

# OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda"

# The Role of Biotechnology Intellectual Property Rights in the Bioeconomy of 2030

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In looking ahead to 2030, we can predict that intellectual property will play a substantial but not determinative role in shaping the Bioeconomy. In contradistinction to other factors such as the general investment climate, public security concerns, regulatory environments, politics and environmental change which will have a *direct* positive or negative impact on the Bioeconomy of 2030, intellectual property will act as a lubricant or retardant, rather than as an independent force, on advancing change.

#### 1. General Observations

Intellectual property sets out the rules that govern who can make, use and sell innovations. It functions by providing the intellectual property holder with the legal right – although not necessarily the practical ability – to prevent imitation of an innovation for fixed periods. In doing so, it provides the intellectual property holder with the possibility of charging monopoly rents over the invention that not only compensates for inventing and developing the invention but that allows him or her to profit. In distinction to other incentive mechanisms – such as public grants and prize systems – intellectual property works through the allocation of private rights that impose costs on technology users. The distribution of the costs and benefits of intellectual property affect rates of innovation not only as between developed and developing countries, but also between fields and types of biotechnology.

According to economic theory, overly narrow intellectual property rights — measured across the dimensions of what can be protected (height), time of protection (length) and activities included in the protection (depth) — lead to underinvestment in research and development as innovators obtain a return that is less than the social value of any invention created. Overly broad intellectual property rights represent, on the other hand, a social cost by diminishing investment in both the use of an invention and improvements and innovative deployments of it. The ideal intellectual property right scope would vary according to the characteristics of the particular invention involved. Given the enormous transaction costs it would take to administer such a system, countries have each adopted standard rules that apply across all technologies. There is room within these rules to make slight adjustments to the height, length and depth of protection for certain categories of invention (e.g., patented pharmaceutical inventions tend to have greater length and depth than most other forms of inventions while plant variety protection are shorter and less deep). In general the intellectual property system still imposes a fairly arbitrary level of protection that does not take into account neither the true social value of inventions nor their costs of development.

To further highlight the arbitrary nature of the existing intellectual property system, we note that there is little good empirical evidence of the actual effect of intellectual property rights (IPR) on innovation and dissemination levels, let alone an indication of how differences in height, length and depth of protection affects outcomes. This renders most discussions of the intellectual property rights in the biotechnology sector – whether calling for greater rights or greater inherent limitations on those rights - speculative. We note that, while there is plenty of anecdotal evidence that without patents, certain inventions would not have come to market and, on the other hand, that patents have slowed or killed important innovation (e.g. agricultural and clinical), we do not know whether, overall, the current patent system overprotects or underprotects patent holders. The majority of the economic and legal literature tends to the former – that is, we have just ended a period of expansion of patent rights the likely effect of which was to stifle rather than enhance innovation – but hard, across the board evidence is difficult to obtain. Another complication to collecting evidence is that not only do patent rights have different impacts on different industries - one just need note how the positions of the information technology and pharmaceutical industries clash in respect of patent reform - but that different biotechnologies, depending on their field of use and mode of application interact with the patent system in a different manner. For example, research tools – which require no regulatory approval and are, as the name implied, used in research – have a very different profile from that of therapies and crops which undergo regulatory review. Industrial applications of biotechnology

similarly differ from health and agricultural biotechnologies in relation to not only regulatory approval, but in terms of industrial structure.

It is also worth noting that there is very rarely only one right involved in an innovative product or process. Even within a single intellectual property regime such as patent law, a number of patents will normally apply to the same innovation. For example, a plant may involve patents covering vectors, DNA sequences, methods, cells containing the sequences and the entire plant (depending on jurisdiction) and use of the plant with other products (e.g., pesticides). In the usual case, these patents are held by different individuals. In addition, there may be other intellectual property rights involved (e.g., plant variety protection<sup>1</sup>) and rights over the physical object itself. Each of these different types of rights engenders different legal agreements to transfer them. While one trades in patents through licences, one transfers physical material through Material Transfer Agreements. The content and enforcement of these rights differs considerably. In fact, one study from the United States indicates that much of the friction in obtaining research material stems from Material Transfer Agreements rather than patent licences.<sup>2</sup> Nevertheless, this study noted that, "there is also some evidence of delays associated with negotiating access to patented research tools."

