[135] The bulk of Mexico's scientific output is from its strong higher education institutions (HEIs) and public research institutions (PRIs). The National Researchers System's policies and the development of technology transfer offices in HEIs and PRIs have contributed to an

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131 See Hagedoorn & Zobel, *supra* note 74 at 1052, 1057–1058.

132 See OECD, *supra* note 11 at 258.

133 See *ibid* at 404–407.

134 See *ibid* at 256–259.

135 See *ibid* at 404–407.

increase in these institutions' scientific output.[136] Private companies have made similar decisions. For instance, Roche Holding AG has increased its investment in R&D from USD$9.4 billion in 2016 to USD$11.8 billion in 2017, Merck & Co., Inc. from USD$6.7 billion to USD$10.1 billion, Novartis AG from USD$9.5 billion to USD$9.6 billion, Pfizer Inc. from USD$7.7 billion to USD$7.9 billion, Sanofi from USD$6.1 billion to USD$6.2 billion, and Eli Lilly and Company from USD$4.8 billion to USD$5.2 billion.[137]

The following Sub-Parts describe examples of projects adopting open models of collaboration in Canada, the United States, and Mexico. These examples illustrate the way in which these models have been implemented in actual projects and the outcome they have so far generated.

A. Canada: Structural genomics consortium

In recent years, the Canadian government has taken steps to improve the breadth, depth, and accessibility of information available to researchers.[138] In particular, Canada's revised science, technology and innovation strategy, *Seizing Canada's Moment: Moving Forward in Science and Innovation*, released in 2014, describes an open science implementation plan for open access and open data initiatives through councils, as well as science-based departments, councils, and agencies.[139] While the full impact of this policy remains to be seen, the policy aims to build on existing strengths in Canada's research infrastructure, including strong performance in R&D expenditures, volume and prestige of publications, and the inclusion of top-rated scientists in government decision-making.[140] In this context, research

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136 See *ibid* at 346.

137 See Barry Jaruzelski, Volker Staack & Robert Chwalik, *The 2017 Global Innovation 1000 Study* (United States of America: PricewaterhouseCoopers, 2017).

138 See "Canada's Draft Action Plan on Open Government 2.0" (last modified 20 August 2019), online: *Government of Canada* <open.canada.ca/en/content/canadas-draft-action-plan-open-government-20> [perma.cc/SB3E-GBZ3].

139 See "Seizing Canada's Moment: Moving Forward in Science, Technology and Innovation" (2014), online: *Government of Canada* <www.ic.gc.ca/eic/site/113.nsf/eng/h_07657.html> [perma.cc/YES3-KTT7].

140 See *ibid*.

organizations like the Structural Genomics Consortium (SGC), examined below, have emerged and continue to evolve.

Founded in 2004 by Aled Edwards, the SGC is a not-for-profit public-private partnership that solves 3D structures of proteins and chemical tools (such as chemical probes[141]) that are biomedically relevant in drug discovery processes.[142] Its main goal is the advancement of science and the discovery of drugs, rather than any personal, institutional, or commercial gain.[143]

The outputs created by the SGC include structures for over 1,500 proteins associated with diabetes, cancer, and infectious diseases such as malaria.[144] The SGC places its outputs in the public domain via the RCSB

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141 The chemical probes created by SGC are potent, selective, and cell-permeable inhibitors of protein function which are essential in early stages of drug discovery. Their relevance for drug discovery lies on the fact that they allow preclinical target validation by stimulating or blocking the activity of proteins involved in epigenetic control. Most medicines work by binding to proteins and influencing their activity. To work effectively, medicines need to find the right protein. Knowing the shape of a protein "target" allows researchers to design drugs with molecules that fit that protein. Having this information from the beginning can reduce the drug discovery process. See "Structural Genomics Consortium: Key Achievements" (last visited 4 October 2019), online: *Structural Genomics Consortium* <www.thesgc.org/about/key_achievements> [perma.cc/W78K-TZKZ]; "Structural Genomics Consortium: FAQ for Non-Scientists" (last visited 4 October 2019), online: *Structural Genomics Consortium* <www.thesgc.org/about/mini_faq> [perma.cc/UC2S-8XUH] ["SGC FAQ"].

142 See Amy Donner, "A Conversation with Aled Edwards" (2014) at 1, online (pdf): *Sci-Business Exchange* <www.researchgate.net/publication/273043571_A_conversation_with_Aled_Edwards> [perma.cc/MRY7-DPH7].

143 See Edwards, *supra* note 37.

144 For more information about the specific areas or projects on which the SGC focus, see "Structural Genomics Consortium: Science" (last visited 4 October 2019), online: *Structural Genomics Consortium* <www.thesgc.org/science> [perma.cc/DSU3-ZU37] [SGC Science].

Protein Data Bank,[145] without any intellectual property restrictions.[146] The protein structures deposited account for approximately 25% of all human proteins and 50% of all proteins from human parasites deposited in the Protein Data Bank each year, and overall 15% of the human proteome. The SGC Scientific Committee approves the proteins structures on which the SGC laboratories will work and includes them in the SGC's Target List.[147]

The SGC has expanded from six member organizations at its foundation in 2004, to 20 members, including nine pharmaceutical companies,[148] and more than 250 active research collaborations.[149] The SGC has six laboratories located at the University of Toronto, the University of Oxford, the State University of Campinas, the Karolinska Institutet, the University of North Carolina at Chapel Hill, and the Goethe University in Frankfurt. Researchers in these six laboratories use, develop, and exchange structural biology, medicinal chemistry, and assay development expertise and protocols. Each

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145 The Protein Data Bank is a repository managed by the Research Collaborative for Structural Bioinformatics Rutgers and University of California, San Diego/San Diego Supercomputer Center for 3D structural data of proteins and nucleic acids that can be used by any scientist around the world to release their data into the public domain for free.

146 The SGC website is licensed under a CC-BY licence.

147 See Donner, *supra* note 142 at 1; SGC FAQ, *supra* note 141.

148 The six original organizations are the University of Toronto, University of Oxford, Universidade Estadual de Campinas, Karolinska Institutet, University of North Carolina at Chapel Hill, and Universität Frankfurt Am Main. The current partners include Abbvie, Bayer, Boehringer Ingelheim, Canada Foundation for Innovation, the São Paulo Research Foundation, Genome Canada, Janssen, GlaxoSmithKline, Merck KGaA (Germany), MSD (Merck Inc, US & Canada), Novartis, the Ontario Ministry of Research, Innovation and Science, Pfizer, Takeda Pharmaceutical Company Limited, and Wellcome. See "Structural Genomics Consortium: Partners" (last visited 4 October 2019), online: *Structural Genomics Consortium* <www.thesgc.org/about/partners> [perma.cc/U2PN-CSDJ].

149 Some of the major collaborators are the Ontario Institute for Cancer Research, Eurofins Pharma Discovery Services, the Center for Integrative Chemical Biology and Drug Discovery at the University of North Carolina at Chapel Hill, and the Icahn School of Medicine at Mount Sinai. See "Structural Genomics Consortium: Collaborators" (last visited 4 October 2019), online: *Structural Genomics Consortium* <www.thesgc.org/collaborators> [perma.cc/XXQ4-6NNT] [SGC-Collaborators].

laboratory has scientists who have been hired specifically to work at the SGC (as opposed to independent professors who have their own research objectives) on the targets, structures, and research objectives agreed on by the SGC in order to achieve the goals it has set for itself. All the laboratories use a common informatics platform to ensure that the information they produce flows and is properly integrated.[150] Additionally, the SGC establishes alliances with scientists from associated areas, patient groups, government agencies, funding bodies, and media to establish an integrated and inclusive innovation process.[151]

The model proposed by the SGC for its research and management includes features of open science and access within a public-private partnership. As part of the open science model, the SGC is committed to keeping all of its outputs patent-free and rapidly disseminating its results. The purpose of adopting this model and posting all of its outputs in the public domain is not only to provide the public with direct access to the knowledge produced, but also to facilitate research and enable companies and academics to use this information (including structural information, reagents, and methods) for the more rapid development of affordable new drugs. The collaboration that the SGC adopts includes allowing certain donors to nominate targets for the protein target list as well as scientists to work in any of the SGC laboratories.[152]

One of the biggest challenges of the SGC's model is balancing the expectations of its different funders. Academic and public funders usually

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150 See "Structural Genomics Consortium: Laboratories", online: *Structural Genomics Consortium* <www.thesgc.org/labs> [perma.cc/7UT5-PEAS].

151 Examples of these alliances include Fibrodysplasia Ossificans Progressiva UK and France, Adult Polyglucosan Body Disease Research Foundation, Teenage Cancer Trust, Genome Canada, Ontario Government (Ministry of Science), and Ontario Genomics. See "Structural Genomics Consortium: Strategic Alliances and Communications" (last visited 4 October 2019), online: *Structural Genomics Consortium* <www.thesgc.org/about/strategic-alliances> [perma.cc/U6XH-85EG]; Donner, *supra* note 142 at 1–2; "Ontario Genomics: Structural Genomics Consortium" (June 2017), online: *Ont Genomics* <www.ontariogenomics.ca/funding-opportunities/awarded-projects/structural-genomics-consortium/> [perma.cc/XA8X-GZKQ]; "Structural Genomics Consortium: Public Engagement" (last visited 4 October 2019), online: *Structural Genomics Consortium* <www.thesgc.org/outreach/public-engagement> [perma.cc/CR7U-UQVJ].

152 These "rights" are reserved for donors of more than USD$8 million. See "SGC FAQ", *supra* note 142.

seek reputational rewards and high profile publications, while private funders value impact and quantitative measures, particularly commercial profit.[153] These differences create tensions regarding the goals and objectives set, as well as the ways in which they can be reached, managed, and furthered without letting any of those funders divert the organization's mission. This ties into the second challenge: maintaining constant funding from both the public and the private sectors. Public funding is necessary to maintain the collaborators' trust that SGC's outputs serve the public good, thereby persuading them to keep contributing to the SGC's research. Private funding maintains a good pace of innovation, since private companies usually have invaluable scientific, technical, and strategic expertise.[154]

The SGC model has brought several advantages for innovation. First, the model catalyzes research by focusing on under-studied diseases and areas of the human genome. This has been made possible in part due to the combination of public and private funding. At its outset, it secured close to USD$100 million from Canadian research organizations, the Wellcome Trust charity, and pharmaceutical companies. In 2011, another USD$50 million was invested. The funding that the SGC has obtained in its three phases combined reaches over USD$425 million.[155] Public and private funding continues to increase because of the benefits that each brings, namely increased trust that the research serves the public good and is not limited by what the market considers profitable, and the resources, tools, skills, and infrastructure that the private sector contributes.[156] Second, the SGC model accelerates research by making its outputs openly available to the scientific community. It has done so because, as previously discussed, open access and sharing reduces needless duplication of efforts: everyone knows what is being done and can build upon it, thus eliminating the costs and time of

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153 See Donner, *supra* note 142 at 2; Morgan Jones et al, *supra* note 97 at 26.

154 See Donner, *supra* note 142 at 2; Aled Edwards, "To Spark Medical Innovation, Canada Should Embrace Open Science" (7 January 2017), online: *The Globe and Mail* <www.theglobeandmail.com/report-on-business/rob-commentary/to-spark-medical-innovation-canada-should-embrace-open-science/article33533010/> [perma.cc/3DVU-DGFC].

155 See Marek Grabowski et al, "The Impact of Structural Genomics: The First Quindecennial" (2016) 17:1 J Struct Funct Genomics 1 at 2; Morgan Jones et al, *supra* note 97 at 63.

156 See Morgan Jones et al, *supra* note 97 at 23–24, 26, 63.

obtaining patents and negotiating licenses.[157] Examples of projects or organizations that have benefited in these terms from the SGC's outputs released under the open science model include Constellation Pharmaceuticals and the Leukemia & Lymphoma Society Partnership.[158]

The SGC's model also accelerates research by creating an open collaborative network of scientists across universities and pharmaceutical companies around the world, all of whom contribute to the innovation process and its resulting products and services. This network has been able to provide not only support for the work itself and the necessary resources, but also an invaluable level of quality control, which tests, detects flaws, and has signalled areas in need improvement.[159]

Third, the SGC's model facilitates the continuous expansion of its public and private members' network. It does so by offering funding and a large academic and commercial scientific network for collaboration, without the need for technology transfer offices or negotiation procedures. It also facilitates the mobilization of people and resources by implementing an open access policy, minimizing transfer and bureaucratic costs, and remaining open to addressing both public and private objectives.[160] Furthermore, many collaborators choose to work with the SGC for personal recognition.[161]

Fourth, the model allows for training and the dissemination of knowledge, skills, and expertise. The collaborative work includes the elucidation of the functional implications of the SGC's structures and protein targets, the screening of the SGC's protein targets against those that collaborators have analyzed, the characterization of the proteins' activities, and a better understanding of the proteins' families and expressions. This knowledge is easily shared and assimilated by most collaborators because there are no patents or other enforced forms of intellectual property limiting its flow, and because it is disseminated quickly through common platforms.[162]

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157 See *ibid* at 22.