History strongly suggests that intellectual property rights function differently depending on a country's level of development as well as the industrial structure it possesses in each of the agricultural, health and industrial fields. National intellectual property law matters relatively little for a country with low or no capacity in one of these fields except to the extent that such laws prevent the importation of important medicines, plants and industrial products. This is clearly an issue in the access to medicines debate but may be less significant in respect of agricultural and industrial biotechnology as well as in relation to other health biotechnologies. Intellectual property laws in developing countries with manufacturing and research capacity as well as in the large developed economies will have a more substantial effect on outcomes. In countries such as China, India and Brazil, intellectual property laws will mediate increased research and industrial capacity by both enabling the development of local expertise through copying and by supporting new innovative companies. One can expect that the height, length and depth of intellectual property rights in these countries will vary in proportion to their level of expertise and development. For their part, intellectual property rights in developed countries will have an effect on research levels, particularly research aimed at meeting the specific agricultural, health and industrial needs of developing countries. Efforts by the university sector to compile lists of patents, to promulgate practices of so-called humanitarian licensing - under which universities retain the right to permit anyone conducting research aimed at the needs of the developing world to do so – and to engage in patent pooling, particularly in the agricultural sector, demonstrate a willingness to experiment with the effective depth of intellectual property rights. Similar efforts are beginning to take root in the health sector although their contours remain murky at present.

Given these three factors – the arbitrary nature of the height, length and depth of intellectual property rights, the lack of firm empirical evidence on the effect of intellectual property rights on levels of innovation and dissemination and the differential impact of intellectual property rights in developed versus developed countries – we envisage a continued heterogeneity of intellectual property rights around the world through to 2030. Efforts to establish ever increasing minimum levels of intellectual property rights around the world seem to be reversing. This conclusion is supported by several factors. First, the push to so-called TRIPS+ trade agreements – trade agreements requiring participating

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<sup>&</sup>lt;sup>1</sup> The International Union for the Protection of New Varieties of Plants (UPOV) provides exclusive rights over seed varieties for agricultural and agro-food use. These rights provide the holder with a legal monopoly (but not necessarily an economic monopoly) for the commercialisation of specific plan varieties, while granting free access to the underlying genome for the purpose of research and plant breeding. The objective is to create a common genetic pool to which each new certificate holder contributes.

<sup>&</sup>lt;sup>2</sup> J.P. Walsh, A. Arora & W.M. Cohen, "Science and the Law. Working Through the Patent Problem" (2003) 299 Science 1021.

nations to grant greater levels of intellectual property protection than required under the agreements of the World Trade Organization – by the United States and Europe are coming to an end. Second, international organisations such as the World Health Organization and the OECD now advance an intellectual property agenda that addresses not only the role of intellectual property in stimulating innovation but its responsibility to ensure that needed products and services reach developing world populations. Third, developing countries have met with increasing success in not only putting restrictions on intellectual property rights on the trade agenda, but of maintaining such restrictions on that agenda. This leads us to conclude that the era of ratcheting up intellectual property rights has at least reached a plateau and may be reversing.

With the increasing heterogeneity of intellectual property rights regimes, we anticipate further development of supplementary and complementary mechanisms to induce innovation and dissemination, particularly in respect of meeting the needs of developing world markets in which IPR does not sufficiently pull innovative activity. Supplementary mechanisms sit outside the intellectual property system and include instruments such as prizes, public sector grants and philanthropy. Complementary mechanisms involve the innovative use of existing intellectual property systems to both induce innovation and to foster collaboration. These include open source and open science initiatives, patent pooling and patent clearinghouses, and licensing practices such as the inclusion of humanitarian clauses as well as clauses permitting broad public sector research. Most of these models are in still in development but show promise. Patent pools have been created around the SARS virus to help foster the development of a vaccine (although no vaccine has yet been produced) and efforts are underway to create pools in agricultural biotechnology<sup>3</sup> and for knock-out mice.<sup>4</sup> Open science licensing experiments are underway through Cambia's BiOS<sup>5</sup> initiative in respect of all biotechnology sectors and PIPRA in the United States is said to be interested in developing open science licences in the agricultural field. Licensing practices have been the subject of guidelines in the United States<sup>6</sup> and at the OECD<sup>7</sup> among other places.

While the above comments apply equally to the three areas of agricultural, health and industrial biotechnology, there are important differences between these sectors in terms of intellectual property rights. While the health and industrial biotechnology sectors rely principally on patents (with some trade secret protection<sup>8</sup>) and property rights over samples, agricultural biotechnology not only confronts these, but plant variety protection, rights derived from the Convention on Biological Diversity and others rights arising from FAO treaties. Thus, the opportunity for blocking rights and lack of coordination is higher in this sector than in the others. Managing not only rights within a particular intellectual property regime but between them requires greater skill and time, leading to higher transaction costs. The European directive on the legal protection of biotechnological inventions<sup>9</sup> attempts to compartmentalize the different types of rights to avoid overlaps but this is likely to be ultimately unstable both as technology advances and as patent practice learns to overcome these legislative restrictions.

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<sup>&</sup>lt;sup>3</sup> See the Public Intellectual Property Resource for Agriculture at www.pipra.org.

<sup>&</sup>lt;sup>4</sup> Francis S. Collins, Janet Rossant and Wolfgang Wurst, "A Mouse for all Reasons" (2007) 128 Cell 9-13.

<sup>&</sup>lt;sup>5</sup> See http://www.bios.net/daisy/bios/home.html.

<sup>&</sup>lt;sup>6</sup> Department of Health and Human Services, National Institutes of Health, Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72090 (Dec. 23, 1999); and National Institutes of Health, *Best Practices for the Licensing of Genomic Inventions* (2005), <a href="http://ott.od.nih.gov/pdfs/70FR18413.pdf">http://ott.od.nih.gov/pdfs/70FR18413.pdf</a>.

Organisation for Economic Co-operation and Development, *Guidelines for the Licensing of Genetic Inventions* (2006), online: <a href="http://www.oecd.org/dataoecd/39/38/36198812.pdf">http://www.oecd.org/dataoecd/39/38/36198812.pdf</a> <a href="http://www.oecd.org/dataoecd/39/38/36198812.pdf">http://www.oecd.org/dataoecd/39/38/38/36198812.pdf</a> <a href="http://www.oecd.org/dataoecd/39/38/3619

<sup>&</sup>lt;sup>8</sup> We note that there is no good data on the relative reliance on trade secrets as opposed to patents. It certainly varies by industry (the food industry relies, for example, heavily on trade secrets whereas the pharmaceutical industry on patents) but again quantification is difficult.

<sup>&</sup>lt;sup>9</sup> EC, Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, O.J. Legislation (1998) No L213.

Current controversies in all three sectors revolve around questions of blocking patents and anticommons effects. Here the evidence is mixed although the agricultural biotechnology field is particularly prone to these difficulties due to the larger variety, depth and overlap of IPRs. Examples such as the delays in being able to bring Golden Rice to market clearly support this concern. However, it remains unclear whether the cumulative effects of multiple patents hamper overall research, are simply less than optimal, or are more than counterbalanced by increased innovation and dissemination elsewhere. Little empirical work exists to address the issue. One study did find, however, that the anticommons effect does impede research although to a modest degree.<sup>10</sup>

## 2. Implication of Intellectual Property for the Bioeconomy

Intellectual property will continue to be controversial up to 2030 although the nature and form of the debate will likely evolve. This is because many of the factors that underscore that controversy relate to fundamental normative clashes and empirical uncertainty that show no signs of abating.

Concerns over the social value of and the health and environmental consequences of new biotechnologies will spill over into debates over intellectual property in the biotechnology realm. While early religious and other deontological concerns over owning life have abated, they are unlikely to disappear. They have, instead, mutated into a general scepticism about biotechnology and commodification that have ironically brought together religious communities with feminist and antiglobalisation advocates. Coalitions of actors opposing embryonic stem cell technology is but one illustration of this. This coalition is largely responsible for the lack of patent protection over embryonic stem cells in Europe and for the ban of the use of federal funds on these cells in the United States. However, whereas changes to European patent law to ban patents over embryonic stem cells do not seem to have effected scientific innovation, restrictions on funding research with embryonic stem cells in the United States seems to have had a negative effect on progress in the field, again illustrating the conclusions reached above about our lack of knowledge of the effects of patents in general.