158 See *ibid*.

159 See Morgan Jones et al, *supra* note 97 at 23.

160 See *ibid* at 29–35, 48.

161 See *ibid* at 31.

162 See Donner, *supra* note 142 at 1–2; "SGC FAQ", *supra* note 141; Edwards, *supra* note 37; Morgan Jones et al, *supra* note 97 at 22, 29–35, 47–48.

The SGC has yet to reach its full potential. Despite the fact that it has successfully reached its stated goals, new partnerships keep forming and more work, funds, and collaboration are required. One of the SGC's latest partnerships is with the Montreal Neurological Institute. This is part of the Neuro Open Science initiative to screen compounds on iPSC-derived cells from patients with Parkinson's disease and Amyotrophic Lateral Sclerosis.[163] It has also partnered with Aché Laboratories (Brazil), Eurofarma Laboratories (Brazil) and the Brazilian Agency for Industrial Research and Innovation to develop inhibitors of proteins important for cancer and parasitic infections. The diseases covered and proposed projects keep increasing, and it is therefore safe to say that further research and collaboration will continue to be necessary.[164]

B. The United States: Sage bionetworks

At the level of federal policy, attention to open science in the United States has increased in recent years. In 2013, the White House Office of Science and Technology Policy (OSTP) released a memo titled "Increasing Access to the Results of Federally Funded Research."[165] Recognizing that increased access to digital data can result in innovation (and ultimately economic growth), the memo directs all federal science agencies conducting more than USD$100 million in R&D per year to develop plans to increase public access to research results, including finding new ways to leverage existing databases. Among the objectives of this plan is the encouragement of public-private collaboration.

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163 See Chanshuai Han et al, "Open Science Meets Stem Cells: A New Drug Discovery Approach for Neurodegenerative Disorders" (2018) 12 Front Neurosci at 5, online: <www.frontiersin.org/articles/10.3389/fnins.2018.00047/full> [perma.cc/ZV7B-6WP7].

164 See "SGC-UNICAMP to Receive R$8.4Million in Public-Private Funding for Open Innovation Medicinal Chemistry Program" (10 March 2015), online: *SGC* <www.thesgc.org/news/campinas-unicamp/sgc-unicamp-receive-r84million-public-private-funding-open-innovation> [perma.cc/MF3S-YTJG].

165 White House Office of Science and Technology Policy (OSTP), "Increasing Access to the Results of Federally Funded Research" (2013) at 2, 4, online (pdf): <www.science.gov/docs/ostp_public_access_memo_2013.pdf> [perma.cc/35FZ-2WRM].

In the private sector, some companies have already been working to develop these kinds of open sharing models. Sage Bionetworks is a non-profit organization co-founded by Stephen Friend and Eric Schadt in 2009 as a spinout of Merck & Co. It aims to accelerate biomedical and health research through the creation of open systems, incentives, and standards to conduct dynamic, large-scale collaborative biomedical research.[166] In order to achieve this, Sage is determined to "make biomedical research more transparent, more reproducible, and more accessible to a broader audience of scientists."[167]

As a way of achieving this mission, Sage encourages pharmaceutical companies, academics, clinicians, and patients to share genomic and biomedical information freely in a shared database that researchers can download and work on. The intention is that this collaborative work will lead to the mapping of actual and specific (as opposed to average) intracellular/biochemical pathways and the creation of computational models of those conditions, thereby contributing to a better understanding of human diseases and drug development.[168]

To pursue its objective, Sage follows an open source model, similar to the one implemented in the software industry by computer programmers. The choice of this model is based on two realizations. The first is that the process of drug discovery depends on the existence of good computational models of diseases, and such models are scarce in many cases. The second is that those models require massive amounts of data, many iterations, and long years of continuous work.[169] Following the open source model, Sage developed Synapse, an open source technology platform that enables collaboration and allows researchers to carry out, share, and reuse data-intensive analyses (datasets) in order to iteratively generate and test hypotheses. In

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166 See Friend & Norman, *supra* note 35 at 299.

167 "Sage Bionetworks: Home" (2018), online: *Sage Bionetworks* <sagebase.org/> [perma.cc/ELH3-VD86]; "Sage Bionetworks: Platforms" (2018), online: *Sage Bionetworks* <sagebionetworks.org/tools-and-resources/#platforms> [perma.cc/XP7G-EEFX].

168 See Jocelyn Kaiser, "Stephen Friend: The Visionary" (2012) 335:6069 Science 651 at 651; Friend & Norman, *supra* note 35 at 298.

169 See Kaiser, *supra* note 168 at 651; Stephen Strauss, "Pharma Embraces Open Source Models" (2010) 28:7 Nat Biotechnol 631 at 631–632; Jonathan M J Derry et al, "Developing Predictive Molecular Maps of Human Disease Through Community-based Modeling" (2012) 44:2 Nat Genet 127 at 129.

addition to providing this platform to researchers, Sage shares the software underlying their computer models of diseases, tools, platforms, and products under open source licenses.[170] Sage releases its non-software creative works under the Creative Commons Attribution license. Even though some of their scientific findings were previously published in closed journals,[171] they are now released in open access journals. Sage's collaborators must share their data and models within the first year following the end of a project, as per the Bermuda principles.[172]

Sage has also adopted a crowdsourcing model by which it engages the community in search of complex biomedical solutions to problems and targets, posted on the DREAM platform.[173] The crowdsourcing model is also used to test new hypotheses.[174] Sage has also launched a number of mobile health initiatives to include patient-centered research. For instance, it launched mPower for Parkinson's disease, MoleMapper for skin cancer, and My BP Lab for blood pressure.[175] In connection with its mobile health initiatives, Sage created Bridge, a web-based platform that determines the operational requirements for a person's participation to be able to ethically generate new data.[176] Likewise, it provides a series of web services designed

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170 See Strauss, *supra* note 169 at 632.

171 The reason for some of their publications in closed journals seemed to be budgetary, as they state that they currently do not have funds to cover the necessary open access fees. See "Sage Bionetworks: Overview" (2018), online: *Sage Bionetworks* <sagebionetworks.org/who-we-are/> [perma.cc/5VWZ-8E9E].

172 See *ibid*; Kaiser, *supra* note 168 at 652.

173 DREAM (Dialog for Reverse Engineering Assessments and Methods) is a network biology initiative led by IBM through which scientific questions regarding computational challenges in systems biology are framed and clinical and genomic data are provided to any interested participants to solve or contribute to. See Friend & Norman, *supra* note 35 at 302.

174 See "Sage Bionetworks: Board" (2018), online: *Sage Bionetworks* <sagebionetworks.org/board-of-directors/> [perma.cc/A7YH-JFF7]; "Sage Bionetworks: Challenges", (2018), online: *Sage Bionetworks* <sagebionetworks.org/tools_resources/challenges/> [perma.cc/RS5K-WDL9].