We anticipate that as synthetic biology and nanotechnology move from theory to practice that these underlying concerns will again influence the debate surrounding intellectual property policy. Past experience indicates, nevertheless, that however vocal these concerns become and whatever changes they bring about in formal intellectual property law, they will have little effect in practice. As Gold and Carbone point out elsewhere, legislative reform without change to underlying practice is unlikely to be effective. This is amply illustrated by the vast amount of policy debate around stem cell and gene patents, which ultimately proved futile in terms of altering practice (unlike changes to practice such as curtailed funding). Scientists and industry, while engaging in discussions about the wisdom of patenting stem cells, will work around changes in patent policy to effectively arrive at the same result. We thus expect much policy debate, much discussion and perhaps even legislative reform, but little change in scientific, health, agriculture or industrial practice.

The lack of strong empirical evidence will continue to hamper attempts to better adjust the law and practice of intellectual property. While we expect that economists, business scholars and sociologists will increasingly attempt to better quantify the effect of patents on encouraging innovation and dissemination, the quickly changing pace of scientific and technological development and associated business strategies will likely outstrip any advance in knowledge. Nevertheless, we expect that we will have a better general understanding of incentive systems – and not simply those premised on

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Scott Stern & Fiona Murray, "Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis" (2005) NBER Working Paper No. W11465.
E. Richard Gold and Julia Carbone, *Myriad Genetics: Caught in the Eye of a Policy Storm*, unpublished manuscript on file with the authors.

intellectual property – by 2030. While our data will always be up to a decade behind the current state of play, we expect that this additional knowledge will lead to greater experimentation both within and supplementary to the intellectual property system.

The central focus of this experimentation will, at least until 2015, be on developing collaborative mechanisms working with existing intellectual property laws. This will occur because of four types of changes. First, developing countries will increasingly move away from simply transplanting legal changes that occur in developed country patent law. Second, higher education institution technology transfer offices will slowly reconfigure themselves to address many of the concerns arising out of Bayh-Dole type legislation. Third, industry, particularly in the health sector, will recognise the importance of collaborating to overcome current problems in the innovation cycle. Fourth, developing countries will push for greater participation in international research teams. Let us examine each change in greater depth.

While Bayh-Doyle is often credited with the rise of the biotechnology industry, this is clearly false. Technology transfer existed well before Bayh-Doyle in the United States and thus the legislation was less transformative than some claim. Further, the world's experience in transplanting Bayh-Doyle to other countries – without marked effect on innovation – indicates that Bayh-Doyle is not responsible for changes in research and development outside the United States. As this recognition slowly permeates the policy field, we expect developing country policy-makers to focus on more strategic uses of intellectual property rather than on simply transplanting legislation ill-adapted to their needs. Technology transfer offices also recognise that the initial era of everything-goes technology transfer has ended. The more sophisticated of these offices long ago recognised that the aim of technology transfer is not to make money for their institutions nor to sign licence agreements, but to better engage industrial partners so that publicly funded research is put to greater use. Much of the controversy about technology transfer in the late 1990s and early 2000s revolved around this misunderstanding. Technology transfer offices will increasingly re-imagine their role as being knowledge brokers and facilitators rather than as business units of universities. They will start measuring themselves in terms of the practical effects of better collaboration such as an increase in various socio-economic factors: i) support to students and post-doctoral fellows, ii) investment in university infrastructure, iii) joint publications between universities and industry, iv) responsiveness to community agricultural, health and industrial needs, and v) economic competitiveness of their communities.

A second change that we envision revolves around the structure of technology transfer offices. Instead of being located and responsible to a single institution, we expect technology transfer offices to specialise in certain fields of activity and seek to represent researchers from a variety of institutions. Other offices will take a more regional approach and seek to provide services to a community incorporated several institutions. Private funders of university research will similarly find that they can add value to the technology transfer process – and thus move their funded research to practical use – by providing expertise in particular subject areas to complement the knowledge of technology transfer officers.

We further anticipate that industry, particularly in the health care field, will increasingly place emphasis on collaborative research projects. This will entail the development of intellectual property management strategies that are open, accessible at a reasonable cost and transparent. Thus, we expect less emphasis to be placed on narrowly proprietary models of intellectual property management and more on models that rely on non-exclusivity and an obligation to share knowledge. Such efforts as the SNP Consortium and the Human Genome Project will be seen as early leaders in the field.