175 See "Sage Bionetworks: Digital Health" (2018), online: *Sage Bionetworks* < sagebionetworks.org/digital-health-studies/> [perma.cc/8YW9-WYAT].

176 See *ibid*. Some of these services include tools to facilitate mobile registration, consent to participate in research studies, and design and schedule surveys,

to fulfill those requirements and support research studies conducted through mobile interfaces.[177]

Sage acts both as a technology service provider and as a research partner.[178] Sage's projects focus on cancer, Alzheimer's, neuropsychiatric diseases, Parkinson's, psychiatric disorders, and neurofibromatosis, among other diseases.[179] Its funding is both public (federal) and private.[180] Sage works concurrently with open access activists, bioethicists, technologists, patient advocacy groups, and independent accredited institutional review boards to develop and update rules, policies, and procedures on data sharing, consent-forms, data protection, data access, and interoperability of data used and shared in Sage's platforms and mobile tools.[181] Some of its current collaborators and collaborative science research studies include the AMP-AD Knowledge Portal (multi-omic data), the Molecular Mechanism of the Vascular Etiology of Alzheimer's Disease (M2OVE-AD), the Neurofibromatosis Therapeutic Acceleration Program (NTAP), the Cancer Systems

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as well as the collection, receipt, transfer and de-identification of survey and study data.

177 See "Sage Bionetworks: Board", *supra* note 174; "Sage Bionetworks: Challenges", *supra* note 174; "Sage Bionetworks: Platforms" , *supra* note 167; Friend & Norman, *supra* note 35 at 302.

178 See "Sage Bionetworks: Digital Health", *supra* note 175.

179 See "Sage Bionetworks: Research" (2018), online: *Sage Bionetworks* <sagebionetworks.org/overview/> [perma.cc/F3C7-9WXA].

180 Some of these sponsors include Academy Health, the American Association for Cancer Research, the All of UsSM Research Program, AstraZeneca, Avon Foundation for Women, Biogen, the Breast Cancer Research Foundation, the Cancer Research Institute, Celgene, the Children's Tumor Foundation, the Defense Advanced Research Projects Agency, the Foundation for the National Institutes of Health, the Helmsley Charitable Trust, Eli Lilly, the Laura and John Arnold Foundation, Merck Serono, the National Institute on Aging, the National Heart, Lung, and Blood Institute, the Neurofibromatosis Therapeutic Acceleration Program, Novartis, the Parker Institute, the Robert Wood Johnson Foundation, the Wellcome Trust Sanger Institute, the St. Baldrick's Foundation, and the Takeda Pharmaceuticals USA Inc. See Kaiser, *supra* note 168 at 651; "Sage Bionetworks: Sponsors" (2018), online: *Sage Bionetworks* <sagebase.org/who-we-are/sponsors/> [perma.cc/D2EB-K2UY].

181 See "Sage Bionetworks: Governance" (2018), online: *Sage Bionetworks* <sagebase.org/governance/> [perma.cc/EK2Z-B34Z].

Biology Consortium (CSBC) and the International Cancer Genome Consortium-Cancer Genome Atlas (ICGC-TCGA) Whole Genome Pan-Cancer Analysis Working Group.[182]

Despite having the above-mentioned support of public funders and partnerships with private companies, one of the main challenges that Sage has encountered in implementing an open source model is the scepticism of some researchers and companies. This translates to a certain level of difficulty in maintaining funding, as many funding agencies strongly promote the pursuit of intellectual property rights rather than data sharing. Furthermore, the policies implemented by many funding agencies and the competition for funding tend to inhibit data sharing and collaboration.[183]

Another challenge Sage has yet to overcome is associated with a potential misuse of data and therefore privacy and consent-based conflicts. Even though Sage has implemented tools and strategies to integrate participants' preferences about privacy protection and future use, its strong support for open access and sharing and democratization of the data it collects leads to granting access to anyone who complies with their access process. This has resulted in ethical concerns involving participants' privacy and consent, particularly regarding the scalability and feasibility of the company's tools and strategies across populations and research projects.[184]

Despite the aforementioned challenges, Sage has been successfully improving, accelerating, modernizing, and democratizing biomedical research.[185] Its founders' belief that biomedical data-intensive research would be more successful and affordable if it were carried out in an open information commons that everyone can access has attracted a number of collabor-

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182 See "Sage Bionetworks: Synapse: Communities" (2018), online: *Sage Bionetworks* <www.synapse.org/#!StandaloneWiki:ResearchCommunities> [perma.cc/9ZUS-MK2L]; "Sage Bionetworks: Collaborative Science" (2018), online: *Sage Bionetworks* <sagebionetworks.org/collaborative-science/> [perma.cc/4R5X-9M37].

183 See Kaiser, *supra* note 168 at 651, 653; Friend & Norman, *supra* note 35 at 299; "Sage Bionetworks: Synapse Docs: FAQ" (2018), online: *Sage Bionetworks* <docs.synapse.org/articles/faq.html> [perma.cc/3VJG-FCCS].

184 See Laura L Rodriguez et al, "The Complexities of Genomic Identifiability" (2013) 339:6117 Science 275.

185 See Strauss, *supra* note 169 at 631–32; Derry et al, *supra* note 169 at 130.

ators with different sizes, backgrounds, interests, and roles.[186] Some of these collaborators include biomedical research centres, hospitals, universities, and companies,[187] who contribute their resources, models, datasets (when possible), analyses, and knowledge.[188] It has also resulted in a number of studies that have directly used Sage's platforms and technologies (including the mobile health applications) or collaborated with them.[189] Sage attracts these multiple partners and collaborators not only by promoting open access and sharing, but also by enabling sharing through its platform (Synapse) and the rules and policies it has developed for consent forms, data sharing, and data protection. For instance, the Cancer Genome Atlas and the Mount Sinai School of Medicine have also selected Synapse to host their data to facilitate their comparative analysis of TCGA genomic data and support their working groups on Alzheimer's and diabetes, respectively.[190]

The inclusion of mobile technologies and the Bridge platform as tools to collect data donated by participants from a larger and more diverse group of people in a more efficient and less costly manner has expanded the data available for analysis. Developing an informed consent process for such an ambitious enterprise raises thorny ethical issues that may deserve additional attention from stakeholders. On the positive side, mobile technologies and the Bridge platform have enabled a number of people and patients to become involved in research that concerns them. It has also benefited the large number of individuals (both researchers and regular citizens) who can

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186 See Friend & Norman, *supra* note 35 at 302–03.