Developing countries have significantly changed their rhetoric about intellectual property since the late 1990s. Instead of opposing intellectual property rights, these countries seek to participate in the intellectual property system on their own terms. The adoption of the WIPO Development Agenda, the Noordwijk Access to Medicines Agenda and work at the WHO by the Intergovernmental Working

Group on Public Health, Innovation and Intellectual Property demonstrate the increased power and engagement of developing countries in intellectual property management. We anticipate that this trend will continue and, in fact grow. Until 2020, we expect changes at two levels. Internationally, developing countries will seek to adapt international agreements to provide for greater flexibility. The end of the TRIPS+ era is one sign of this but we expect more in other fora (e.g. WIPO, WTO, OECD, CBD, FAI, WHO, UNCTAD, UNITAID and so on). Domestically, we expect the existing trend of having developing countries adapt increasingly 'developed country' intellectual property laws to continue. The open question is whether, in adopting these laws, developing countries will exercise the flexibilities that they are winning on the international stage. Current practices indicates that they are not and we believe that it is more likely than not that this trend will continue. That is, while developing countries will fight for greater flexibility, they will not actual make use of it.

The implication of the above is that while there will likely emerge treaties on indigenous knowledge (also called traditional knowledge) and increasing regulation of genetic resources, these will be largely ineffective. Negotiations have been slow and will likely to continue to be slow but by 2015-2020 we expect international agreements or protocols to be signed in this field. Nonetheless, practice will either largely ignore these treaties or address them by requiring title holders to sign away their rights with little or no compensation. We do expect certain developing country research institutions – rather than communities of origin – to attempt to leverage these new international treaty rights to provide them with more say in international research projects. However, this will likely constitute only one additional reason among many for increased collaboration with developing country research institutions. We do not anticipate that communities of origin of either indigenous knowledge or genetic resources will benefit in any real way from any such negotiations.

On the other hand, developing country research institutions will increasingly rely on the changing international intellectual property landscape to push for more involvement in international research collaborations. Gone will be the era in which developing country researchers accept that their developed country partners will be solely responsible for patenting and technology transfer. Research entities in the developing world will continue to push for a greater role not only in carrying out research, but in managing the use of the results of that research.

The changes made to intellectual property practice – which will be much more significant than those made to intellectual property law – to 2015 will set the stage for developments in the Bioeconomy to 2030. These changes will affect the agriculture, health and industry sectors differently. We turn to this next.

# 2.1 Agricultural Biotechnology

It is most likely that the agricultural field will see the greatest impact of the above changes in biotechnological intellectual property in respect of the Bioeconomy of 2030. To address concerns of climate change and food security as well as the increasing convergence of agricultural and health biotechnologies, pressure will increase on finding collaborative mechanisms to manage intellectual property. These will be offset, although more in theory than in practice, by an increasing number of intellectual property rights in this sector.

As pressure increases to find ways of adapting current agricultural products to an environment altered through climate change, more emphasis will be placed on the application of biotechnologies to supplement traditional cross breeding of plants and animals. Researchers will need to draw on physical and informational databases to identify research targets that can best respond to

<sup>12</sup> To accelerate plant breeding, plant breeders use modern biotechnologies such as marker assisted selection to shorten development times, thereby reducing the time to recuperate development costs.

environmental change. Simplified and standard Material Transfer Agreements and intellectual property licence agreements will be required to sustain this research effort. Developing country research institutions will be drawn into research out of both politics and necessity to make sure that developed products are adapted to not only the physical environment, but the social and political environment in developing countries.

We expect a similar trajectory in respect of food security. Developing countries will place less emphasis on intellectual property rights in the abstract after learning that changing intellectual property laws have little practical effort. Rather, they will concentrate on participating in research projects so that they maintain a negotiating position to ensure access to developed products. As the large developing countries become increasingly sophisticated in their science and technology, we expect their researchers, industry and governments to act more like their developed country counterparts than like their developing world partners. We thus envision a large biotechnology gap dividing the richer from the poorer developing countries. This gap will be expressed by an increasing convergence of intellectual property policies between the large developed and the successful developing countries.

#### 2.2 Health Biotechnology

To obtain the full benefits of the Bioeconomy in 2030 in health biotechnology, greater collaboration will be needed on at least two fronts. First, in order to overcome the increasing difficulty of identifying new drug targets, greater collaboration between industry partners and the public sector will be required. Second, to better enable regulators to evaluate the safety and efficacy of new medication, industry will need to share platforms with regulators across the world. Both sets of collaborations will depend on developing strategies that open access to proprietary technologies and to share the benefits arising from their use.