187 Some of Sage's collaborators include Ashoka, CHDI Foundation, the Center for Research and Interdisciplinary, the Fred Hutchison Cancer Research Center, the Institut Pasteur, Inspire2Live, the Life Science Discovery Fund, the Listwin Family Foundation, the NCI Integrative Cancer Biology Program, the Parker Foundation, Quintiles Transnational, Rock Health, Traitwise, Tsinghua University, University of Miami Center for Computational Science, and Wilson Sonsini Goodrich & Rosati. See "Sage Bionetworks: Partners" (2018), online: *Sage Bionetworks* <sagebase.org/who-we-are/partners/> [perma.cc/5VLN-2QRL].

188 See Friend & Norman, *supra* note 35 at 299; Derry et al, *supra* note 169 at 130; Strauss, *supra* note 169 at 632.

189 See "Sage Bionetworks: Publications" (2018), online: *Sage Bionetworks* <sagebionetworks.org/publications/> [perma.cc/6T2P-7PXV].

190 See Friend & Norman, *supra* note 35 at 301.

access and work on this data.[191] The combination of policies that promote more open sharing and access to data; diverse players; and tools (such as Synapse, Bridge, and DREAM) that allow the use of new technologies has been conducive to more in-depth and diverse research. This research has accelerated innovation and even set the basis for the development of precision medicine.[192] This combination has also promoted knowledge dissemination and capacity building in a larger community. Concurrently, the impact of Sage's policies and platforms on innovation has greatly increased the economic value of not only the organization itself, but that of its partners, collaborators, projects, technology, and knowledge generated. Sage's success has attracted the interest of other players such as Apple, who adopted Sage's Parkinson mPower[193] app into its ResearchKit and CareKit health platforms and then hired Sage's co-founder to help them enter the health care market.[194]

C. Mexico

Unlike Canada and the United States, Mexico has yet to see major movement toward federal encouragement of data-sharing. Mexico has also not yet seen the emergence of a successful company or organization that has adopted an open model of collaboration in human health genomics. Although Mexico is a signatory to the Latin American Non-Commercial Open Access Ecosystem,[195] and despite having the necessary scientific and technological basis,[196] Mexico's pharmaceutical and biotechnology com-

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191 See *ibid* at 299.

192 See *ibid* at 301; Derry et al, *supra* note 169; Strauss, *supra* note 169.

193 For more information on this app, see John Wilbanks & Stephen H Friend, "First, Design for Data Sharing" (2016) 34 Nat Biotechnol, online: <www.nature.com/articles/nbt.3516> [perma.cc/8BQY-FA4C].

194 See Kif Leswing, "Apple Hires Sage Bionetworks Cofounder" (23 June 2016), online: *Business Insider* <www.businessinsider.com/apple-hires-sage-bionetworks-cofounder-2016-6> [perma.cc/Y2LC-KPP7].

195 See "Declaration of Mexico in Favor of the Latin American Non-Commercial Open Access Ecosystem" (last visited 25 January 2019), online: *Declaración de México* <www.accesoabiertoalyc.org/declaracion-mexico-en/> [perma.cc/JC99-QNHT].

196 For instance, Mexico's National Institute of Genomic Medicine (INMEGEN)

panies and research centres do not have a prolific track record in the context of innovation. In fact, most of them centre their activities on the development of generics, similar medications,[197] and biological products.[198] They also rarely engage in patenting practices (as evidenced by less than 150 patents in the past 15 years) and there is little collaboration between Mexican companies in the pharmaceutical and biotechnology sectors.[199] The

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led the Mexican Genome Diversity Project and the National Autonomous University of Mexico (UNAM) hosts the Indigenous Genomic Library. The aim of the Genomic Library is to allow researchers to evaluate the several genetic components associated with the susceptibility or resistance to certain diseases common among the Mexican population, including indigenous and mestizo populations. The Library currently includes the DNA of 13 Indigenous peoples. See Maria Luisa Santillan, "Huellas de nuestra historia genética" (2014), online: *Cienca Universidad Nacional Autóma de México* <ciencia.unam.mx/leer/337/Huellas_de_nuestra_historia_genetica> [perma.cc/DWP6-2DRX]; "Recibe la FQ donativo de Fundación Coca Cola para conformar la Genoteca Indígena" (2 September 2012), online: *Facultad de Química: Universidad Nacional Autóma de México* <quimica.unam.mx/recibe-la-fq-donativo-de-fundacion-coca-cola-para-conformar-la-genoteca-indigena/> [perma.cc/E3VE-4NJE].

197 Similar medicines are those that may contain the same active ingredient, dosage form, route of administration, and identification therapeutic regimen as the innovator's and/or patent holder's, but they lack the certification of bioequivalence. A certification of bioequivalence is a pharmacokinetics analysis that determines whether two products are, for all purposes and intents, the same. See Claudia Burr et al, *Ruta para Recibir Atencion Medica en el IMSS e ISSSTE* (Centro de Contraloria Social Y Estudios de Construccion Democratica, 2013).

198 See Christian Lopez Silva, "México retoma un liderazgo regulatorio sobre medicamentos biotecnológicos y biocomparables" (2012) 148:1 Gac Médica México 83 at 84–88; Pierre Moise & Elizabeth Docteur, "Pharmaceutical Pricing and Reimbursement Policies in Mexico" (2007) OECD Health Working Paper No 25 at 34–35.

199 See Sergio Javier Jasso Villazul, "Innovación y colaboración universidad-empresa en la industria biofarmacéutica en México" in *Vinculacion Las Universidades Con Los Sect Product Casos En Iberoamerica*, 1st ed (Unión de Universidades de América Latina y el Caribe, 2016) 125 [Jasso Villazul, "Innovación y colaboración"]; Javier Jasso Villazul, "Innovación y patentamiento en empresas del sector salud en México" (paper delivered at the Conferência Internacional LALICS, Rio de Janeiro, 11 & 12 November 2013) [Jasso Villazul, "Innovación y patentamiento"]; Mexico, Instituto Nacional de Medicina Genómica Programa Annual de Trabajo, *Programa Anual de Trabajo 2016 del Instituto Nacional de Medicina Genómica*, (Mexico: Instituto Nacional de Medicina Genómica, 2016) at 17; Miguel Angel Margain, "IMPI en Cifras"

few cases of collaboration usually involve universities and public research centres, and occasionally companies (most of them foreign) in large cities (Mexico City and Monterrey).[200] As previously discussed, innovation is an interactive, collaborative, communal, and systemic process, in which sharing and collaborating greatly influences the outcome of the research. The insufficient collaboration between Mexico's pharmaceutical, biotechnology companies, research centres, other national and international centres and companies has led to poor dissemination of knowledge.[201] Deficient collaboration among Mexican companies is therefore an important factor for explaining Mexico's scarce innovation history.