A perfect crucible for developing methods to ensure such collaborative platforms is synthetic biology. This field faces a large number of early stage patents that commentators fear will slow down research through an anti-commons effect. If synthetic biology is to move ahead, industry and public sector partners will therefore need to address difficulties in accessing foundational knowledge. Already, experimentation is taking place through such efforts as the BioBricks Foundation, based on forming a scientific commons in synthetic biology. Success in developing innovative platforms for managing intellectual property will be key not only to this field but to such emerging areas such as nano-biotechnology and beyond.

#### 2.3 Industrial Biotechnology

The industrial biotechnology will face some of the same pressures as in the agricultural and health biotechnology fields but at an attenuated level. As regulation becomes a greater concern, there may be need to share platform technology. However, it is not expected that patent rights will be distributed on quite the scale as in agricultural or health biotechnologies, nor that the ethical concerns involving traditional agricultural practices and access to essential health products will exist.

Of the three sectors examined, we expect practices in industrial biotechnology intellectual property to follow rather than to lead intellectual property policy development.

# 3. Developing Countries

We see the existing division between those developing countries with industrial and scientific capacity and those without this capacity increasing toward 2030. Countries such as China, India, Brazil and South Africa will adopt intellectual property systems domestically that increasingly resemble those in

the United States, Europe and Japan. They will, for the most part, continue to ignore many of the flexibilities that international law provides in terms of calibrating intellectual property systems in favour of greater harmonisation with the leading developed countries. Other countries, such as Kenya, Indonesia and similar middle developing countries will either have to undergo radical change in order to catch up with China and India or see the gap between them and these countries continue to expand. These middle countries will need to develop ways to finance innovation largely outside of the traditional intellectual property regime, if they hope to keep up scientifically. To these countries, intellectual property will continue to be considered more of a cost than a benefit. Nevertheless, there is the opportunity to develop collaborative platforms between research institutions on a regional basis that could help these countries advance.

As noted above, developing countries will likely push for increased protection through property-like rights for indigenous knowledge and genetic resources. Many of the same governments pushing for such recognition, particularly within patent laws, will ignore them domestically. Other countries without much presence in biotechnology may implement these treaties, but to little practical effect. As noted above, if there are any benefits derived from such rights, we do not believe, based on current practice, that these benefits will find their way to the indigenous peoples involved.

There is an opportunity to resist the scenario of an increasing gap between the leading developing countries and other developing countries. To do so, these other developing countries will need to increase communications between those negotiating international treaties and those implementing and managing intellectual property nationally. Further, these countries will need to invest in better education of their researchers. In particular, this training should encourage researchers to think on a regional basis and to develop regional platforms for the exchange and creation of intellectual property. Priority thus needs to be placed on building capacity at public research institutions operating on a regional level. Even more important is the need to identify business strategies that developing countries can practically put into place to attract financing and to develop locally created biotechnology into products that serve both national and international communities. Unfortunately, relatively little effort is being placed on this form of capacity building <sup>14</sup> as international attention continues to focus on international agreements that we argue will have little practical effect.

#### 4. Conclusions

The Bioeconomy in 2030 will be the product of factors that lie largely outside of the intellectual property field. If countries, industry and public institutions manage to develop collaborative platforms for sharing and disseminating knowledge and innovation, then we can expect a dynamic Bioeconomy with reduced regulatory costs in 2030. If such platforms are not created, we can expect increased transaction costs, increased regulatory costs and less innovation.

Mid-level developing countries are at a crossroads in the Bioeconomy. While countries such as China, India and Brazil will reformulate their intellectual property laws and practices to increasingly conform to those in Europe, the United States and Japan, mid-level countries will either be left behind or collaborate at a regional level to keep pace with their more powerful developing country cousins. The key for these middle level countries is to develop capacity not only in science and technology, but in

<sup>13</sup> This is less apparent in agriculture. As an example, India's *sui generis* plant protection regime is compatible with the UPOV system and allows farmers to replant seed varieties produced from either genetic modification or conventional cross breeding.

<sup>&</sup>lt;sup>14</sup> We do note that one of us (Gold) has organised and participated in such a training programme in Eastern Africa funded by the Foundation for Sustainable Enterprise and Development. See <a href="http://www.cipp.mcgill.ca/en/capacity/training/">http://www.cipp.mcgill.ca/en/capacity/training/</a>.

research platforms at the regional level, mechanisms to attract financing of locally created technologies and to identify distribution channels both internally and into developed country markets.	