The roots of this deficient collaboration may lie in part with Mexico's *Genomic Sovereignty Act*.[202] Instituted in 2011, this law regulates human genome research, including the exportation of DNA samples from Mexican nationals. Although the law serves many important purposes, including the protection of the confidentiality of genomic information and protection against genetic discrimination and exploitation, the seclusion of certain types of human genomic research under federal regulation for the protection of genetic patrimony creates significant challenges for collaboration.[203] Further limits are imposed by uncertainty about the legal status of scientific databases, including the possibility of intellectual property rights being enforced over the databases themselves.[204]

(2015), online (pdf): *Instituto Mexicano de la Propiedad Industrial en Cifras* <www.gob.mx/cms/uploads/attachment/file/60532/IMPI_en_CIFRAS_2015.pdf> [perma.cc/R3XB-EWVS].

200 See Jasso Villazul, "Innovación y colaboración", *supra* note 199 at 11.

201 See Jasso Villazul, "Innovación y colaboración", *supra* note 199; Jasso Villazul, "Innovación y patentamiento", *supra* note 199.

202 Augusto Rojas-Martínez, "Confidentiality and Data Sharing: Vulnerabilities of the Mexican Genomics Sovereignty Act" (2015) 6 J Community Genet 313 at 316.

203 See generally J Mario Sequeiros-García, Pablo Francisco Oliva-Sánchez & Garbiñe Saruwatari-Zavali, "Genomic Sovereignty or the Enemy Within" (2013) 19:2 Acta Bioethica 269.

204 See generally Robert Caso & Rossana Ducato, "Open Bioinformation in the Life Sciences as a Gatekeeper for Innovation and Development" (2015) in L Development & Innovation 1.

In spite of this, Mexico presents great potential for change. On the one hand, the data of the Mexican Genome Diversity Project and the Indigenous Genomic Library are released under open access policies. Scientific publications are also increasingly adopting open access policies. For instance, Latindex and SciELO Mexico, information systems created or managed by the UNAM, focusing on scientific, technical, and professional journals from Latin America, the Caribbean, Spain, and Portugal, offer a directory and catalogue of scholarly journals and access to the full-text online journal articles.[205] Furthermore, the Science and Technology law and associated regulations have been recently amended to oblige the *Consejo Nacional de Ciencia y Tecnología* to fund the creation of national repositories that offer open access to scientific, technological, and innovation-related information. Mexico has also joined open access international declarations, initiatives, and consortiums.[206]

Furthermore, organizations like the Mexican Association of Synthetic Biology (Biosintética) have been created to facilitate partnerships and collaborations among companies, universities, and research centres in order to stimulate innovation and the country's economy. Biosintética is a collective non-profit organization that combines the efforts of researchers and students. It has launched TiSynBio, a database of pre-competitive and competitive information on synthetic biology[207] and also hosts a technology transfer office to provide support in the development of access policies and commercialization strategies.[208] Looking forward, Mexico may draw inspiration from its own success in innovative sharing models outside the framework of human genetics. Mexico's Seeds of Discovery project, for instance, is an

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205 See "Portal De Portales Latindex" (2011), online: *Portal Portales Latindex* <www.latindex.ppl.unam.mx/> [perma.cc/MM4Y-A8ZC]; "Acerca de: Portal De Portales Latindex" (2011), online: *Portal Portales Latindex* <www.latindex.ppl.unam.mx/index.php/about> [perma.cc/LZK4-TYEW]; "SciELO: Mexico" (last visited 5 October 2019), online: *SciELO: Scientific Electronic Library Online* <www.scielo.org.mx/scielo.php> [perma.cc/935Y-USZL].

206 See e.g. art 4-XIII Ley de Ciencia y Tecnología (Mexico) [*Ley de Ciencia y Tecnología*]; "Mexico - Open Science Country Note", online: *Innovation Policy Platform* <www.innovationpolicyplatform.org/content/mexico-open-science-country-note> [perma.cc/F6EC-BANQ].

207 See "Biología sintética en Mexico" (2014), online: *Biología Sintética en Mexico - red synbioMX* <synbiomx.org/2014/01/15/biologia-sintetica-en-mexico/> [perma.cc/EUJ9-B2HH].

208 See *ibid*.

agricultural project that has drawn attention for its willingness to share seed freely on request to researchers worldwide.[209]

Conclusion: Lessons Learned

Innovation is essential: "[T]he progress and well-being of humanity rest on its capacity to create and invent new works in the areas of technology and culture."[210] Today, the scientific and technological advancements in medicine, genomics, and information technology are impressive; however, more research, understanding, and innovation is needed if these advancements are to meet the expectations they have created.

Biomedical science has become more advanced, meaning that resulting innovations are more complex, multidisciplinary, and drawn-out. For instance, innovation in the omics fields demands proper understanding of the ongoing advances in a wide variety of scientific domains such as physiology, pharmacology, enzymology, and cell biology.[211] Furthermore, big data has shown great potential for the development of personalized medicine.[212] In view of this, the innovation process in genomics requires very substantial investments, specialized infrastructure, and specialized human resources.[213]

Economic incentives and higher investment are important, but do not constitute the only requirements for successful innovation. As previously discussed, the pharmaceutical industry continues to increase its expenditure on R&D, yet the number of breakthroughs is decreasing.[214] In the last 25

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209 See "The CIMMYT Germplasm Bank: Activities and Accomplishments" (last visited 25 January 2019), online: *Seeds of Discovery* <seedsofdiscovery.org/the-cimmyt-germplasm-bank-activities-and-accomplishments/> [perma.cc/PMG4-22DT].

210 World Intellectual Property Organization, "What is Intellectual Property" (2003) 450 WIPO 2 at 3.

211 See Morgan Jones et al, *supra* note 97 at 12.

212 See Daniel Richard Leff & Guang-Zhong Yang, "Big Data for Precision Medicine" (2015) 1:3 Engineering at 277; Akram Alyass et al, "From Big Data Analysis to Personalized Medicine For All: Challenges and Opportunities" (2015) 8:33 BMC Med Genomics 1 at 1.

213 See Hall & Bagchi-Sen, *supra* note 12 at 232; Morgan Jones et al, *supra* note 97 at 12, 65. See also Ali-Khan et al, *supra* note 72 at 3.

214 See Friend & Norman, *supra* note 35 at 298; Balasegaram et al, *supra* note 72 at 1.

years, the global pharmaceutical industry has seen a decrease in innovative productivity, despite more than USD$250 billion being invested in biomedical research annually. This is partly because the industry allocates much of its resources to marketing, and to products that have a reliable and profitable market, such as me-too drugs, beauty products, slightly improved products and services.[215] More importantly, the complexities of the innovation process, its cumulative nature (i.e. the fact that knowledge builds on prior understandings and development), and its multidisciplinary character have suggested that the most common proprietary model of innovation is not entirely effective. Furthermore, despite the impressive scientific and technological advancements seen to date, personalized medicine and most areas of omics are still developing, leaving much work to be done before we fully understand their functionality, benefits, and risks.[216]

These characteristics and conditions have made actors and stakeholders in the public and the private sectors aware that they are either unable to take on the whole R&D process by themselves, or that they find it too expensive, burdensome, and time-consuming to do so.[217] Together with the frustration amongst researchers regarding the impediments to innovation that stem from the proprietary approaches to data, a growing number of these actors and stakeholders are more open to trying alternative models, such as open models of collaboration.[218] Most of these models – public domain, open science, open source, protected commons, open innovation, public-private partnerships, and crowdsourcing – share elements of open access, wide-sharing of data and research outputs, and in some cases, lack of intellectual property.[219] The objective of implementing open models of

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215 See Hope, *supra* note 30 at 54; Angell, *supra* note 36 at 74–93.

216 See Michael Brooks, "Stem Cell Research: Time for a Dose of Realism" (2017) 356 Brit Med J j443 1 at 1; Timothy Caulfield et al, "Confronting Stem Cell Hype" (2016) 352:6287 Science 776; Alessandro R Marcon et al, "Representing a 'Revolution': How the Popular Press Has Portrayed Personalized Medicine" (2018) 20:9 Genet Med 950 at 950.

217 See Morgan Jones et al, *supra* note 97 at 10.

218 See Morgan Jones et al, *supra* note 97 at 12; Rouleau, *supra* note 76; Shaw, *supra* note 49 at 147; Allarakhia, *supra* note 34 at 760; Hagedoorn & Zobel, *supra* note 74; Balasegaram et al, *supra* note 72 at 2,4-5; Gold, *supra* note 34.

219 See e.g. Ali-Khan et al, *supra* note 72 at 3; Gold, *supra* note 34 at 2; Rouleau, *supra* note 76 at 1–2.

collaboration is to reduce duplication of efforts and secrecy. Open models enable collaboration where roles and efforts are assigned in accordance with the actors' expertise, abilities, and resources, thus generating and extracting the most value possible from the resources, knowledge, and innovation available.[220] Other advantages commonly associated with open models of collaboration are broader networks of expertise, maximized opportunities for further research, and an accelerated innovation process. In addition, the wider sharing policies characteristic of the open science and open source models are expected to improve the quality of information.[221] These emerging models could benefit particularly from insight from scientific communities with direct knowledge of what researchers need for innovation to flourish.[222]

In this article, we have offered examples of companies or projects that have adopted models of collaboration in genomics in Canada, the United States, and Mexico to assess whether these benefits have in fact materialized. In Canada, we focused on the SGC. The SGC adopted the model of a public-private partnership operating in open science terms. Accordingly, all of the 3D structures of proteins, chemical tools, and any data they produce are released prior to publication (when possible), openly and patent free. In the United States, we focused on Sage Bionetworks. Sage adopted open source and crowdsourcing models. In accordance with the open source model, it openly and freely shares the technology platforms, software, and tools that it creates in order to enable researchers to carry out, share, and reuse data-intensive analyses. As part of the crowdsourcing model, it launched challenges for the community to engage in solving complex biomedical problems. In Mexico, however, we could not identify any ongoing large-scale project that adopted any of the open models of collaboration that we discussed in this article. Instead, we found that despite certain relevant genomic projects such as the Mexican Genome Diversity Project and the Indigenous Genomic Library, Mexico's biotechnology and pharmaceutical industries are, to date, incipient. Furthermore, most of its pharmaceutical and biotechnology companies and research centres do not collaborate. Be-

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220 See Morgan Jones et al, *supra* note 97 at 12 & 59; Ali-Khan et al, *supra* note 71 at 4.

221 See Morgan Jones et al, *supra* note 97 at 21–23, 29, 31, 59; Gold, *supra* note 34 at 2. See generally Hope, *supra* note 30.

222 Federica Fusi et al, "Building Global Genomics Initiatives and Enabling Data Sharing: Insights from Multiple Case Studies" (2018) 22:4 OMICS: J Integrative Biology 237 at 237.

yond these social and structural limitations, the current protectionist legal framework in Mexico also impedes the implementation of open models of collaboration. These major limitations explain the absence of open models of collaboration in Mexico.

Largely due to its open science model, the SGC has reported protein structures for 15% of the human proteome, partnered with fifteen academic and industry institutions, led to more than 250 active research collaborations, has received over USD$400 million in investment (approximately USD$160 million by the public sector, USD$30 million by the private sector, and USD$250 million by public and private sectors), has donated more than 1,000 privately owned advanced compounds, and developed ten new companies.[223] Sage Bionetworks' open source, crowdsourcing, and open science models have resulted in a number of collaborations and biomedical advancements, and in the involvement of the public in the provision of important health data to better understand diseases such as Parkinson's.[224] Both projects have stated that open collaboration with minimal transaction costs and the broad network of diverse collaborators have been a major factors in the results they have achieved.

However, despite these overall positive outcomes, it is important to bear in mind that both projects focus their activities on pre-competitive stages of the innovation process. Whether open models of collaboration could work in other stages, whether those positive results will continue in the long term, and the extent to which the model of collaboration contributes to the outcomes of the projectm remain to be determined. In other words, we must still develop metrics to determine where and how open models of collaboration would best advance innovation. Some of the factors that have been suggested for consideration as part of these metrics are attitudes towards the model, investments (such as monetary resources, infrastructure, and human capital), the goals (such as publications, milestones, and outputs), and the partnerships formed.[225] In fact, both projects reported important challenges and concerns that could eventually have a negative impact on the sustain-

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223 See Donner, *supra* note 142 at 1; Morgan Jones et al, *supra* note 97 at 42; Gold, *supra* note 34 at 3.

224 See Megan Doerr et al, "The mPower Study, Parkinson Disease Mobile Data Collected Using Research Kit" (2016) 3:160011, Scientific Data; Derry, *supra* note 170 at 2; Strauss, *supra* note 170 at 632.

225 See e.g. Ali-Khan, *supra* note 72 at 3–4.

ability of the project and on the assessment of whether the chosen open model of collaboration can be deemed successful.

One primary concern is securing funding. As we have previously mentioned, unraveling the complexity of genomics and personalized medicine requires the participation of many actors and stakeholders, not only in terms of scientific and technical contributions, but also in terms of resources. With respect to the latter, an important insight is that the innovation process in genomics and personalized medicine requires the involvement of both the public and the private sectors. The involvement of the public sector can validate the trust the public has in the research and in the decision to release the outputs into the public domain. It also helps to de-risk underdeveloped and new areas of research, which attracts members of the private sector to collaborate in the subsequent stages of the innovation process.[226] The involvement of the private sector brings a competitive and innovative edge.[227] Therefore, maintaining a constant and sustainable interest in both sectors is essential yet complicated, particularly given that both of them have their own particular goals and practices. In this sense, the open models of collaboration that eschew intellectual property (notably open science and open source) can induce fear of losing a competitive advantage, therefore acting as a deterrent for investment or collaboration.[228] Another challenge is developing and maintaining the necessary infrastructure and policies to manage different collaborations and to secure sensitive information, especially in view of the exponential growth that projects adopting these models of collaboration can have.[229] Finally, although outside of the main focus of this article, we note that it is not sufficient to simply create innovative technology, knowledge, and works; they must also be made readily accessible to those who need them.[230]

To conclude, while we are supportive of using open models of collaboration in genomics innovation, we recognize that there are still significant uncertainties about the actual effect that these models will have on the in-

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226 See Morgan Jones, *supra* note 97 at 24.

227 See *ibid* at 36, 63.

228 See *ibid* at 24, 34.

229 See Ali-Khan, *supra* note 72 at 4; Morgan Jones, *supra* note 97 at 35; Hagedoorn & Zobel, *supra* note 74 at 1058.

230 See Ali-Khan, *supra* note 72 at 3; Gold et al, *supra* note 6 at 2; Hope, *supra* note 30 at 22, 121.

novation process. These effects may in fact differ depending on the stage of the innovation process, and we must develop formal metrics to properly assess them. Proponents also need to develop harmonized and transparent governance models for open projects in order to cultivate public trust in open science and facilitate its broader adoption by members of the research community. However, we see clear societal benefits in innovation models that enable collaboration and partnerships, that can allocate resources more efficiently, and that empower and include different stakeholders. These models have the potential to advance new and ongoing, commercial and non-profitable areas as well as heavily researched and neglected areas. The SGC and Sage are just two of examples of projects in Canada and the US that have decided to explore the benefits of open models of collaborations. More projects are shifting as well: OpenBionics,[231] Google's DeepVariant's,[232] Montreal's Neurological Institute and Hospital,[233] AstraZeneca-Academic Drug

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231 OpenBionics is a start-up company whose objective is to develop low-cost bionic/robotic hands. The company releases the designs for several of its prototypes under an open source license, isncluding oftware and know-how for the development of anthropomorphic, underactuated, modular, adaptive, lightweight, and intrinsically compliant robot and prosthetic hands. See Minas V Liarokopis et al, "Open Source, Affordable, Modular, Light-Weight, Underactuated Robot Hands" (paper delivered at IEEE/RSJ International Conference on Intelligent Robots and Systems, Chicago, 2014), online (pdf) : *Openbionics* <openbionics.org/EMBC2014_Liarokapis_AffordableProstheticFingers.pdf> [perma.cc/26GU-URJ3]; Kostakis, *supra* note 103 at 4–5.

232 DeepVariant is a tool that uses artificial intelligence to learn to identify all the mutations that an individual inherits from their parents. Google releases DeepVariant's code under an open source license. See Megan Molteni, "Google Is Giving Away AI That Can Build Your Genome Sequence" (8 December 2017), online: *Wired* <www.wired.com/story/google-is-giving-away-ai-that-can-build-your-genome-sequence/> [perma.cc/9PFA-MDUL].

233 Montreal's Neurological Institute and Hospital is building one of the largest libraries of brain imaging, clinical demographic, and genetic and cellular data, as well as biological samples from patients with neurological disorders. It is also creating a drug discovery platform and an informatics system. Most of the data, images, and information contained in these projects are released under an open science model. See Gold, *supra* note 34 at 2; Rouleau, *supra* note 76 at 1.

Discovery Consortium (ADDC),[234] Biogen-Genetech,[235] Crowdsourcing: Prize4life[236] and Dream Challenges[237] are examples. In Mexico, where the science and innovation framework is much younger – underdeveloped in some areas and overly protectionist in others – substantial reforms may be necessary in order to promote the development of open models of collaboration. Changes in policy and practices to encourage Mexican researchers to innovate via open collaborative models could be important to ensuring a stronger genomics innovation sector in this country.

Beyond the compelling theory and the growing, but still anecdotal, evidence, the benefits of open models of collaboration must be assessed more rigorously and systematically in order to strengthen the case for their broad use. The suitable place and role of intellectual property, if any, in the contemporary innovation system will also need to be clearly determined. Perhaps the two systems will be able to coexist and complement each other,

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234 The Consortium is composed of 1,000 researchers across over 100 universities in 35 countries. In this case, Astra Zeneca provides ADDC access to its high-quality compound library in order to facilitate the identification and screening of potential drugs. See Arunodoy Sur, "5 Models Of Open Innovation And Emerging Alliances In The Biotech And Biopharma Industry" (23 August 2016), online: *Cheeky Sci* <cheekyscientist.com/models-of-open-innovation-emerging-alliances-biotech-biopharma-industry/> [perma.cc/Z7WE-Q89A].

235 See Sur, *supra* note 234. This alliance aimed to develop rituxan (rituximab), a monoclonal antibody therapy to treat rheumatoid arthritis.

236 Prize4Life, Inc was created to accelerate the discovery and development of a treatment for ALS by awarding USD$1 million to the first person to identify an ALS biomarker. Since the first biomarker was found, it has worked with biotechnology companies to integrate the new biomarker into clinical trials. See Robin Trei, "Case Studies: 'Prize4Life: Finding a Biomarker for ALS'", online: *InnoCentive* <www.innocentive.com/resources-overview/case-studies/> [perma.cc/PM47-KJ9A].

237 The Prostate Cancer DREAM Challenge was launched in March 2015 to improve the prediction of survival and toxicity of the chemotherapy medication docetaxel in patients with metastatic prostate cancer. It included 550 participants from different countries, universities, not-for-profits, technology companies, and biotechnology and pharmaceutical companies who were split into more than 50 teams. They produced nearly 1,200 models and 160 submissions. See "Solving Prostate Cancer Challenges with Open Innovation" (19 June 2017), online: *Idea Connect* <www.ideaconnection.com/open-innovation-success/Solving-Prostate-Cancer-Challenges-with-Open-Innovati-00646.html> [perma.cc/Y4YH-TNS2].

however, it would be premature to say this will be the case. One thing is certain: the basis for an innovation framework in the twenty-first century should not be focused solely on economic incentives to innovate. An optimal system should address the economic and scientific value of knowledge as a source of further innovation, while considering the moral value of access and inclusion. Open models of collaboration can provide this foundation, which is often missing in science and innovation policy.